VITAL SIGNS INC
Form 10-K
December 14, 2005

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, 2005.

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

COMMISSION FILE NUMBER 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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. o Yes x No

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

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 o 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. o

Indicate by checkmark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act) x Yes o No

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

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates (for this purpose, persons and entities other than executive officers, directors, and 5% or more shareholders) of the registrant, as of the last business day of the registrant's most recently completed second fiscal quarter (March 31, 2005), was approximately $227,887,820.

Number of shares of Common Stock outstanding as of November 30, 2005: 12,597,844

Documents incorporated by reference: Definitive Proxy Statement for 2006 Annual Meeting of Shareholders (Part III).

VITAL SIGNS, INC.

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In this Annual Report, references to Vital Signs, we, us and our refer to Vital Signs, Inc. and its subsidiaries. Actar , Actar D-Fib , Aspirator Aspirator Plus BabyBlue II , Babysafe , Breas®, Breas HA50 , Breas PV10 , Breas PV10i , Breas PV101 , Breas PV102 , Breas PV403 , Breas PV501 , Breas SC20 , Broselow®, Broselow-Hinkle , Broselow-Luten , C-CCleencuff , Code Blue II , CUFF-ABLE , Gas-Lyte , Greenlight II, iMask , INFUSABLE®, iSleep , Kurtis MSD , Limb-O , Micro ABG , Misty OX®, , Pedi Blue II , Quick-ABG , SURE-LOK , TurboHeater , T-V Vital Seal , Vital View , Vital View II, Vivo 30 , and Vivo 40 are our trademarks. We also have several registered and unregistered color scheme trademarks related to the Broselow product line. All other trademarks used in this Annual Report are the property of their respective owners.

When we refer to our fiscal year in this Annual Report, we are referring to the fiscal year ended on September 30 of that year. Unless the context expressly indicates a contrary intention, all references to years in this Annual Report are to our fiscal years.

PART 1

Item 1. ***Business***

Vital Signs, Inc. was initially incorporated in New York in 1972 and reincorporated in New Jersey in 1988. Our principal executive offices are located at 20 Campus Road, Totowa, New Jersey 07512; our telephone number at that location is (973) 790-1330.

Our company

We are a leading designer, manufacturer and marketer of airway management products for the anesthesia, respiratory/critical care and sleep disorder markets. We sell our products in over 70 countries worldwide. We offer one of the broadest single-patient use anesthesia and respiratory/critical care product lines in the industry and have developed numerous first-to-market products which are now considered industry standards. In addition, we sell therapeutic products for patients suffering from sleep disorders and provide sleep disorder diagnoses at sleep labs and centers that we operate. We also deliver technology services to FDA regulated companies.

We categorize our product and service offerings within our four business segments: anesthesia, respiratory/critical care, sleep disorder and pharmaceutical technology services, which we describe in more detail below. See Note 18 of the notes to consolidated financial statements contained herein for certain financial information about our segments.

Anesthesia

We have been supplying products to the anesthesia market for 33 years. Our single-patient use anesthesia products and systems are designed to deliver oxygen and anesthesia from a gas source, such as an anesthesia machine, to a patient s pulmonary system. They also remove anesthetic gases, carbon dioxide and expiratory oxygen from a patient and link a patient to various monitors. Our principal anesthesia products consist of face masks, breathing circuits and general anesthesia products. We believe that the breadth of our product offerings gives us the advantage of being able to sell customized circuits composed of multiple products. Historically, we have included the products sold by our Thomas Medical Products subsidiary within this segment. Thomas Medical is an original equipment manufacturer that produces vascular access products for sale to other health care product providers. These providers use Thomas Medical s offerings as components of their products or kits or as finished products. For fiscal 2004 and 2005, our anesthesia segment contributed 45.0% and 48.1%, respectively, of our net revenue.

Respiratory/critical care

We have been supplying products to the respiratory/critical care market for over 25 years. Our primary respiratory products are arterial blood gas syringes and kits, manual resuscitators and blood pressure cuffs. We also distribute critical care equipment kits and modules, which are color coded to allow emergency room workers to quickly and accurately determine the proper equipment size to use with pediatric patients. For fiscal 2004 and 2005, our respiratory/critical care segment contributed 22.9% and 21.9%, respectively, of our net revenue.

Sleep disorder

Building upon our airway management expertise and our long-time experience with continuous positive airway pressure systems, we began providing sleep disorder products and services in the late 1990s. We believe that we are the only company that both operates sleep centers to diagnose obstructive sleep apnea and manufactures and sells products designed to treat that condition. As of September 30, 2005, we operated 52 sleep diagnosis labs and centers in seven states in the United States and in Washington D.C. At these sleep labs and centers, 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 the patient follow-up diagnostic and monitoring services and may, under certain circumstances, be in a position to sell our sleep disorder products to the patient. Our principal sleep disorder products, currently marketed primarily outside of the United States, are personal ventilation systems, which are used in the treatment of obstructive sleep apnea to prevent temporary airway closure during sleep. For fiscal 2004 and fiscal 2005, sleep disorder and personal ventilation products and services accounted for 23.9% and 21.4 %, respectively, of our net revenue.

Pharmaceutical technology services

In 1996, we began providing regulatory consulting services to clients, helping them to develop and validate systems and processes for their manufacturing, infrastructure, research and development, laboratory and quality assurance departments. In 2002, with our acquisition of our Stelex subsidiary, we expanded our services to include computer systems compliance. In addition, we have developed and currently market proprietary software products used in conjunction with our services to help clients comply with FDA regulations. We deliver these technology services to FDA regulated companies primarily in the pharmaceutical sector, as well as to medical device, diagnostic and biotechnology companies. Our clients include some of the largest pharmaceutical companies in the world. For fiscal 2004 and fiscal 2005, pharmaceutical technology services accounted for 8.2% and 8.6%, respectively, of our net revenue.

Market overview

Anesthesia and respiratory/critical care.

In response to rising health care costs, managed care companies and other third-party payors have placed pressure on health care providers to reduce costs, which could hamper our revenue growth. Yet, we believe that efforts to contain rising health care costs have increased the preference for single-patient use medical products, which we believe improve the productivity of health care professionals, reduce overall provider costs and improve patient care.

We believe that single-patient use medical products provide the United States health care industry with the following benefits:

> *cost effectiveness*, by lowering the labor costs associated with sterilizing, reassembling and re-testing reusable products, lowering inventory costs, reducing the initial capital outlays for stocking new reusable products and improving the ability to allocate costs directly to individual patients;

improved patient care, by reducing the risk of contracting infections from reusable products that have been inadequately sterilized, thereby reducing the risk of additional post-operative patient care; and

reduced set up time, resulting from the fact that many single-patient use products can be packaged in disposable kits, allowing medical practitioners to reduce set up time and thereby perform more procedures.

As a result of these factors, we believe that single-patient use medical products have become the products of choice in the United States anesthesia and respiratory/critical care markets.

We view the international markets as a significant growth opportunity for our company as single-patient use products have not fully penetrated those markets. We believe that in developed countries, heightened concern regarding cross-contamination and sterilization costs are resulting in single-patient use medical products replacing traditional reusable products. We believe that the trend towards utilizing single-patient use products is accelerating in developing countries as health care standards improve. In addition, many developing markets have high incidences of communicable respiratory diseases and are becoming increasingly aware of the value of single-patient use respiratory products.

Single-patient use anesthesia products and systems are designed to deliver oxygen and anesthesia from a gas source, such as an anesthesia machine, to a patient s pulmonary system. They also remove anesthetic gases, carbon dioxide and expiratory oxygen from a patient and link the patient to various monitors. Face masks and breathing circuits constitute our primary anesthesia product offerings.

Single-patient use respiratory/critical care products are designed to assist hospitals with their infection control programs by helping to reduce infections caused by cross-contamination when products are used by more than one patient. These products also offer patient benefits as they are generally lighter than reusable products resulting in better patient care, for example by causing less torque on the endotrachael tube. We believe that in recent years there has been an increasing incidence of respiratory illnesses, such as asthma and emphysema, due in part to an increasingly susceptible aging population, environmental pollution, smoking-related illnesses and communicable diseases with significant respiratory impact, such as tuberculosis, HIV and influenza. People with these conditions have a need for our products, such as manual resuscitators and arterial blood gas kits, in emergency care situations.

Sleep disorder

Obstructive sleep apnea is considered to be one of the most common sleep problems. Obstructive sleep apnea, or OSA, is a condition that causes the soft tissue in the rear of the throat to narrow and repeatedly close during sleep. Oxygen deficiency, elevated blood pressure and increased heart rate caused by OSA are related to increased risk of cardiovascular morbidity, stroke and heart attack. Additionally, OSA may result in excessive daytime sleepiness, reduced cognitive functions, including memory loss, lack of concentration, depression and irritability. According to National Center on Sleep Disorders Research, approximately 20 million in the United States alone suffer from obstructive sleep apnea and more than 18 million of those remain

untreated. Increased awareness of OSA among doctors and patients in recent years is expected to continue fueling growth of the OSA diagnostic and treatment industry.

The diagnosis of obstructive sleep apnea typically requires monitoring a patient during sleep. During overnight testing, which usually takes place in a clinical setting, respiratory parameters and sleep patterns are monitored along with other vital signs, providing information about the quality of an individual s sleep. A report by Frost & Sullivan indicates that by 2003, there were approximately 2,800 sleep labs and centers in the United States. We believe that this represents a significant expansion over the number of such labs and centers that existed in the United States two decades earlier.

Continuous positive airway pressure therapy, commonly referred to as CPAP therapy, has evolved as the primary method for the treatment of obstructive sleep apnea, in part because it is less invasive and more cost-effective than surgery. Unlike surgery, which may only result in reduced snoring, we believe that CPAP therapy actually reduces the occurrence of obstructive sleep apnea. During this therapy, a patient sleeps with a nasal or facial mask connected by a tube to a small portable airflow generator that delivers room air at a predetermined continuous positive pressure. The continuous air pressure acts as a pneumatic splint to keep the patient s upper airway open and unobstructed. As a result, the cycle of airway closures, which leads to the disruption of sleep and other symptoms that characterize obstructive sleep apnea, is prevented.

CPAP is generally not a cure but a therapy for managing obstructive sleep apnea, and therefore, must be used on a daily basis as long as treatment is required. Patient compliance has been a major factor in the efficacy of CPAP treatment. Early generations of CPAP units provided limited patient comfort and convenience. More recently, product innovations to improve patient comfort and compliance have been developed.

Pharmaceutical technology services

Pharmaceutical, diagnostic, biotechnology and medical device companies are strictly regulated by the United States Food and Drug Administration. The FDA s regulatory framework covers virtually every aspect of these companies operations. FDA regulations mandate that these companies maintain highly detailed records to enable them to demonstrate compliance with complex requirements. Companies that fail to comply with FDA regulations may be delayed or prevented from commercializing new products and product enhancements and may have existing products removed from the market.

The tasks of developing FDA compliance programs and monitoring their performance are complex and time-consuming. Enforcement of FDA requirements 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 against the violating company. We believe that many FDA regulated companies do not maintain the internal staff necessary to meet the increased requirements and FDA scrutiny and therefore require consultants to help them become and remain compliant. We also believe that regulated companies are under continuing scrutiny with regard to the quality and compliance of critical computer systems and will continue to require external help to develop and implement these systems.

Principal products and services

Our principal products and services fall into four segments: anesthesia, respiratory/critical care, sleep disorder, and pharmaceutical technology services, which are described below.

Anesthesia

Anesthesia products were our first line of business and continue to be our leading source of revenue. Our single-patient use products and systems are designed to deliver oxygen and anesthesia from a gas source, such as an anesthesia machine, to a patient s pulmonary system. They also remove anesthetic gases, carbon dioxide and expiratory oxygen from a patient and link a patient to various monitors. We offer a wide variety of products which are designed to be compatible with the anesthesia equipment manufactured by most companies. Our anesthesia segment accounted for 45.0% of our net revenue in fiscal 2004 and 48.1% of our net revenue in fiscal 2005.

Our primary anesthesia products and systems include:

Anesthesia breathing circuits are single-patient use devices used to ventilate and carry oxygen and anesthesia to a patient while under general anesthesia during surgery as well as to connect the patient to an anesthesia machine and to 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 a patient. Each traditional breathing circuit consists of flexible hoses, a breathing bag, and a Y and elbow attachment. Because the breathing circuit needs of hospitals vary significantly, we offer a large variety of circuits designed to be compatible with anesthesia equipment manufactured by 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. In late 2000, we introduced the patented product Limb-O™, 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. The expiratory portion of the tube contains warmed exhalation gas which helps to warm the inspiratory gas. The Limb-O™ competes with the traditional two limb system on the basis of the added benefit of heat and moisture provided to the patient and the reduction of bulk and weight associated with traditional two limb circuits and is an alternative to the tube within a tube circuit.

Face masks are single-patient use devices which cover the nose and mouth of a patient while general anesthesia is being administered. In 1981 we became the first company to sell the now-standard air-filled clear cushion face mask 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, thereby 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 increase as single-patient use products become more accepted in international hospitals.

General anesthesia systems are customized single-patient use anesthesia kits that we assemble which can include more than 20 of our single-patient use products, such as air filled cushion face masks, breathing circuits, blood pressure cuffs and temperature monitoring probes. We market these kits under the name *GAS* . Our sales representatives use detailed questionnaires to assist each customer in determining the particular products that an institution desires in its anesthesia kits. We then assemble our *GAS* kits to meet an institution s specific needs.

Pressure infusors are single patient use devices utilized hospital wide to apply pressure to a sealed bag of fluid, such as intravenous solutions or blood products. Our *INFUSABLE*® pressure infusor is a patented system consisting of a pressure gauge, an inflatable bladder and a bulb to pump air into the bladder. Our *INFUSABLE*® has a mesh netting into which a package of sterile fluid or solution bag is placed. The fluid is connected to the patient monitoring system and the pressure on the solution bag is set at a level designed to maintain the pressure required by the monitoring system. Our *INFUSABLE*® is also designed to deliver blood or fluids to a patient at a rapid rate, usually under trauma conditions.

Fiberoptic laryngoscope systems are single-patient use devices used by anesthesiologists to assist in correctly placing an endotracheal tube within the trachea of a patient. Our *Vital View* 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 patient and physician of infection associated with reusable metal blades and handles. We believe that hospital capital outlays for stocking emergency crash carts can be reduced by purchasing our single use system rather than a reusable fiberoptic system.

Laryngeal airway devices are single use airway devices used for airway management during general anesthesia procedures. We have several patented features intended to address known complications, including a reinforced tongue within the tip of the sealing cuff to resist over-folding and ribbed slots to minimize the possibility of occlusion by a patient s epiglottis.

We also manufacture a wide range of accessories and components for use with our anesthesia products, including heat/moisture exchangers, bacterial/viral filters, anesthesia breathing bags (including latex-free bags), airways, temperature monitoring devices and other components.

In addition to the products and systems described above, through our wholly-owned Thomas Medical Products, Inc., subsidiary, we act as an original equipment manufacturer. We manufacture devices which provide access primarily to the vascular system by medical professionals, including introducers, sheaths, dilators, hemostasis valves and catheters. These products are sold primarily to other health care product providers to be used in their products or kits or as a finished product.

Respiratory/critical care

Our respiratory/critical care segment accounted for 22.9% of our net revenue in fiscal 2004 and 21.9% of our net revenue in fiscal 2005.

Our primary respiratory/critical care products and systems include:

Arterial blood gas syringes and collection kits 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. We offer a broad line of disposable arterial blood gas syringes and collection systems in both standard configurations and in kits that are customized to meet a specific hospital s needs and to function with the hospital s blood gas analyzers. We offer syringes containing our *SURE-LOK* needle protection device to protect the health care worker from the risk of being punctured by a needle.

Manual resuscitators are single-patient use devices which are squeezed by hand to force oxygen into a patient s lungs. Manual resuscitators 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. Our *Code Blue II* 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, our *Code Blue II* resuscitators are relatively inexpensive and are delivered fully assembled.

Blood pressure cuffs are single-patient use devices which are wrapped around the arm or thigh of a patient to obtain a blood pressure reading. Our *CUFF-ABLE*® 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 *CUFF-ABLE*® blood pressure 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.

Hyperinflation systems are devices used for patient resuscitation. We offer both our *Babysafe* and traditional hyperinflation systems for infant resuscitation in transport and prior to tracheal suctioning. These products are used in labor and delivery rooms and in neonatal intensive care units, where controlling the spread of infection is particularly critical. *BabySafe* offers the ability to adjust and limit the level of

pressure that can be delivered during resuscitation. Oxygen can be delivered with limited risk of barotrauma. These systems are available in a variety of configurations and sizes to meet the needs of infants.

Continuous positive airway pressure systems, commonly referred to as CPAP systems, consist of a compact flow generator connected to a dual-port, air-filled cushion face mask and are used as therapy for various respiratory diseases. The face mask is attached to a single-patient use positive end expiratory pressure valve designed to maintain positive airway pressure in the lungs, allowing for more oxygen to diffuse into a patient s blood system. 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. Our facemask CPAP systems are now being used successfully in the hospital and pre-hospital setting to treat patients with cardiogenic pulmonary edema and other respiratory deficiencies.

Heated humidification systems provide a flow of warm moist air to a patient at risk from loss of body temperature and drying of the lung linings. Our *MistyOx*® line consists of two respiratory products that deliver hydration to a patient, a nebulizer which delivers medium to high flow and high concentrations of oxygen to patients, combined with a regulated heater. These products may be used by infants, children and adults in many areas of the hospital, including emergency, recovery and critical care.

CPR training mannequins are training aids for teaching cardiopulmonary resuscitation, commonly known as CPR. Our *Actar*® training mannequin provides a low cost alternative to many of the other training mannequins on the market. Its low cost allows each trainee to practice on his or her own mannequin rather than waiting to take turns on a single mannequin used by an entire class. Our newest model, *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.

Broselow® pediatric emergency products. The Broselow/Hinkle 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 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. This patented system, licensed to Vital Signs, consists of a tape measure having nine 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.

In addition to the products and systems described above, we also manufacture a wide range of accessories and components for use with our respiratory/critical care products and systems, including bacterial/viral filters and heat and moisture exchangers.

Sleep disorder

Our sleep disorder segment encompasses our sleep disorder and personal ventilation products and sleep diagnosis services. We have designed our sleep disorder 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. CPAP is a common method for treating obstructive sleep apnea. We have manufactured and distributed CPAP systems for more than a decade for other respiratory applications and actively entered the sleep apnea market in 1997 through our acquisition of an equity 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 CPAP 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 sleep 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 System Corporation. We provide our sleep diagnostic services exclusively in the United States.

Our sleep disorder segment accounted for 23.9% of our net revenue in fiscal 2004 and 21.4% of our net revenue during fiscal 2005.

Our primary sleep disorder and personal ventilation products are listed below. Other than the *Breas PV10 , PV10i , HA50* and the *iMask* , all of these products are currently sold only outside of the United States.

CPAP flow generators are electromechanical devices which deliver continuous positive airway pressure through a nasal or full face 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. Our Breas *PV10* is a high-end standard CPAP device meeting normal needs for obstructive sleep apnea treatment. Our Breas *PV10i* , which has been cleared by the FDA for sale in the United States, is a self-adjusting CPAP device that uses patterned recognition technology to respond to changes in an individual s breathing patterns. This device can adjust treatment pressure, 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 and thus may create discomfort for the user. With the *PV10i* , the mean treatment pressure is lower, because of the automatically self-adjusting changes in airway pressure. Clinical studies have demonstrated that patients prefer the lower pressure provided by the *PV10i* to other devices available in the marketplace.

Bi-level CPAPs are electromechanical devices which allow inspiratory and expiratory pressures to be independently adjusted to a patient. Our Breas *PV10i* is used to treat more severe obstructive sleep apnea and chronic obstructive pulmonary disorders and is designed to be comfortable for the user.

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. Our Breas *Vivo 30* and *Vivo 40* bi-level ventilators are advanced devices that allow 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 inspiratory and expiratory levels independently, which we believe promotes more comfortable and more natural respiratory support. These ventilators may also be operated from an external battery so they can be used during transportation and while traveling. Our Breas *PV403* homecare ventilator supports the ventilation needs of patients suffering from respiratory insufficiency diseases. Patients that use the *PV403* may suffer from neuromuscular (Duchene s), or other restrictive or obstructed diseases. The *PV403* is an advanced mixed homecare ventilator which can provide volume and pressure ventilation. It has various settings that make it very flexible for a broad range of applications. It has both internal and external battery capability and is well suited to be used for transport and traveling.

Humidification systems, such as our Breas *HA50* humidification system, are heated humidifiers for use with CPAP or ventilation devices. We believe that heated humidifiers are an important factor in the comfort of certain CPAP users.

We also provide sleep diagnostic and therapeutic services through our Sleep Services of America subsidiary. At September 30, 2005, we operated 52 sleep labs and centers in seven states in the United States and in Washington D.C. Of these facilities, 11 of our laboratories are accredited by the American Academy of Sleep Medicine and have applications submitted or pending for several other sleep laboratories. Sleep Services of America is accredited by the Joint Commission on Accreditation of Healthcare Organizations in ambulatory and homecare.

At our sleep center and sleep laboratory facilities, which typically accommodate two or three 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 obstructive 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, including 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 compile into a sleep report. The referring physician receives a sleep report which includes an interpretation, by a physician who is not affiliated with us, of the data and a diagnosis of the sleep-related problem, if any.

Over the past two years, we have eliminated sleep diagnostic centers that had marginal profitability and have focused our efforts on centers affiliated with hospitals, such as Johns Hopkins, the University of Maryland, Duke University and Westchester University Medical Center. The operation of sleep labs and centers provides us with direct access to patients at the point of diagnosis. We believe that the knowledge derived from these facilities enables us to improve our sleep treatment products and develop complementary sleep disorder and personal ventilation products.

Our ability to sell our sleep disorder and personal ventilation products in these facilities is restricted by strict federal regulations which prohibit us from diverging from a physician s prescription. If a physician prescribes a sleep disorder or personal ventilation product by name other than one of our own products for a patient at one of our sleep labs or centers, we are prohibited by federal regulations from substituting our own product.

Pharmaceutical technology services

Through our Stelex subsidiary, we provide regulatory compliance and validation consulting services to FDA regulated companies, primarily in the pharmaceutical sector, and also to diagnostic, biotechnology and medical device companies. We advise our clients by helping them establish and monitor processes designed to satisfy FDA requirements. 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. At September 30, 2005 our pharmaceutical technology services staff consisted of 101 professionals. 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.

In addition, though our Vital Path subsidiary, we have developed and currently market proprietary software products that we use in conjunction with our services to help clients comply with FDA regulations.

Our pharmaceutical technology services segment accounted for 8.2% of our net revenue in fiscal 2004 and 8.6% of our net revenue in fiscal 2005.

Sales, marketing and distribution

United States sales

Anesthesia and respiratory/critical care. We sell our anesthesia and respiratory/critical care products to hospitals in the United States through our own sales force, which is led by our Vice President of Sales. At September 30, 2005, our United States sales force consisted of 57 sales representatives and seven 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 United States, 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.

Many of our customers are members of group purchasing organizations. Group purchasing organizations provide their members access to discounted prices on products by negotiating discounts with manufacturers like us. Unlike distributors, group purchasing organizations do not themselves make purchases, carry inventory or physically handle product. We have agreements with several leading group purchasing organizations, including Amerinet, Broadlane, Consorta, Healthsouth, Healthtrust, MedAssets (HSCA), Novation and Premier. Group purchasing organizations provide access to discounted prices for their members by negotiating a group price for their member hospitals and health care providers. During fiscal 2004 and fiscal 2005, 24% and 34%, respectively, of our sales from the anesthesia and respiratory/critical care segments to United States hospitals was derived from group purchasing organization contracts that were utilized by member hospitals.

As we develop new products that can be sold by our United States sales force, 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.

Sleep disorder. Sales of our sleep disorder and personal ventilation products in the United States have been minimal to date, due in part to our need to obtain necessary FDA clearances and due in part to the dominant position that our competitors have in the home supply dealer channel. We believe that our principal means of selling our sleep disorder and personal ventilation products will be introducing those products to patients when they are visiting our sleep laboratories.

As of September 30, 2005, the sales and marketing department of our SSA subsidiary consisted of two field persons, a director of marketing communications and a Vice President of Sales. The primary focus of this team is to increase the patient volumes at existing labs and centers and negotiate contracts with new sleep labs and centers. SSA seeks to differentiate itself from many of its competitors by providing hospitals a range of marketing options from direct marketing to an *al la carte* selection of services, increasing the number of laboratory beds and improving the utilization of existing beds.

Pharmaceutical technology services. We sell our pharmaceutical technology services through our Stelex subsidiary which, at September 30, 2005 employed a team of eight sales account managers, four marketing support persons and one director of business development. Our pharmaceutical technology services sales team is responsible for obtaining new business in the continental United States and Puerto Rico by calling on pharmaceutical companies, diagnostic and biotechnology companies and medical device manufacturers regarding compliance with FDA regulations.

International sales

We sell our products in over 70 countries worldwide. For fiscal 2004 and 2005, international sales accounted for approximately 25% and 24%, respectively, of our net revenues.

Commencing in 2002, we sold our anesthesia and respiratory/critical care products in nine European and certain other related international markets primarily through a strategic alliance with Rusch GmbH, a manufacturer of medical devices. However, during our 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. In light of this acquisition, the parties agreed to determine the distributor agreement, effective as of November 30, 2005. For a period of time we expect to continue to sell through a number of Rusch s country specific organizations. We are simultaneously evaluating alternative distribution methods, including establishing direct distribution channels for some countries and partnering with third-party distributors in other countries. Developing a distribution network is a difficult, expensive and time-consuming process and we may be unsuccessful in developing our new international distribution network. If we are unable to establish new channels promptly and effectively, our international sales of anesthesia and respiratory products may be adversely impacted in fiscal 2006 by the termination of our distribution agreement with Rusch.

We operate a wholly owned subsidiary in the United Kingdom which is responsible for distributing and selling our anesthesia, respiratory, critical care and Breas products throughout the United Kingdom and Ireland. It employs twenty two individuals, including nine sales representatives and one field-based sales manager.

Our sales in Asia, Latin America, Canada and Europe/Middle East are supervised by four regional managers whose responsibilities include, but are not limited to, the identification, qualification, appointment and continued training and support of local, territory-specific distributors.

We sell our sleep disorder and personal ventilation products 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. At September 30, 2005, Breas direct sales force consisted of 38 people.

See Management s discussion and analysis of financial condition and results of operations for additional information concerning our international sales.

Marketing

Our marketing staff works 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, 2005 we employed 43 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 2005 was the development of a new generation of sleep and ventilation products at our Breas subsidiary.

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.

Manufacturing and quality control

We manufacture most 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. 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, bacterial/viral filters, blood pressure cuffs, pressure infusors, arterial blood gas syringes, heated humidification circuits, nebulizers, manual resuscitators, introducers, and sleep therapy products. 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 in 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 13485 standards.

Key supplier relationships

In 1980, we acquired the exclusive rights to our air-filled cushion anesthesia facemask through a collaboration arrangement with Respironics, Inc. 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. We expect our current exclusive supply agreement with Respironics to extend 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.

We rely on numerous other vendors to supply the key components of some of our products. During fiscal 2005, a component vendor advised our Breas subsidiary that it was unable to deliver a sufficient quantity of a key component at our required specifications. As a result, Breas was unable to bring a new sleep disorder and personal ventilation product line to market in a timely manner. Since we had pre-announced the availability of that product line, orders for pre-existing products were reduced substantially and the unavailability of the new products negatively affected Breas 2005 revenues. Limited shipments of the new product line began during the fourth quarter of fiscal 2005. We believe that this supply issue has now been adequately resolved.

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 determined 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 confidentiality, 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 disorder business segments. 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.

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.

From time to time we may take recall actions with respect to particular lots of a specific product that has been distributed. Such actions are logged in our records and are available to the FDA during inspections. We also may file notices with the FDA describing such actions.

The FDA classifies medical devices 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, post-market 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 and 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. If we decide to develop any products that are categorized by the FDA as Class III medical devices, the time, effort and expense required to obtain the necessary clearances will increase significantly.

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. 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.

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 Conformité Européene, 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 pre-market 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 disorder business segment are subject to additional regulation from various state and local regulatory authorities. There has been a

trend developing in the United States 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 United States 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. For an additional discussion on reimbursement matters, see Third party reimbursement below.

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 labs and centers is restricted by strict federal regulations which prohibit us from diverging from a physician s prescription. If a physician prescribes a CPAP product by name 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 regulation by both United States and foreign authorities intended to protect the privacy of those individuals by requiring that we maintain the confidentiality of their information.

In 1996, the United States 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 United States 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 Sleep Services of America 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 United States 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 foreign, federal, state and local laws and regulations 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 United States 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 CPAP 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 United States, 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.

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, technique, 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 business segments or both. Our primary competitors in each of our product and service categories include the following entities and their affiliates:

Product/service category	Primary competitors
Anesthesia	King Systems Corporation Medline Industries Smith Industries
Respiratory/critical care	Ambu International A/S Cardinal Health Critikon, Inc./General Electric Medical Services Fisher & Paykel Healthcare Teleflex Tyco International Viasys Invacare
Sleep disorder	Fisher & Paykel Healthcare Resmed Respironics Tyco International Various hospital and locally maintained sleep centers
Pharmaceutical technology services	Day & Zimmerman Taratec The Washington Group Numerous regional consulting companies.

Employees

As of September 30, 2005, we had 1,177 full-time employees and 54 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 United States have statutory benefits comparable to collective bargaining agreements. Our full-time employees by department at September 30, 2005 were:

Department	Number of employees
Manufacturing and quality control	616
Sales and marketing	152
Sleep Center technical personnel	173
Regulatory consultants	101
Research and development	43
Administration	92
Total	1,177

Website

We maintain a website at www.vital-signs.com where we make available the proxy statements, press releases and reports on Forms 3, 4 and 5, 8-K, 10-K and 10-Q (and any amendments to those reports) that we and our insiders file with the SEC. These reports and other materials are made available as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. Press releases are also issued via electronic transmission to provide

access to our financial and product news. In addition, we provide notification of and access to voice and Internet broadcasts of our quarterly and annual results.

Item 1A. ***Risk Factors***

You should carefully consider the risks described below and all other information contained in this Annual Report. If any of the following risks, as well as other risks and uncertainties that are not yet identified or that we currently think are immaterial, actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of our shares could decline, and shareholders may lose all or a substantial part of their investment.

Risks related to our industry

Public and private sector health care organizations continue to exert substantial cost containment pressures that could adversely impact our prices and our profitability.

In recent years, widespread efforts have been made in both the public and private sectors to control health care costs, including the prices of products sold by us. Such efforts may have a material adverse effect on the pricing of, and demand for, our products. Health care organizations are evaluating approaches to reduce costs by decreasing the frequency with which a treatment, device or product is used. Cost containment has also caused the decision-making function with respect to purchasing to shift in many cases from the physician to the administrator at the health care institution, resulting in an increased emphasis on reduced price, as opposed to product features and clinical benefits. Efforts by U.S. governmental and private payors to contain costs will likely continue, and we expect that international health care markets will follow a similar trend toward cost containment.

The time and expense needed to obtain regulatory approval and respond to changes in regulatory requirements could adversely affect our ability to commercially distribute our products and services and generate revenue therefrom.

We are subject to extensive worldwide regulation with respect to product clearance and enforcement activities. This causes us to experience long approval cycles, uncertainty with respect to the timing of the introduction of new or modified products, risk with respect to approvals and substantial expenses. Our products are subject to extensive regulation by the United States Food and Drug Administration, commonly known as the FDA, and certain similar foreign regulatory agencies. Additionally, some of the services we provide in our sleep disorder segment are subject to additional regulation from various local regulatory agencies.

The FDA regulates the pre-clinical and clinical testing, manufacture, labeling, distribution and promotion of medical devices. It can take several years to receive the appropriate approvals from the FDA and we cannot assure you that we will always obtain such approvals. If we decide to develop any products that are categorized by the FDA as Class III medical devices, the time, effort and expense required to obtain the necessary clearances will increase significantly. In

addition, the products that we manufacture or distribute pursuant to FDA clearances or approvals are subject to pervasive and continuing regulations by the FDA. Noncompliance with applicable requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing clearances or approvals and criminal prosecution. The FDA also has the authority to require us to repair, replace or refund the cost of any device that we manufacture or distribute.

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. Non-compliance with foreign regulations may carry the same or increased risks, liabilities and exposures as non-compliance with FDA requirements. Foreign regulatory authorities also have the authority to require us to repair, replace or refund the cost of any device that we manufacture or distribute.

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 complex regulations by both United States and foreign authorities intended to protect the privacy of those individuals by requiring that we maintain the confidentiality of their information. Implementation and compliance with these regulations are costly.

Even after receiving FDA and foreign regulatory clearance or approval, our products may be subject to product recalls, which may harm us.

The FDA and similar governmental authorities in other countries have the authority to make a mandatory recall or order the removal from the market of our products in the event of material deficiencies or defects in design, manufacture, or labeling of devices. Any recall of our products may materially adversely affect our profitability, divert managerial resources and harm our reputation.

We may lose significant customers as a result of substantial consolidation within the health care industry.

Over the past several years, the health care industry, including many of our customers, has undergone significant consolidation, and we expect this trend to continue. We are subject to risks and uncertainties that result from mergers and acquisitions involving our customers. If, as a result of such mergers or combinations, our customers lose control of the purchasing function, decide to use one of our competitors or reduce their orders for our products, our revenues may be materially adversely affected.

Government and private insurance plans may not reimburse our customers for our products, which could result in reductions in sales or selling prices for our products.

The cost of medical care in the United States and many other countries is funded substantially by government and private insurance programs. If such funding becomes limited or unavailable to our customers, our business may be adversely affected. Although we do not generally receive

payment for our products or services directly from these payors other than for our sleep diagnostic services, our continued success is dependent upon the ability of patients or our customers to obtain adequate reimbursement for our products and services. In most major markets, our products are purchased primarily by hospitals which in turn bill third-party payors or bill patients directly who then seek reimbursement from third-party payors.

In the United States, 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 indications, or is experimental, unnecessary or deemed to be inappropriate treatment for the patient. Third-party payors are also increasingly challenging prices charged for medical products and services. We cannot assure you that our products will be considered cost-effective by third-party payors, that reimbursement will be available, or that payors reimbursement policies will not adversely affect our ability to sell our products on a profitable basis, if at all.

Health care reimbursement systems vary from country to country and, accordingly, we cannot assure you that third-party reimbursement available under one system will be available for procedures utilizing our products under any other reimbursement system. Lack of, or inadequate reimbursement by, government and other third-party payors for our products would have a material adverse effect on our business, financial condition and results of operations.

Health care reform proposals are gaining substantial support in the United States Congress and state legislatures and could impact the profitability of our business.

The United States health care industry is subject to several reform proposals, including more stringent regulations. It is uncertain whether and when such proposals would become legal requirements affecting our business, but we cannot assure you that any such changes will not have a material adverse effect on our business. Changes in the law or new interpretations of existing laws may have a dramatic effect on the costs associated with doing business and the amount of reimbursement our customers receive from both government and third-party payors. Federal, state and local government representatives will, in all likelihood, continue to review and assess alternative regulations and payment methodologies.

We incur expenses to comply with environmental health and safety laws and regulations.

We are subject to numerous environmental health and safety laws and regulations, including those governing the use and disposal of hazardous materials. We incur expenses to comply with such laws and regulations and any violation of these laws and regulations could have a material adverse effect on our business, financial condition and results of operations.

Risks related to our business

The markets for our products and services are highly competitive and we compete against substantially larger companies.

Competition among medical device companies is intense. If we are unable to compete effectively with existing or future competitors, we may be prevented from retaining our existing customers or from attracting new customers, which could materially impair our business. There are a number of companies that currently offer, or are in the process of developing, products that compete with products that we offer. We cannot assure you that some of these competitors will not succeed in developing products that are more effective and/or less expensive than those currently used or produced by us or that would render some products offered by us obsolete or non-competitive. Many of our competitors have greater financial, research and development, manufacturing and marketing resources than we have and may be in a better position than we are to withstand the adverse effects on gross margins and profitability caused by price decreases prevalent in this competitive environment.

The presence of group purchasing organizations may affect our competitive position, our pricing and ultimately our profits.

Our ability to sell our products to hospitals depends on our relationships with group purchasing organizations. In fiscal 2005, sales of our anesthesia and respiratory/critical care products related to our group purchasing arrangements amounted to $30.0 million, representing 33.9% of our net revenue from United States hospital sales. In 2006, our contracts with several of the group purchasing organizations with which we have relationships will terminate unless the parties mutually agree to renew them. In fiscal 2005, we had net revenues of $17.0 million under the contracts subject to termination or renewal in 2006. We cannot assure you that we will be able to renew these contracts at the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with group purchasing organizations, our competitive position would likely suffer. In addition, some group purchasing organizations have tested the use of new internet bidding procedures in order to maximize their abilities to negotiate lower prices with suppliers. Movement to these bidding modalities has been implemented by some organizations and has resulted in lower pricing in some instances. We cannot assure you that continued movement to these bidding modalities will not increase. This may result in lower pricing or failure to secure contracts with these organizations.

We could lose customers and our business could be adversely affected if our competitors implement new technologies before we do.

The market for our products is characterized by frequent product improvements and evolving technology. Our revenue and profitability could be adversely affected by technological change. To compete effectively, we must anticipate and adapt to technological changes and offer, on a timely basis, competitively priced products with new and improved features that meet evolving industry standards and customer preferences. We may choose to develop or invest in new technologies that prove to be ineffective, do not gain market acceptance or are incompatible with technologies of our customers. As new technologies develop, we may be forced to implement these new technologies at a substantial cost to us in order to remain competitive. In addition, competitors may implement new technologies which allow them to offer lower-priced and/or superior quality products which may render our products obsolete or uncompetitive.

We are dependent on a single supplier for one of our key products.

Since 1980, we have purchased our anesthesia face masks from a single source, Respironics, Inc., which maintains a site in the People s Republic of China at which it manufactures face masks for our anesthesia segment. If we are unable to obtain our anesthesia face masks from Respironics, our business and revenue would be significantly and adversely affected. Sales of our anesthesia face masks, and products and systems which include our anesthesia face masks, such as our general anesthesia systems and breathing circuits, represented approximately 15.1% of our net revenue during our fiscal year ended September 30, 2005. We expect our current exclusive supply agreement with Respironics to extend through 2011. If the supply of our anesthesia face masks from Respironics is interrupted or ceases for any reason, we would experience significant disruption in our business. We are not aware of any alternate manufacturer or supplier with the present capacity to manufacture anesthesia face masks in the quantities we require. Pursuant to our agreement with Respironics, we are precluded from purchasing anesthesia face masks from other sources unless Respironics is unable to supply face masks in accordance with the agreement. In the event of such an interruption or termination of our supply agreement, we may not be able to obtain anesthesia face masks in a sufficient quantity or at a cost-effective price, which would have a material adverse effect on our business, financial condition and results of operations.

We are dependant on a limited number of suppliers for key components of some of our products and delivery delays or the loss of vendors could adversely affect our business.

We rely on vendors to supply the key components of some of our products. During fiscal 2005, a component vendor advised our Breas subsidiary that it was unable to deliver a sufficient quantity of a key component at our required specifications. As a result, Breas was unable to bring a new sleep disorder and personal ventilation product line to market in a timely manner. Since we had pre-announced the availability of that product line, orders for pre-existing products were reduced substantially and the unavailability of the new products negatively affected Breas 2005 revenues. We cannot assure you that we will not experience similar delays from this or other vendors of key components in the future. In the event we are unable to obtain components for any of our products, or are unable to obtain components on commercially reasonable terms, we may not be able to manufacture or distribute our products on a timely and competitive basis, or at all. If we experience any delays in component availability, the cost incurred in locating alternative suppliers could have a material adverse effect on our business, financial condition and results of operations.

If we lose key personnel, or are unable to attract and retain additional highly skilled personnel required to lead our company and to enable us to grow our activities, our business would likely suffer.

Our success is dependent on key personnel, including Terry D. Wall, our president and chief executive officer, Barry Wicker, our executive vice president and chief operating officer, and other members of our senior management. Mr. Wall is 64 years of age and has recommended to our Board of Directors that it plan on naming a successor chief executive officer by December 2008. Mr. Wall has no intention of discontinuing active involvement in our company either before or after his successor has been named, but believes that his specific role beyond 2008 will

have to be assessed as that time period approaches. Once Mr. Wall s successor has assumed the position of chief executive officer, Mr. Wall s active involvement may consist of leading special projects that take advantage of Mr. Wall s substantial experience in identifying new products for future sale by our company. Mr. Wicker is 65 years of age and has indicated that he plans to remain as an executive officer of the Company at least through the end of the 2006 fiscal year, and to assess retirement possibilities at the end of such year. Even after retirement as an officer, Mr. Wicker s desire is to remain as a member of our Board of Directors and to provide ongoing counsel to us. We have no employment agreement with Mr. Wall, Mr. Wicker or any other executive officer. If Mr. Wall were to cease working for our company prior to the time that we transition to a new chief executive officer, or if we are unable to identify a viable successor to Mr. Wall, or if Mr. Wicker were unavailable to provide advice to us, our business would likely suffer.

To successfully expand our operations, we will need to attract and retain additional, highly skilled individuals, particularly in the areas of sales, marketing, manufacturing and finance. If we cannot attract sufficient skilled individuals, we may not be able to successfully grow our business and our business, financial condition and results of operations would be materially adversely affected.

Our success depends upon the development of new products and product enhancements, which entails considerable time and expense.

We place a high priority on the development of new products to add to our product portfolio and on the development of enhancements to our existing products. Product development involves substantial expense and we cannot be certain that a completed product will generate sufficient revenue for our business to justify the resources that we devote to research and development related to such product. The time and expense required to develop new products and product enhancements is difficult to predict and we cannot assure you that we will succeed in developing, introducing and marketing new products and product enhancements. Our inability to successfully develop and introduce new or enhanced products on a timely basis or at all, or to achieve market acceptance of such products, could materially impair our business.

Price changes in the raw materials we use could have a material adverse effect on our financial condition and results of operations.

The principal raw material used to produce our products is plastic resin, a petro-chemical compound. We have elected to purchase plastic resin under short term contracts rather than entering into long term contracts or commodity futures or derivative instrument transactions. We are, therefore, subject to fluctuations in the price of plastic resin that may result from changes in the price of petroleum-based products generally, increases or decreases in demand during a given period, or for other reasons. As a result of price competition, we may be unable to pass on to customers the higher manufacturing costs we would incur if there were a significant increase in the price of plastic resin or other raw materials, which would negatively impact our profit margins and our results of operations.

If we are unable to identify, complete and integrate future acquisitions, our business may suffer.

We have supplemented internal growth with product, technology and business acquisitions in the past, and intend to do so in the future. Our acquisition strategy is subject to inherent risks, including the following:

- viable acquisition candidates may not be available to us on price and other terms that are satisfactory to us;
- we may be unable to integrate acquired companies effectively into our business;
- we may be unsuccessful in commercializing products that we manufacture pursuant to acquired or licensed patents;
- acquired companies may require more capital resources and/or management attention than we anticipate at the time of acquisition;
- we may have limited or no direct prior experience in new markets or countries that we enter;
- we may be unable to retain the key employees of the acquired business who are necessary to manage these businesses;
- we may suffer adverse customer reaction to the business combination;
- our due diligence may fail to identify liabilities and exposures which, once discovered, materially adversely affect our ability to operate the newly acquired business profitably; and
- management focus on our existing businesses may be diverted.

In addition, an acquisition could materially impair our operating results by causing us to incur debt or requiring us to amortize acquisition expenses and acquired assets.

We are subject to legal proceedings which, if determined adversely to us, could materially and adversely impact us.

We are engaged in certain substantial legal proceedings. In one instance, former shareholders of our Vital Pharma subsidiary are seeking damages of approximately $14 million relating to the sale of that subsidiary to us in January 1996. The Vital Pharma shareholders claims, which are contractual in nature and thus not subject to any insurance policy that we maintain, have been presented to an arbitrator for determination. While we believe that we have meritorious defenses, we are unable to predict the outcome of this arbitration.

We are also involved in a number of negligence and product liability lawsuits relating to an anti-adhesion product for gynecological surgery known as Intergel. Intergel was manufactured by Lifecore Biomedical, Inc. and distributed by Ethicon, Inc., a subsidiary of Johnson & Johnson.

Our subsidiary, Vital Pharma, Inc., packaged the Intergel product into plastic containers. Although we believe that we have meritorious defenses to this litigation, as well as indemnification protection from Lifecore and product liability insurance as described below, we cannot be certain that monetary damages will not be recoverable against Vital Pharma. For addition information regarding our involvement in legal proceedings, see Item 3 - Legal proceedings.

The amount of damages claimed in the Vital Pharma and Intergel matters is substantial. If we are required to pay significant sums in these matters, our consolidated results of operations, cash flows and financial condition could be materially and adversely affected.

We cannot be certain that our product liability insurance will be sufficient to protect us against significant exposure to product liability risks.

We are exposed to potential product liability resulting from the use of our products. We presently maintain product liability insurance coverage of $20 million 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 materially adversely affected. 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. We have been advised by the carriers of our primary and umbrella liability insurance policies that in light of the number of lawsuits involving the Intergel product, we may be underinsured. To the extent that we are underinsured in the Intergel matter, it would be necessary for us to rely on indemnification protection given to us by the manufacturer of the Intergel product and legal causes of action that we believe we have against the distributor of the Intergel product, which may or may not be successful.

We manufacture and sell a significant portion of our products in markets outside the United States, subjecting us to various risks relating to international activities.

International sales accounted for approximately 24% of our net revenue during fiscal 2005. Such sales are subject to several risks that are separate and distinct from those we face in our United States operations, including:

- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- foreign customers who may have longer payment cycles than customers in the United States;
- difficulties in enforcing intellectual property rights;
- currency losses that may arise as a result of the fact that not all of our sales are denominated in United States dollars;

- compliance with foreign medical device manufacturing and sales regulations in the countries in which we sell and/or manufacture our products;
- changes in trade policies and in domestic and foreign tax policies in the countries in which we sell and/or manufacture our products;
- possible changes in export or import restrictions in the countries in which we sell and/or manufacture our products;
- the modification or introduction of other governmental policies or regulations in the countries in which we sell and/or manufacture our products; and
- political uncertainties in countries in which we sell and/or manufacture our products, in particular in the People s Republic of China, where our supplier of anesthesia face masks is located.

Any such factor may affect our international operations and our potential for growth in markets outside of the United States and may have a significant adverse effect on the sales of our products and our profitability.

Our international sales may be adversely affected as a result of the termination of our strategic alliance and distribution contract with one of our primary international distributors.

In November 2005, our strategic alliance and distribution agreement with Rusch International was terminated by the parties following the acquisition by Rusch s parent of one of our competitors. Prior to the termination of this agreement, Rusch was our distributor of anesthesia, respiratory/critical care products in nine European countries where it has a direct sales force. For our fiscal year ended September 30, 2005, sales through Rusch accounted for 0.9% of our net revenues. At least for a period of time, we expect to continue to sell through a number of Rusch s country-specific distribution channels. We are simultaneously evaluating alternative distribution methods, including establishing direct distribution channels for some countries and partnering with third-party distributors in other counties. Developing a distribution network is a difficult, expensive and time-consuming process and we may be unsuccessful in implementing a new network. Factors that may inhibit the implementation of a new international distribution network include difficulties in locating qualified personnel, difficulties in developing direct relationships with customers and/or effective local distributors and responding to competing needs for company resources and management attention. We cannot assure you that we will not lose customers or business or that we will be able to sustain the revenue levels that we achieved while we were represented by Rusch.

If we are unable to maintain relationships with distributors, our business may be adversely affected.

Certain hospitals require us to sell products to them through distributors. For fiscal 2005, approximately 22% of our net revenues was distributed through Cardinal Health Corporation, McKesson-General Medical Corp. and Owens & Minor, Inc. If our relationships with these distributors were damaged and we were unable to

develop relationships with other distributors, our business, financial condition and results of operation could be materially adversely affected.

We may not be able to obtain new patents or protect our existing patents, which could enable third-parties to use our technology.

Our ability to compete effectively depends in part on our ability to maintain the proprietary nature of our technologies and manufacturing processes, which includes the ability to obtain, protect and enforce patents on our technology and products. If we are unable to obtain new patents and protect our existing patents, our competitive position may suffer. We own or have licensed patents that cover several aspects of our anesthesia, respiratory/critical care and sleep disorder segments. Others may challenge our patents and, as a result, our patents could be narrowed, invalidated or rendered unenforceable. Competitors may develop products similar to ours which our patents do not cover. In addition, our current and future patent applications may not result in the issuance of patents in the United States or foreign countries. Further, there is a substantial backlog of patent applications at the United States Patent and Trademark Office, and the approval or rejection of patent applications may take several years. Additionally, many of our products are not protected by patents, but rather are distinguished by product features that others may seek to copy.

Our competitive position is dependent in part upon unpatented trade secrets which we may not be able to protect.

Our competitive position is also dependent upon unpatented trade secrets. Trade secrets are difficult to protect and we cannot assure you that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets. If other companies are successful in copying our trade secrets and developing products similar to ours, we may lose our competitive position and our revenue may be significantly impacted.

We seek to protect our trade secrets, know-how and other unpatented proprietary technology, in part, with confidentiality agreements with select employees. We cannot assure you, however, that:

- these agreements will not be breached;
- we will have adequate remedies for any breach; or
- trade secrets, know-how and other unpatented proprietary technology will not otherwise become known to or independently developed by our competitors.

We hold licenses with third parties that are necessary to produce some of our products. The loss of such licenses would prevent us from manufacturing, marketing and selling these products, which could harm our business.

Our success is dependent in part on our ability to operate without infringing or misappropriating the proprietary rights of others.

We have been sued in the past, and may in the future be sued again, for infringing the intellectual property rights of others. In addition, we may find it necessary, if threatened, to initiate a lawsuit seeking a declaration from a court that we do not infringe the proprietary rights of others or that others rights are invalid or unenforceable. Even if we prevail in such litigation, infringement proceedings can be very expensive and time-consuming. If we do not prevail in an infringement litigation, we may be required to pay damages and expenses, and we would be required to stop the infringing activity or obtain a license. Any required license may not be available to us on acceptable terms, or at all. In addition, some licenses may be nonexclusive, and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license or are unable to design around a patent, we may be unable to sell some of our products, which 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 on potential risk of patent infringement litigation.

Government regulation restricts the manner in which we may sell our obstructive sleep apnea products to customers of our sleep centers and the manner in which we relate to referring physicians.

We operate sleep centers in the United States that diagnose obstructive sleep apnea and other sleep disorders. Our ability to sell our Breas products in our sleep centers is restricted by strict regulations which prohibit us from diverging from a physician s prescription. If a physician prescribes a continuous positive airway pressure, or CPAP, product other than a Breas product for a patient at one of our sleep centers, we are generally prohibited by federal regulations from substituting a Breas product. Federal anti-kickback and anti-referral regulations strictly limit the extent to which we may provide anything of value to physicians who refer Medicare or Medicaid patients to our sleep centers. Any failure by us to comply with these regulations may result in significant regulatory actions, including criminal prosecution and large fines, which could have a material adverse effect upon our business, financial condition and results of operations.

If we are unable to support our continued growth, our business may suffer.

As we grow, the complexity of our operations increases, placing greater demands on our management. Our ability to manage our growth effectively depends in part upon our ability to implement and improve our financial and management information systems on a timely basis and to effect other changes in our business. If we fail to manage our growth effectively, our business could suffer. Unexpected difficulties during expansion, the failure to attract and retain qualified employees, the failure to successfully replace or upgrade our management information systems, the failure to manage costs or our inability to respond effectively to growth opportunity or plan for future expansion could cause our growth to slow down or could require us to reduce our size.

A significant shift in technologies or methods used in the treatment of sleep apnea could make our sleep centers and products obsolete or less attractive.

The development of new technologies or methods could reduce demand for our sleep centers and our products. For example, pharmaceutical advances could result in different methods of treating sleep apnea and a reduced need for our CPAP therapy products. The emergence of a low-invasive cost-effective surgery to treat sleep apnea could also diminish demand for our sleep centers and products.

If a natural or man-made disaster strikes one or more of our manufacturing facilities, we may be unable to manufacture certain products for a substantial amount of time and our revenue could decline.

We have three manufacturing facilities located in the United States and one manufacturing facility located in Sweden. These facilities and the manufacturing equipment and personnel know-how that we use to produce our products would be difficult to replace and could require substantial lead-time to repair or replace. Our facilities may be affected by natural or man-made disasters. In the event that one of our facilities was affected by a disaster, we would be forced to attempt to shift production to our other manufacturing facilities or rely on third-party manufacturers, and our other facilities or a third-party manufacturer may not have the capability to effectively supply the affected products. Although we have insurance for damage to our property and the interruption of our business, this insurance may not be sufficient in scope or amount to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

Requirements associated with the evaluation of internal controls required by Section 404 of the Sarbanes-Oxley Act of 2002 have required and will require significant company resources and management attention.

Although we believe that we are currently in compliance with Section 404 of the Sarbanes-Oxley Act, we may in the future identify material deficiencies that we may not be able to remediate on a timely basis. If we are not able to comply with the requirements of Section 404 in a timely manner, we could be subject to scrutiny by regulatory authorities, such as the SEC or the NASDAQ National Market, and the trading price of our stock could decline. Moreover, effective internal controls, particularly those related to revenue recognition, are necessary for us to produce reliable financial reports and are important in helping us to prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our stock could drop significantly.

Risks related to purchasing our common stock

Our quarterly operating results are subject to fluctuation which may impact the price of our stock.

Our operating results have, from time to time, fluctuated on a quarterly basis and may be subject to similar fluctuations in the future. These fluctuations may result from a number of factors, including:

- the introduction of new products by us or our competitors;
- actions taken by group purchasing organizations;
- timing of orders by our customers;
- the mix of our product sales;
- competitive pricing in different regions in which we sell our products;
- timing and cost of regulatory clearances and approvals of our products;
- the cost, effect and success of our promotional and marketing programs;
- the effect of the flu season on our respiratory/critical care business;
- loss of any of our key management or technical personnel;
- product liability lawsuits against us;
- changes in health care policy in the United States and internationally;
- conditions in the financial markets in general or changes in general economic conditions;
- changes in stock market analyst recommendations regarding our common stock, other comparable companies or the medical device industry generally, or lack of analyst coverage of our common stock;
- changes in accounting principles;
- expenditures incurred by us for research and development; and
- expenditures incurred by us to comply with enhanced regulatory obligations and internal control requirements.

Any of these factors may cause the price for our common stock to fluctuate and therefore decrease the value of any investment in our company.

A substantial portion of our assets includes goodwill and an impairment in the value of our goodwill would have the effect of decreasing our earnings or increasing our losses.

As of September 30, 2005, goodwill represented 30.4% of our total assets. If we are required to record an impairment charge to earnings relating to goodwill, it will have the effect of decreasing

our earnings or increasing our losses. Goodwill represents the excess of the total purchase price of our acquisitions over the fair value of the net assets acquired. The accounting standards on goodwill and other intangible assets, which we adopted as of October 1, 2001, require goodwill to be reviewed at least annually for impairment, and does not permit amortization. In the event that impairment is identified, a charge to earnings will be recorded and our stock price may decline as a result.

A large percentage of our outstanding common stock is held by, and subject to pledges by, insiders, and, as a result, the trading market for our common stock is less liquid and our stock price can be volatile.

As of November 30, 2005, we had 12,593,579 shares of common stock outstanding. Approximately 33% of such shares are beneficially owned by Terry D. Wall, our chief executive officer, and his wife and an additional 19% of such shares are beneficially owned by trusts established for the benefit of the Walls children. Such trusts are administered by a trustee who has no current or prior relationship with Vital Signs. Companies like ours, with a relatively small percentage of shares held by the public, can be subject to a more volatile stock price. Our stock price, and therefore your investment in our company, may be volatile.

A substantial portion of the shares owned by Terry D. Wall, his wife and such trusts have been pledged to secure loans made by third-parties. Such loans may be called in the future. Sales of a substantial number of such shares may have a disruptive effect on the market price of our common stock.

Our major shareholders exercise significant influence on us and they may pursue policies with which you disagree.

As of November 30, 2005, Terry D. Wall, our chief executive officer, and his wife beneficially owned approximately 33% of our common stock. In addition, the trusts established for the benefit of the Walls children beneficially owned approximately 19% of our common stock. As a result, Mr. Wall and his wife have a significant influence in electing our directors, appointing new management and approving any action requiring the approval of our shareholders, including any amendment to our certificate of incorporation and approval of mergers or sales of substantially all of our assets. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company or discouraging others from making tender offers for our shares, which could prevent stockholders from receiving a premium for their shares.

Our certificate of incorporation, our by-laws and New Jersey law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Anti-takeover provisions in our certificate of incorporation make it more difficult for a third-party to acquire us, even if doing so would be beneficial to our shareholders. These provisions include:

the authorization of the issuance of up to 4,000,000 shares of our preferred stock without further approval of our shareholders;

the election of directors on a staggered term basis; and

the elimination of shareholder action by written consent.

Similarly, our bylaws establish procedures, including advance notification procedures, with regard to the nomination, other than by or at the direction of our board of directors, of candidates for election as directors or for shareholder proposals to be submitted at shareholder meetings.

We are also subject to the New Jersey Shareholders Protection Act, an anti-takeover provision. In general, that Act prevents a shareholder owning 10% or more of a New Jersey public corporation s outstanding voting stock from engaging in business combinations with that corporation for five years following the date the shareholder acquired 10% or more of the corporation s outstanding voting stock, unless board approval is obtained prior to the time that the shareholder reaches the 10% threshold.

These provisions are expected to discourage different types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with our board of directors. At the same time, however, these provisions make it more difficult for a third-party to successfully acquire us, even if the acquisition were beneficial to our shareholders, and thus could prevent shareholders from receiving a premium for their shares.

Item 1B. ***Unresolved Staff Comments***

Not applicable

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	**Square Feet**
Totowa, New Jersey* (executive offices, principal manufacturing and warehouse facilities)	158,000
Englewood, Colorado* (manufacturing, warehouse and office space)	88,000
Burnsville, Minnesota (manufacturing, warehouse and office space)	29,688
Molnlyke, Sweden* (Breas manufacturing, warehouse and office space)	27,000
Malvern, Pennsylvania (Thomas Medical manufacturing, warehouse and office space)	33,000
Bensalem, Pennsylvania (Stelex office space)	13,000
Glen Burnie, Maryland (Sleep Services of America office space)	7,500
Littlehampton, United Kingdom (Vital Signs, Ltd warehouse and office space)	12,000

* We own this facility.

Item 3. ***Legal Proceedings***

Vital Pharma shareholder litigation

On December 6, 1999 a complaint was filed against us on behalf of 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 January 1996. In August 2000 the court ordered the plaintiff to submit such 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 has been completed and post-arbitration briefs have been presented. We are currently waiting for the arbitrator to render a decision, which may come at any time. Plaintiffs originally claimed damages in the pre-interest amount of approximately $8.0 million. In plaintiffs post-arbitration brief to the arbitrator, plaintiffs argued that the final calculation of their damages could be in excess of $14,000,000. We have recorded a reserve in connection with this proceeding in an amount not exceeding plaintiffs claim.

Intergel litigation

A number of negligence and product liability lawsuits have been filed, primarily in Palm Beach County, Florida, over an anti-adhesion product for gynecological surgery known as Intergel. Intergel was manufactured by Lifecore Biomedical, Inc. and distributed by Ethicon, Inc., a subsidiary of Johnson & Johnson. Our subsidiary, Vital Pharma, Inc., packaged the Intergel product into plastic containers.

Vital Pharma provided the packaging pursuant to a written contract which contains express provisions requiring that Lifecore indemnify Vital Pharma in the event Lifecore was responsible for injuries resulting from the product. Vital Pharma also agreed to indemnify Lifecore with respect to any breaches by Vital Pharma of its obligations under the contract. Lifecore, through its insurer, has been reimbursing Vital Pharma s legal fees for all of the litigation relating to Intergel in which Vital Pharma has been involved.

The first action involving Intergel in which Vital Pharma was named as a party was commenced in 2003 in the United States District Court for the Northern District of California. On January 28, 2004, the same plaintiff filed a similar action in California state court. On October 21, 2004, the plaintiff voluntarily dismissed the state court action without prejudice. Subsequently, Vital Pharma has been named as a defendant in 59 other Intergel lawsuits with virtually identical allegations. Additional claims may be filed in the future. 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. To our knowledge, none of the plaintiffs have claimed that use of the Intergel product resulted in deaths or birth defects.

We have notified the carriers of our primary and umbrella liability insurance policies of the existence of the claims in the Intergel lawsuits. As part of a reservation of rights letter, the carriers have advised us that we may be underinsured. Based on the insurance that we do have, as supplemented by Lifecore s indemnification obligations and our view that our Vital Pharma

subsidiary has meritorious defenses to these actions, we believe that we are adequately protected with respect to these matters. In light of the different stages of each of the proceedings and the protections that we have, we cannot quantify the exposure, if any, to us. In light of the foregoing, we have not established a reserve for these matters.

Other litigation

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 Matters to a Vote of Security 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	64	President, Chief Executive Officer and Director
C. Barry Wicker	65	Executive Vice President, Chief Operating Officer and Director
William Craig	49	Executive Vice President and Chief Financial Officer
Alex Chanin	37	Executive Vice President and Chief Information Officer
Anthony P. Martino	59	Vice President, Quality and Regulatory Affairs

* As of September 30, 2005.

Terry D. Wall founded Vital Signs in 1972 and has been President, Chief Executive Officer and a director of Vital Signs since that time. 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.

Barry Wicker has served as a director and an Executive Vice President of Vital Signs since 1985, with primary responsibility for sales and marketing. He has also served as our Chief Operating Officer since June 2005. Mr. Wicker joined Vital Signs in 1978 as National Sales Manager and became Vice President-Sales in 1981. Prior to joining us, he held various marketing and sales positions with The Foregger Co. over a 20 year period.

William Craig joined us as our Chief Financial Officer in March 2005. Prior to joining Vital Signs, Mr. Craig worked for a year as an independent Sarbanes-Oxley Act consultant and as interim chief financial officer of DMFS, Inc., a privately held direct mail and fulfillment company. From September 1999 to February 2004, Mr. Craig was the Executive Vice President - Finance and Administration and Chief Financial Officer for Matheson Tri-gas, Inc., a manufacturer and marketer of industrial gases and technical equipment. Before joining Matheson, Mr. Craig spent nearly five years as an executive, most notably with Empire of Carolina, Inc, a consumer product manufacturer that traded on the AMEX. Prior to that time, Mr. Craig worked for five years with GE Capital. In earlier years, Mr. Craig worked in merchant banking, as well as with what is now Deloitte and Touche and General Motors. He has a Bachelor of Arts degree from Wake Forest University, a Master of Business Administration degree from Texas A&M University, and is a certified public accountant. He also has a number of scientific publications.

Alex Chanin has served as Executive Vice President and Chief Information Officer for Vital Signs since January 2004. He served as President of our Stelex, Inc. subsidiary from 2003 to 2004 and Vice President of Stelex from April 2002 to 2003. Mr. Chanin was one of the founding partners - in 1991 - of Stelex, prior to our 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.

Anthony Martino joined us as our Vice President, Research and Development in 1996. He has served as our Vice President, Quality and Regulatory Affairs since December 1996.

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, Related Stockholder Matters and Issuer Purchases of Equity Securities***

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, 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
Fiscal Year Ended September 30, 2005:			
Quarter ended December 31, 2004:	$ 39.84	$ 31.84	$ .06
Quarter ended March 31, 2005:	42.93	35.22	.07
Quarter ended June 30, 2005:	45.72	38.33	.07
Quarter ended September 30, 2005:	48.80	41.81	.07

As of December 9, 2005, there were approximately 310 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 2005, the Company declared and paid cash dividends of $.27 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, 2005, including the Company s 2003 Investment Plan, prior Investment Plan, as amended and restated as of May 30, 2001, 1991 Director Stock Option Plan, 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	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity Compensation Plans Approved by Shareholders	582,211	$ 29.32	1,619,602
Equity Compensation Plans Not Approved by Shareholders			
Total:	582,211	$ 29.32	1,619,602

The following table provides information about purchases made by the Company of its Common Stock during the quarter ended September 30, 2005:

Period		(a) Total Number of Shares Purchased	(b) Average Price Paid Per Share	(c)(1) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d)(1) Maximum Dollar Amount That May Yet be Purchased Under the Plans or Programs
7/1/2005	7/31/2005	3,100	$42.91	3,100	$16,237,835
8/1/2005	8/31/2005	6,600	$43.26	6,600	$15,952,064
9/1/2005	9/30/2005	18,100	$43.27	18,100	$15,168,132
Total		27,800	$43.22	27,800	$15,168,132

Our board of directors has authorized a total expenditure of up to $35 million for the repurchase of Vital Signs' stock. Our board of directors authorized the expenditure of $20 million on May 8, 2003 and authorized an additional expenditure of $15 million on February 8, 2005. From fiscal 2003 through September 30, 2005, we repurchased 613,300 shares for $19,832,000, at an average price of $32.30 per share. No repurchases have been made since October 6, 2005.

Item 6. ***Selected Financial Data***

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and notes to those consolidated financial statements, beginning on page F-1, and Management s discussion and analysis of financial condition and results of operations . The consolidated statement of income data for the years ended September 30, 2005, 2004 and 2003, and the consolidated balance sheet data as of September 30, 2005 and 2004, are derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report. The consolidated statement of income data for the years ended September 30, 2002 and 2001, and the consolidated balance sheet data as of September 30, 2003,

2002 and 2001, are derived from our audited consolidated financial statements, which are not included in this Annual Report.

Year ended September 30, (Dollars in thousands, except per share amounts)	2005	2004	2003	2002	2001
Consolidated statement of income data:					
Net revenue	$ 194,037	$ 183,991	$ 182,163	$ 174,018	$ 163,142
Cost of goods sold and services performed	95,507	91,374	91,608	86,803	78,080
Gross profit	98,530	92,617	90,555	87,215	85,062
Operating expenses:					
Selling, general and administrative	51,025	50,115	51,338	44,216	41,063
Research and development	7,011	7,036	5,871	6,615	6,937
Restructuring charge	213	539			
Impairment and other charges (benefits) (1)			133	(3,428)	2,107
Goodwill amortization (2)					1,120
Other (income) expense - net	(78)	612	717	305	(390)
Total operating expenses	58,171	58,302	58,059	47,708	50,837
Operating income	40,359	34,315	32,496	39,507	34,225
Interest income	(1,672)	(824)	(654)	(638)	(976)
Interest expense	36	26	910	179	1,028
Total other (income) expense	(1,636)	(798)	256	(459)	52
Income from continuing operations before provision for income taxes and minority interest	41,995	35,113	32,240	39,966	34,173
Provision for income taxes	15,093	12,498	12,802	13,225	9,794
Income from continuing operations before minority interest	26,902	22,615	19,438	26,741	24,379
Minority interest in net income of subsidiary	602	447	248	241	9
Income from continuing operations (3)	26,300	22,168	19,190	26,500	24,370
Earnings from continuing operations per common share:					
Basic	2.08	1.73	1.49	2.05	1.93
Diluted	2.06	1.72	1.48	2.03	1.90
Basic weighted-average number of shares outstanding	12,616	12,793	12,905	12,896	12,633
Diluted weighted-average number of shares outstanding	12,789	12,907	12,985	13,036	12,850
Dividends declared and paid per common share	0.27	0.24	0.19	0.16	0.16

(1) For fiscal 2001, excludes special charges associated with operations currently classified as discontinued operations; the impairments charges for that year relate primarily to the writedown of certain investments. During fiscal 2002, we reversed $5.0 million in litigation accruals as a result of the successful conclusion of a patent infringement suit. This benefit was offset in part by an impairment charge of $1.6 million related principally to our Chinese distributor, based on an evaluation of its business. The charge in fiscal 2003 relates to the write-off of certain amounts due from our Chinese distributor.

(2) In October 2001, we adopted SFAS No. 142, Goodwill and Other Intangible Assets. Assuming no amortization of goodwill for the year ended September 30, 2001, income from continuing operations would have been $25.2 million for that year.

(3) 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.

At September 30, (Dollars in thousands)	2005	2004	2003	2002	2001
Consolidated balance sheet data:					
Cash and cash equivalents	$ 81,767	$ 76,468	$ 55,660	$ 29,303	$ 31,029
Working capital	119,555	112,853	98,469	86,600	70,493
Total assets	253,702	236,064	223,078	205,077	191,560
Total long term debt including current portion			1,690	1,955	2,199
Total shareholders equity	232,706	216,223	202,222	187,815	160,626

For information regarding acquisitions effected during the past five years, see Management s discussion and analysis of financial condition and results of operations - Overview .

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

The following discussion should be read in conjunction with our consolidated financial statements and notes to those consolidated financial statements, included elsewhere in this Annual Report.

Forward Looking Statements

This Annual Report contains forward-looking statements (as such term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934) that are based on our management s beliefs and assumptions and on information currently available to us. These statements may be found throughout this Annual Report, particularly in Items 1, 1A and this Item 7. These sections contain discussions of some of the factors that could cause actual results to differ materially from the results projected in our forward-looking statements. When used in this Annual Report, the words or phrases will likely result, expects, intends, will continue, is anticipated, estimat projects, management believes, we believe and similar expressions are intended to identify forward-looking statements within the meaning of th Exchange Act and the Securities Act. Forward-looking statements include plans and objectives of management for future operations. These forward-looking statements involve risks and uncertainties and are based on assumptions that may not be realized. Actual results and outcomes may differ materially from those discussed or anticipated.

All forward-looking statements are subject to known and unknown risks and uncertainties, including those discussed in Item 1A, that could cause actual results to differ materially from historical results and those presently anticipated or projected. No forward-looking statement is a guarantee of future performance. We wish to caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date made. You should read our cautionary statements as being applicable to all related forward-looking statements whenever they appear in:

- this Annual Report and materials referred to in this Annual Report; and
- our press releases.

Overview

We are a leading designer, manufacturer and marketer of airway management products for the anesthesia, respiratory/critical care and sleep disorder markets. We sell our products in over 70 countries worldwide. We offer one of the broadest single-patient use anesthesia and respiratory/critical care product lines in the industry and have developed numerous first-to-market products which are now considered industry standards. In addition, we sell therapeutic products for patients suffering from sleep disorders and provide sleep disorder diagnoses at sleep labs and centers that we operate. We also deliver technology services to FDA regulated companies.

Anesthesia

Our single-patient use anesthesia products and systems are designed to deliver oxygen and anesthesia from a gas source, such as an anesthesia machine, to a patient s pulmonary system, remove anesthetic gases, oxygen and carbon dioxide from a patient and link a patient with various monitors. Our principal anesthesia products consist of face masks, breathing circuits and general anesthesia products. See Item 1 - Business - Principal products and services - Anesthesia. We also include within this segment the products sold by our Thomas Medical Products subsidiary. Thomas Medical is an original equipment manufacturer that primarily manufactures vascular access products for sale to other health care product providers to be used in their products or kits or as a finished product.

Revenues in our anesthesia segment are driven primarily by the extent to which our hospital customers perform general surgeries and by the aging of the populations in the geographical markets that we serve. In addition, because most of our anesthesia products are single use products, we benefit when hospitals undertake programs to reduce the frequency of infections, known as nosocomial infections, which originate or occur within their settings. Revenues in this segment are negatively impacted by the trend among hospitals to allow group purchasing organizations to negotiate long-term contracts with medical device manufacturers on their behalf. See Item 1 - Business - Sales, marketing and distribution - United States sales. Expenses in our anesthesia segment are driven primarily by the cost of raw materials, labor costs and freight expenses. During recent periods, our petrochemical based raw materials, such as resins, and freight expenses have been impacted by high gas prices, gas shortages and plant shutdowns resulting from Hurricane Katrina.

In March 2005, we acquired the disposable airway management device business from a subsidiary of Baxter International Inc. for approximately $10.1 million, including related transaction costs. This acquisition was structured as an asset purchase pursuant to which we acquired certain manufacturing assets related to the disposable airway management device business valued at approximately $1.3 million, and inventory, including anesthesia circuits, face masks, heat and moisture exchanger filters and other associated anesthesia components valued at approximately $1.2 million. The excess of the purchase price over the fair value of the net assets acquired, which has been allocated to goodwill, was approximately $7.7 million. The results of operations of this business, including revenues of approximately $4.5 million, are included in our results of operations for our anesthesia segment from March 2, 2005.

Respiratory/critical care

Our primary respiratory/critical care products are arterial blood gas syringes and kits, manual resuscitators and blood pressure cuffs. Our respiratory/critical care segment responds to the growing needs of hospitals to provide respiratory relief and emergency care. We believe that in recent years there has been an increasing incidence of respiratory illnesses, such as asthma and emphysema, due in part to an increasingly susceptible aging population, environmental pollution, smoking-related illnesses and communicable diseases with significant respiratory impact, such as tuberculosis, HIV and influenza. These trends, together with concerns regarding the spread of nosocomial infections, drive our sales of respiratory products. As in our anesthesia segment, revenues in this segment have been negatively impacted by the emergence of group purchasing organizations and expenses in this segment are driven principally by raw materials costs, labor costs and freight expenses.

Sleep Disorders

We serve the sleep disorder market as both a provider of diagnostic services and a manufacturer of therapeutic products focused on sleep disorders. Through our Sleep Services of America, or SSA, subsidiary, we provide sleep diagnostic testing services in the United States in free standing labs and, through contracts with hospitals, in hospital facilities, for patients suspected of suffering from obstructive sleep apnea. As of September 30, 2005, we operated 52 sleep centers. We have focused our efforts on labs and centers affiliated with hospitals, such as Johns Hopkins and the University of Maryland. Our diagnostic services business is driven by the growing awareness of the existence and significant consequences of obstructive sleep apnea. Our principal expense in our sleep diagnostic business is the cost of employing the technicians who operate our sleep labs and centers.

Our Breas Medical AB, or Breas, subsidiary is a European manufacturer of personal ventilators for obstructive sleep apnea and long term ventilation. Our sleep disorder products 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. Our sleep disorder products employ continuous positive airway pressure, or CPAP, which is a common method for treating obstructive sleep apnea. We have manufactured and distributed CPAP systems for more than a decade. Our sales of sleep disorder and other personal ventilation products have been made principally in international markets. These sales depend principally on the prevalence of sleep disorders and the acceptance by patients and care-givers in developed markets of treatment modalities for obstructive sleep apnea. Like our anesthesia and respiratory/critical care businesses, our Breas subsidiary faces the challenge of controlling raw material, labor and freight costs. To date, we have had only limited sales of our sleep disorder products in the United States due in part to the need to obtain regulatory clearance and in part to the dominance by our competitors in selling to home supply dealers. Our United States strategy is to sell these products primarily through our sleep centers.

Pharmaceutical technology services

We deliver technology services to FDA regulated companies primarily in the pharmaceutical sector. In addition, we also provide services 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 and have begun to sell dedicated compliance software to our clients. We entered the pharmaceutical regulatory services market in

1996 and expanded into computer system compliance though our acquisition in 2002 of Stelex Inc. This segment benefits from regulatory efforts to systemize compliance by the regulated community and by our clients efforts to control costs through the outsourcing of compliance functions. Our principal costs in this segment are our labor costs. We also incur technology-related expenses as part of our development of compliance software.

Net revenues

Net revenues consist of sales of our anesthesia, respiratory/critical care and sleep disorder and personal ventilation products and revenues from our sleep disorder diagnostic services and pharmaceutical technology services. The amount and percentage of our net revenue derived from each of our business segments was as follows during the periods indicated:

Fiscal year ended September 30,	**2005**		**2004**		**2003**	
($ in thousands)	**Net revenue**	**%**	**Net revenue**	**%**	**Net revenue**	**%**
Anesthesia	$ 93,337	48.1	82,791	45.0	75,949	41.7
Respiratory/critical care	42,423	21.9	42,079	22.9	45,829	25.2
Sleep disorder and personal ventilation	41,517	21.4	44,053	23.9	45,580	25.0
Pharmaceutical technology services	16,760	8.6	15,068	8.2	18,105	9.9
Rebate allowance adjustment (1)					(3,300)	(1.8)
Total	$194,037	100.0	183,991	100.0	182,163	100.0

(1) This rebate allowance adjustment relates to our anesthesia and respiratory/critical care segments. See - Critical accounting policies - Revenue recognition below.

For all product sales, revenue is recognized when title to the product passes to the customer. For product sales to all customers except for certain domestic distributors, title passes upon shipment of the product by us. For sales through certain domestic distributors, title passes when the product is received by that distributor.

Gross revenues associated with our anesthesia and respiratory/critical care products are reduced by the amount of rebates due on sales to distributors. See -Critical accounting policies - Revenue recognition for a description of how we calculate those rebates. Sales to distributors represented 24.7%, 25.4% and 26.1% of our net sales during the years ended September 30, 2005, 2004 and 2003, respectively.

We have provided a reconciliation of gross to net product sales, as well as a comparison with service revenues, below:

Fiscal year ended September 30, (In thousands)	2005	2004	2003
Gross sales	$220,504	$203,314	$194,295
Rebates (1)	(55,917)	(47,809)	(44,439)
Other deductions (2)	(4,006)	(3,711)	(3,977)
Net sales	160,581	151,794	145,879
Service revenues	33,456	32,197	36,284
Total net revenues	$194,037	$183,991	$182,163

(1) See Critical accounting policies - Revenue recognition for information regarding approaches we have taken in calculating rebates.

(2) Other deductions consist of discounts, returns and allowances for credits.

For service revenue in the sleep disorder and pharmaceutical technology services segments, revenue is recognized when the service is performed.

Research and development

The focus of our research and development efforts, and the amount of such expenses that we incur, vary from year to year and quarter to quarter based on the specific needs of our business. Thus, for example, when changes were required in our sleep disorder and personal ventilation product line during the past two years, 43% of our research and development investment was focused upon our sleep disorder segment in fiscal 2005 and 47% of our research and development investment was focused upon that segment in fiscal 2004. For fiscal 2005, 2004 and 2003, we incurred research and development expenses of $7.0 million, $7.0 million and $5.9 million, respectively.

International sales

Our products are sold in over 70 countries worldwide. The table below sets forth our international sales, by segment, for the periods presented:

Fiscal year ended September 30, (In thousands)	2005		2004		2003	
	Net revenues	Percent of total revenues	Net revenues	Percent of total revenues	Net revenues	Percent of total revenues
Anesthesia	$ 8,357	4.3%	6,907	3.8%	6,146	3.4%
Respiratory/critical care	13,617	7.0%	12,755	6.9%	12,653	6.9%
Sleep disorder	24,820	12.8%	26,924	14.6%	26,521	14.6%
Pharmaceutical technology services						
Total	$46,794	24.1%	46,586	25.3%	45,320	24.9%

For international sales other than in the United Kingdom, where we operate a wholly-owned distributor, we rely primarily on third-party distributors. Commencing in 2002, we sold our anesthesia and respiratory/critical care products in nine European and certain other related international markets primarily through a strategic alliance with Rusch GmbH, a manufacturer of medical devices. However, during our 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. In light of this acquisition, the parties terminated the distributor agreement, effective as of November 30, 2005. For a period of time we expect to continue to sell through a number of Rusch s country specific organizations. We are simultaneously evaluating alternative distribution methods, including establishing direct distribution channels for some countries and partnering with third-party distributors in other countries. If we are unable to establish new channels promptly and effectively, our international sales of anesthesia and respiratory products may be adversely impacted in fiscal 2006 by the termination of our distribution agreement with Rusch.

Foreign exchange risks

Our international business exposes us to foreign exchange risks, particularly with respect to our sleep disorder segment and, more particularly, with respect to international sales of our sleep disorder and personal ventilation products by our Breas subsidiary. Sales of such products by our Breas subsidiary are translated from Swedish kroner to United States dollars. The relative strength of the Swedish kroner as compared to the United States dollar, in fiscal 2005 and 2004, has resulted in a foreign exchange translation benefit in reporting Breas revenue and operating losses. See Quantitative and qualitative disclosures about market risk .

Acquisitions

As part of our growth strategy, we pursue licensing agreements, strategic acquisitions and the purchase of technology. During the five year period ended September 30, 2005, we made or completed the following acquisitions:

- We acquired a 100% equity interest in Breas over a period from June 1997 through April 2002. Breas is engaged in the manufacture and sale of sleep disorder and personal ventilation products.
- We acquired a controlling interest in National Sleep Technologies, Inc. over a period from June 1998 through June 2000. In 2002, National Sleep Technologies merged with a subsidiary of The Johns Hopkins Health System Corporation, to form SSA. We own a 70% equity interest in SSA, which operates our sleep diagnostics business. The portion of SSA that we do not own is principally owned by Johns Hopkins and is recorded as a minority interest in our consolidated financial statements.
- We acquired a 100% equity interest in Stelex in 2002. We provide pharmaceutical technology services through this subsidiary
- In March 2005, we acquired a disposable airway management device business from a subsidiary of Baxter International, Inc. to improve our market share in the anesthesia segment.

These acquisitions have been accounted for as purchases and, accordingly, are included in our consolidated financial statements from the respective dates of acquisition.

Results of operations

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

Fiscal years ended September 30,	**2005**	**2004**	**2003**
Consolidated statement of income data:			
Net revenue	100.0 %	100.0 %	100.0 %
Cost of goods sold	49.2	49.7	50.3
Gross profit:			
Anesthesia	53.7	54.4	53.8
Respiratory/critical care	52.7	51.8	54.3
Sleep disorder	47.3	45.3	43.7
Pharmaceutical technology services	38.6	38.6	45.2
Total	50.8	50.3	49.7
Operating expenses:			
Selling, general and administrative	26.3	27.2	28.2
Research and development	3.6	3.8	3.2
Restructuring and impairment	0.1	0.3	0.1
Other (income) expense, net	0.0	0.3	0.4
Total operating expenses	30.0	31.7	31.9
Interest income, net	(0.8)	(0.4)	0.1
Provision for income taxes	7.8	6.8	7.0
Income from continuing operations	13.6	12.0	10.5
Net income	13.6	12.0	7.8

Comparison of results for the year ended September 30, 2005 to the year ended September 30, 2004

Net revenues

Total net revenue increased by 5.5%, from $184.0 million for fiscal 2004 to $194.0 million for fiscal 2005. The percentage increase would have been 4.9% but for the impact of favorable foreign exchange rates. Of our total net revenue, $147.2 million, or 75.9%, were derived from domestic sales and $46.8 million, or 24.1%, were derived from international sales. Domestic revenues increased by 7.2%, from $137.4 million for fiscal 2004 to $147.2 million for fiscal 2005. International sales increased by $0.2 million. The international sales increase would have been a 1.8% decrease were it not for favorable foreign exchange rates.

We have set forth below the net revenues by business segment for fiscal 2005 compared to fiscal 2004.

Net revenue by business segment

For the year ended September 30,			**Percent**
(Dollars in thousands)	**2005**	**2004**	**change**
Consolidated statement of income data:			
Anesthesia	$ 93,337	$ 82,791	12.7%
Respiratory/critical care	42,423	42,079	0.8%
Sleep disorder	41,517	44,053	(5.8)%
Pharmaceutical technology services	16,760	15,068	11.2%
Total	$194,037	$183,991	5.5%

Anesthesia. Sales of anesthesia products increased by 12.7% from $82.8 million for fiscal 2004 to $93.3 million for fiscal 2005. This increase was due to volume growth in anesthesia circuits, including a 43.9% increase in sales of our patented anesthesia circuit, Limb-O , to $11.8 million, a 22.0% increase in sales of traditional anesthesia breathing systems to $36.3 million resulting from the acquisition of the Baxter disposable airway management product line and volume increases in sales of products by our Thomas Medical Products subsidiary. Domestic sales of anesthesia products increased 12.0%, from $75.9 million to $85.0 million. International sales of anesthesia products increased 21.0%, from $6.9 million to $8.4 million.

Respiratory/critical care. Sales of respiratory/critical care products increased 0.8%, from $42.1 million for fiscal 2004 to $42.4 million for fiscal 2005, resulting from volume growth in our Broselow-Luten System, CPAP and ABG product lines, offset by a decline in the domestic sales of our blood pressure cuffs. We attribute the $1.3 million increase in sales of our Broselow-Luten system to growing awareness by hospitals of the special risks associated with treating pediatric patients in the emergency room. Domestic sales of respiratory/critical care products declined by 1.8%, from $29.3 million to $28.8 million. International sales of respiratory/critical care products increased by 6.8% from $12.8 million for fiscal 2004 to $13.6 million for fiscal 2005, reflecting higher sales volumes in our ABG and CPAP product lines.

Sleep disorder. Our sleep disorder segment revenues decreased by 5.8% from $44.0 million for fiscal 2004 to $41.5 million for fiscal 2005. The percentage decrease would have been 8.0% but for the impact of favorable foreign exchange rates.

Revenues from our diagnostic services decreased by 2.5% from $17.1 million for fiscal 2004 to $16.7 million for fiscal 2005. In fiscal 2004, our SSA subsidiary closed 14 sleep labs and centers and opened nine new sleep labs and centers. In the continuing sleep labs and centers, revenue increased 22.3% from fiscal 2004 to fiscal 2005.

Revenues from the sale of sleep disorder and personal ventilation products at our Breas subsidiary decreased 7.8% from $26.9 million for fiscal 2004 to $24.8 million for fiscal 2005. The percentage decrease would have been 11.4% but for the impact of favorable foreign exchange rates. During fiscal 2005, a component vendor advised Breas that it was unable to deliver a sufficient quantity of a key component at our required specifications. As a result, Breas was unable to bring a new sleep disorder and personal ventilation product line to market in a timely manner. Since we had pre-announced the availability of that product line, orders for pre-existing products were reduced substantially and the unavailability of the new products negatively affected Breas 2005 revenues. Limited shipments of the new product line began during the fourth quarter of fiscal 2005. We believe that this supply issue has now been adequately resolved.

Pharmaceutical technology services. Service revenues in our pharmaceutical technology services segment increased by 11.2%, from $15.1 million for fiscal 2004 to $16.8 million for fiscal 2005, resulting in part from increased sales of our ComplianceBuilder software product and in part from increased project work. The increased project work reflects improved demand from certain new and existing pharmaceutical and medical device clients.

Gross profit

We have set forth below the dollar amount of our gross profits and our gross profit margins for each of our four segments:

For the year ended September 30, (Dollars in thousands)	2005 Gross profit	2005 Gross profit margin	2004 Gross profit	2004 Gross profit margin
Anesthesia	$ 50,082	53.7	$ 45,026	54.4
Respiratory/critical care	22,357	52.7	21,801	51.8
Sleep disorder	19,627	47.3	19,974	45.3
Pharmaceutical technology services	6,464	38.6	5,816	38.6
Total	$ 98,530	50.8	$ 92,617	50.3

Gross profit dollar improvements in our anesthesia and respiratory/critical care segments correspond to the sales volume increases in those segments. The decline in gross profit margin in the anesthesia segment resulted from the inclusion of the Baxter disposable airways product into the sales mix at a lower margin. The increase in gross profit margin in the respiratory/critical care segment was due to the effect of a one-time inventory writedown of $1.0 million in fiscal 2004.

The gross profit dollar decline in our sleep disorder segment resulted from the sales volume declines in diagnostic services and sleep disorder/personal ventilation products, which was offset in part by a cost savings resulting from the closing of 14 poorly performing sleep labs and centers. The gross profit margin in sleep disorder diagnostic services increased from 49.4% in fiscal 2004 to 53.1% in fiscal 2005, reflecting our efforts to close these facilities. The gross profit at Breas increased from 42.8% in fiscal 2004 to 43.4% in fiscal 2005 as the sales mix changed to include an increased percentage of higher margin new personal ventilation products.

Gross profit dollar improvements of approximately $0.6 million in our pharmaceutical technology services segment corresponded to the sales volume increase. Gross profit margin for fiscal 2004 and 2005 remained constant at 38.6%.

Operating expenses

Selling, general and administrative expenses. Selling, general and administrative expenses increased by 1.8%, from $50.1 million for fiscal 2004 to $51.0 million for fiscal 2005. The increase resulted primarily from increased freight costs resulting from increased sales volumes, the impact of foreign exchange translation at Breas, increased compensation cost, increased accounting fees primarily related to Sarbanes-Oxley compliance and increased group purchasing organization fees. These increases were partially offset by reductions in legal expense and reduced health care costs.

Research and development. Research and development expenses were approximately $7.0 million for both fiscal 2004 and fiscal 2005. We continue to invest in the development of the new Breas family of sleep CPAP and personal ventilation equipment, and single use products for anesthesia and respiratory/critical care.

Restructuring and impairment. During fiscal 2005, we completed the closure of our California plant and charged $0.2 million to restructuring expense. During the fiscal 2004, we recognized a $0.5 million restructuring charge associated with the closing of our California plant, a reduction

in force at our Totowa, New Jersey headquarters and the closing of the Breas sales office in Belgium.

Other (income) expense, net. For fiscal 2005, other net income of $0.1 million resulted from a litigation settlement, gains on sales of assets and realized foreign exchange gains, offset in part by charitable contributions consisting of product donations. For fiscal 2004, other net (income) expense of $0.6 million resulted from costs associated with an acquisition that we did not pursue, severance costs and charitable product donations.

Other items

Interest income, net. Interest income, net doubled from $.8 million for fiscal 2004 to $1.6 million for fiscal 2005, resulting from an increase in the level of cash and cash equivalents being invested and an increase in interest rates.

Income tax. The provision for income tax expense for fiscal 2005 and 2004 was $15.1 million and $12.5 million, respectively, reflecting effective tax rates of 35.9% and 35.6% for these periods, respectively. The tax rate increase to 35.9% resulted from the expiration of certain net operating loss carryforwards. See Note 15 of the notes to consolidated financial statements.

Discontinued operations. The net gain from our Vital Pharma discontinued operations was $0.1 million for fiscal 2005, as compared to a $0.1 million loss for fiscal 2004. See Note 2 of the notes to consolidated financial statements.

Comparison of results for the year ended September 30, 2004 to the year ended September 30, 2003

Net revenues

Total net revenue increased by 1.0%, from $182.2 million for fiscal 2003 to $184.0 million for fiscal 2004. The 1.0% increase would have been a 0.9% decrease were it not for favorable foreign exchange rates. Of our total net revenue, $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 by 0.4%, from $136.9 million for fiscal 2003 to $137.4 million for fiscal 2004. The 0.4% increase resulted from a 9.0% increase in our anesthesia segment which offset declines in our respiratory/critical care, sleep disorder and pharmaceutical technology services segments. International revenues increased by 2.8%, from $45.3 million for fiscal 2003 to $46.6 million for fiscal 2004. The 2.8% increase would have been a 4.6% decrease were it not for favorable foreign exchange rates.

We have set forth below the net revenues by business segment for fiscal 2004 compared to fiscal 2003.

Net revenue by business segment

For the year ended September 30, (Dollars in thousands)	2004	2003	Percent change
Consolidated statement of income data:			
Anesthesia	$ 82,791	$ 75,949	9.0%
Respiratory/critical care	42,079	45,829	(8.2%)
Sleep disorder	44,053	45,580	(3.4%)
Pharmaceutical technology services	15,068	18,105	(16.8%)
Rebate allowance adjustment (1)		(3,300)	N/A
Total	$ 183,991	$ 182,163	1.0%

(1) This rebate allowance adjustment relates to our anesthesia and respiratory/critical care segments. See - Critical accounting policies - Revenue recognition and Notes 1 and 16 of the notes to consolidated financial statements for a description of the rebate allowance adjustment.

Anesthesia. Sales of anesthesia products increased by 9.0% from $75.9 million for fiscal 2003 to $82.8 million for fiscal 2004. This increase was due to volume growth in anesthesia circuits, including Limb-Θ , 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 by 8.7%, from $69.8 million to $75.9 million. International sales of anesthesia products increased by 12.4%, from $6.1 million to $6.9 million, principally from the European distribution agreement with Rusch.

Respiratory/critical care. Sales of respiratory/critical care products decreased by 8.2%, from $45.8 million for fiscal 2003 to $42.1 million for fiscal 2004. Domestic sales declined 11.6%, from $33.2 million to $29.3 million, resulting from increased competition within the segment. International sales increased by 0.8% from $12.7 million for fiscal 2003 to $12.8 million for fiscal 2004, reflecting higher sales volumes through our distributor arrangement in Europe with Rusch.

Sleep disorder. Our sleep disorder revenues decreased by 3.3% from $45.6 million for fiscal 2003 to $44.0 million for fiscal 2004. The 3.3% decrease would have been a 10.2% decrease were it not for favorable foreign exchange rates.

Revenues from our diagnostic services decreased by 5.8% from $18.2 million for fiscal 2003 to $17.1 million for fiscal 2004. We closed 14 sleep labs and centers and opened nine new sleep labs and centers in fiscal 2004. In the continuing sleep labs and centers, revenue increased 16.1%.

Revenues from sales of sleep disorder and personal ventilation products at our Breas subsidiary decreased by 1.7% from $27.4 million fiscal 2003 to $26.9 million for fiscal 2004, resulting from increased competition in our ventilator product line and from discontinuing certain original equipment manufacturer, or OEM, products as a result of an increased focus on our own manufactured products. The 1.7% decrease would have been a 12.8% decrease were it not for favorable foreign exchange rates.

Pharmaceutical technology services. Service revenues in our pharmaceutical technology services segment decreased by 16.8%, from $18.1 million for fiscal 2003 to $15.1 million for fiscal 2004. During fiscal 2004, our larger pharmaceutical customers reduced their external resource usage with respect to FDA regulatory compliance needs.

Gross profit

We have set forth below the dollar amount of our gross profits and our gross profit margins for each of our four segments:

For the year ended September 30,				
(Dollars in thousands)	**2004**		**2003**	
	Gross profit	**Gross profit margin**	**Gross profit**	**Gross profit margin**
Anesthesia	$45,026	54.4	$40,880	53.8
Respiratory/critical care	21,801	51.8	24,866	54.3
Sleep disorder	19,974	45.3	19,921	43.7
Pharmaceutical technology services	5,816	38.6	8,188	45.2
Rebate adjustment			(3,300)	NA
Total	$92,617	50.3	$90,555	49.7

Gross profit dollar and margin improvements in our anesthesia segment resulted from sales volume increases at our Thomas Medical Products subsidiary and cost improvement projects at our New Jersey plant. The declines in gross profit dollars and margin in our respiratory/critical care segment resulted primarily from sales volume declines and inventory writedowns of $1.0 million. In both the anesthesia and respiratory/critical care segments, we were impacted by pricing pressures resulting from the membership of our customers in group purchasing organizations.

We experienced a gross profit dollar decline of $2.1 million in our sleep disorder segment as a result of volume and price reductions at our Breas subsidiary. These declines were more than offset by the cost saving effect of closing poorly performing sleep labs and centers. The gross profit percentage in our sleep diagnostics business increased from 45.0% in fiscal 2003 to 49.4% in fiscal 2004, while the gross profit percentage in our Breas subsidiary decreased from 43.6% in fiscal 2003 to 42.8% in fiscal 2004.

The declines in gross profit dollars and margin in our pharmaceutical technology services reflect the decline in service revenues resulting from reduced FDA regulatory compliance needs.

Operating Expenses

Selling, general and administrative expenses. Selling, general and administrative expenses decreased by 2.4%, from $51.3 million for fiscal 2003 to $50.1 million for fiscal 2004. The decrease consists primarily of cost reductions, primarily at our Breas sales offices and in our pharmaceutical technology services subsidiary, and a reduction in bad debt expense, offset in part by an increase resulting from foreign exchange rate changes.

Research and development. Research and development expenses increased by approximately $1.1 million, or 19.8%, from $5.9 million for fiscal 2003 to $7.0 million for fiscal 2004, as we invested in the development of new products for our Breas subsidiary.

Restructuring and impairment. During the third quarter of fiscal 2002, we recognized an impairment charge of $1.6 million relating principally to a Chinese distributor based on an evaluation of its business in China. At that time, we believed that we would be able to

renegotiate our agreement with our Chinese distributor to preserve some of our business in that country. In May of 2003, we retained counsel in China to commence certain legal actions against our distributor to collect our accounts receivable, and in the third quarter of fiscal 2003 we wrote-off all amounts due from this distributor, amounting to $0.5 million. In September 2003, we received $0.4 million in cash from this distributor and we recovered certain inventory. Accordingly, in the fourth quarter of fiscal 2003, we recorded that payment as income. See Note 11 of the notes to consolidated financial statements.

During the year ended September 30, 2004, we recognized a $0.5 million restructuring charge resulting from the closing of our California plant, a reduction in force at our Totowa, New Jersey headquarters and the closing of the Breas sales office in Belgium.

Other (income) expense, net. For fiscal 2004, other (income) expense, net of $0.6 million resulted from charitable product donations, costs associated with an acquisition that we did not pursue and severance costs For fiscal 2003, other (income) expense, net of $0.7 million consisted primarily of costs of a public offering that we did not pursue, charitable product donations and costs relating to the closing of several redundant sales offices operated by our Breas and pharmaceutical technology services subsidiaries.

Other items

Interest income, net. Interest income increased by 26.0%, from $0.6 million for fiscal 2003 to $0.8 million for fiscal 2004, resulting from an increase in the level of cash and cash equivalents being invested. Interest expense decreased from $0.9 million for fiscal 2003 to less than $0.1 million for fiscal 2004. Interest expense for fiscal 2003 included $0.8 million of interest relating to past taxes due resulting from an Internal Revenue Service examination, and interest of $0.1 million a loan that was paid off in December 2003.

Income tax. The provision for income tax expense for fiscal 2004 and fiscal 2003 was $12.5 million and $12.8 million, respectively, reflecting effective tax rates of 35.6% and 39.7% for these periods, respectively. We included in the provision for fiscal 2003 an additional provision of $1.1 million resulting from a routine examination by the Internal Revenue Service of our 1997, 1998 and 1999 Federal income tax returns. Also, in fiscal 2003, in order to reflect the results of the IRS examination, we re-filed certain state tax returns for prior periods, resulting in additional tax expense of $0.3 million and interest expense of $0.1 million.

Discontinued operations. On October 30, 2003, we sold the assets of our Vital Pharma subsidiary to Pro Clinical, Inc. We received $0.5 million in cash and a three-year note receivable from ProClinical for $2.0 million. The note is secured by a first lien against all of the assets sold. No gain or further loss was recorded on the sale. On December 29, 2003, we sold certain related real estate. We have accounted for these sales on a cost recovery basis. The net loss, after applying the tax benefit, from discontinued operation was approximately $0.1 million for fiscal 2004 and approximately $5.0 million for fiscal 2003.

Liquidity and capital resources

We believe that the funds generated from operations, along with our current working capital position and the net proceeds to be received by Vital Signs in this offering, will be sufficient to satisfy our capital requirements for at least the next twelve months.

Cash flows

Historically, our primary liquidity requirements have been to finance business acquisitions and to support operations. We have funded these requirements primarily through internally generated cash flow.

During fiscal 2005, operating activities provided $30.9 million of net cash. Investing activities used $15.5 million of net cash, including $9.9 million for the acquisition of the Baxter disposable airway management product line and capital additions of $5.6 million. Financing activities used $9.4 million, consisting of $9.1 million for the repurchase of common stock and $3.4 million paid for dividends, which were offset in part by $3.1 million of cash received from the exercise of stock options.

During fiscal 2004, operating activities provided $35.1 million of net cash. Investing activities used $3.7 million of net cash, including capital additions of $5.3 million. Financing activities used $11.2 million, consisting of $8.1 million for the repurchase of common stock, $3.1 million paid for dividends and $1.7 of principal payments on long-term debt, which were offset in part by $1.7 million of cash received from the exercise of stock options.

During fiscal 2003, operating activities provided $33.4 million of net cash. Investing activities used $4.5 million of net cash, including capital additions of $4.7 million, offset in part by $0.2 million of net proceeds from the sale of certain investment securities. Financing activities used $4.6 million, consisting of $2.6 million for the repurchase of common stock, $2.5 million paid for dividends and $0.3 million of principal payments on long-term debt, which were offset by $0.8 million of cash received from the exercise of stock options.

Cash and working capital

Cash and cash equivalents were $81.8 million at September 30, 2005 as compared to $76.5 million at September 30, 2004. At September 30, 2005, our working capital was $119.6 million compared to $112.9 million at September 30, 2004. At September 30, 2005, the current ratio was 7.9 to 1 and at September 30, 2004 the current ratio was 7.8 to 1.

Debt

We have no committed lines of financing.

Working capital and capital expenditures

Our current policy is to retain working capital and earnings for use in our business, subject to the payment of certain cash dividends. Such funds may be used for the buyback of our common stock, business acquisitions, product acquisitions and product development, among other things. We regularly evaluate and negotiate with domestic and foreign medical device companies

regarding potential business or product line acquisitions, licensing arrangements and strategic alliances.

Capital expenditures for the fiscal year ended September 30, 2005 were approximately $5.6 million, and included expenditures for the capitalized costs of software development ($1.9 million); computer hardware and software to upgrade our management information systems ($0.6 million); tools and molding for use at our Breas facility ($1.2 million); molds and equipment at both our Thomas Medical Products facility ($0.4 million) and our Colorado manufacturing plant ($0.3 million); equipment and building improvements at our New Jersey facility ($0.4 million) and Thomas Medical Products facility ($0.4 million); new laboratory equipment ($0.1 million) for our sleep labs; and patents ($0.2 million). For information regarding capital expenditures by segment, see Note 18 of the notes to the consolidated financial statements.

Dividend and stock buybacks

Our board of directors had authorized a total expenditure of up to $35 million for the repurchase of our common stock, including the expenditure of $15 million authorized by our board of directors on February 8, 2005. During the past three fiscal years, we repurchased 613,300 shares for $19.8 million, at an average price of $32.30 per share.

Commitments and contingencies

The following table sets forth, at September 30, 2005, the amounts of payments due under our operating leases and other long-term obligations for the time periods described below:

Payments Due by Period

Dollars in thousands			**One year**	**Three**	
		Less than	**to three**	**years to**	**More than**
Contractual obligations	**Total**	**one year**	**years**	**five years**	**five years**
Operating leases	$4,040	$1,312	$2,354	$374	
Long-term debt					
Capital leases					
Purchase obligations					
Other					

At September 30, 2003, 2004 and 2005, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships. We do not have material relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties other than what is disclosed in Note 19 of the notes to the consolidated financial statements.

Critical accounting policies

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:

Revenue recognition

Net revenues consist of sales of our anesthesia, respiratory/critical care and sleep disorder/ personal ventilation products and revenues from our sleep disorder diagnostic services and pharmaceutical technology services. For all product sales, revenue is recognized when title to the product passes to the customer. For product sales to all customers except for certain domestic distributors, title passes upon shipment of the product by us. For sales through certain domestic distributors, title passes when the product is received by the customer. For service revenue, revenue is recorded when the service is performed.

Our sales to United States distributors are made at our distributor list price. Because the end-user (i.e., a hospital) is typically entitled, on a case by case basis, to a price lower than our distributor list price, the distributor is then due a rebate, equal to the difference between the distributor list price and the final lower contract price, when shipment is made to the end user. In order to properly reflect our sales to distributors, we record the gross sale at our distributor list 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 the amount of rebates claimed by the distributors through documentation but not yet reimbursed plus an estimate by us of the amount of future rebates due on any inventory that the distributors are holding at the end of each period.

Prior to fiscal 2003, we utilized an historical moving average to estimate the allowance for rebates. Based upon a review that we conducted in fiscal 2003 in connection with the preparation of our second quarter financial report, we concluded that the moving average estimate did not necessarily result in the appropriate liability due to the distributor. Accordingly, we changed our method of estimating rebate claims to record the allowance for rebates based upon the documentation provided by the distributor for shipments and inventory not yet shipped. We also recorded a $3.3 million expense to increase the amount of our allowance for rebates. Over the years, our information systems have improved. During the second quarter of fiscal 2005, we concluded that rebates due could be better measured by utilizing current period rebate data to determine an estimated rebate percentage, by distributor and product, and applying that percentage to the current period gross sales by distributor and product. We believe that there was no material financial statement impact between our current approach and the approach we adopted in fiscal 2003.

The allowance for rebates was $7.3 million and $8.2 million at September 30, 2005 and September 30, 2004, respectively. Rebate expense was $55.9 million and $47.8 million for the years ended September 30, 2005 and 2004, respectively.

Amortization of goodwill

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 last completed this impairment test during the three month period ended March 31, 2005 and found no impairment. We also review the carrying value of other long-lived assets on a periodic basis, or whenever events or changes in circumstances indicate that the amounts may not be recoverable. If we determine that the carrying amount of an asset may not be recoverable, we then estimate the future undiscounted cash flows expected to result from the use of the asset and its eventual disposition. We will recognize an impairment loss if the carrying value of the assets exceeds the estimated future undiscounted cash flows of those assets. See Note 1 of the notes to our consolidated financial statements presented elsewhere herein. We have not incurred material impairment charges since fiscal 2001. 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 $77.2 million at September 30, 2005 and $69.5 million at September 30, 2004.

Allowance for doubtful accounts

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 $0.5 million at September 30, 2005 and $0.6 million at September 30, 2004. 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.

Claims and proceedings

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 other than legal proceedings for which accruals have been provided, 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 to the extent that such contingencies are measurable.

Inventory obsolescence

We establish an allowance for inventory obsolescence. The allowance is determined by performing an aging analysis of the inventory; based upon this allowance, inventory is stated at the lower of cost, using the first in, first out method, or its net realizable value. During fiscal 2004, we wrote-off certain inventory amounting to $1.0 million. Our inventory allowance for obsolescence was $0.7 million at September 30, 2005 and $1.2 million at September 30, 2004.

Recent accounting pronouncements

For information regarding new accounting pronouncements, see Note 1 of the notes to consolidated financial statements.

Item 7A. ***Quantitative and qualitative disclosures about market risk***

We are exposed to market risks, including the impact of material price changes and changes in the market value of our investments and, to a lesser extent, interest rate changes and foreign currency fluctuations. In the normal course of business, we seek to limit the impact of market risks on earnings and cash flows.

The impact of interest rate changes is not material to our financial condition. We do not enter into interest rate transactions for speculative purposes.

For fiscal 2005, our international net revenue represented approximately 24.1% of our total net revenues. Our Breas subsidiary, located in Sweden, represented 53% of our total international net revenues during fiscal 2005. We do not enter into any derivative transactions, including foreign currency transactions, for speculative purposes. We have not entered into any derivative instrument transactions, such as foreign exchange forward or option contracts, as of September 30, 2005.

Our primary risk involving price changes relates to raw materials used in our operations. We are exposed to changes in the prices of resins and latex for the manufacture of our products. We do not enter into commodity futures or derivative instrument transactions. Except with respect to our single source of supply for facemasks, we seek to maintain commercial relations with multiple suppliers and when prices for raw materials rise to attempt to source alternative supplies.

Item 8. ***Financial Statements and Supplementary Data***

The following audited consolidated financial statements and related report are set forth in this Annual Report on the following pages:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors

Vital Signs, Inc.

We have audited the accompanying consolidated balance sheets of Vital Signs, Inc. and Subsidiaries as of September 30, 2005 and 2004 and the related consolidated statements of income, stockholders equity and comprehensive income and cash flows for each of the three years in the period ended September 30, 2005. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Vital Signs, Inc. and Subsidiaries as of September 30, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2005, in conformity with U.S. generally accepted accounting principles.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company s internal control over financial reporting as of September 30, 2005, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated November 29, 2005 expressed an unqualified opinion thereon.

GOLDSTEIN GOLUB KESSLER LLP
New York, New York

November 29, 2005

VITAL SIGNS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEET

	September 30, 2005	2004
	(In thousands of dollars)	
A S S E T S		
Current Assets:		
Cash and cash equivalents (Note 1)	$ 81,767	$ 76,468
Accounts receivable, less allowances for rebates and doubtful accounts of $7,821 and $8,725, respectively (Notes 1, 16 and 17)	34,417	31,876
Inventory (Notes 1 and 3)	16,659	16,766
Prepaid expenses (Note 4)	2,917	2,816
Other current assets (Note 5)	1,016	1,596
Total current assets	136,776	129,522
Property, plant and equipment net (Notes 1 and 6)	29,938	29,900
Goodwill net (Notes 1 and 2)	77,167	69,506
Deferred income taxes (Notes 1 and 15)	1,141	1,184
Other assets (Notes 1 and 7)	8,680	5,952
Total Assets	$ 253,702	$ 236,064
L I A B I L I T I E S A N D S T O C K H O L D E R S E Q U I T Y		
Current Liabilities:		
Accounts payable	$ 6,347	$ 5,114
Accrued expenses (Note 8)	8,203	8,168
Income taxes payable (Note 15)	2,671	3,387
Total current liabilities	17,221	16,669
Minority interest	3,775	3,172
Commitments and contingencies (Notes 2, 12 and 13)		
Stockholders Equity (Note 14):		
Common stock no par value; authorized 40,000,000 shares, issued and outstanding 12,593,579 and 12,715,243, respectively	18,832	24,279
Accumulated other comprehensive income (Note 1)	2,012	3,059
Retained earnings	211,862	188,885
Stockholders equity	232,706	216,223
Total Liabilities and Stockholders Equity	$ 253,702	$ 236,064

See Notes to Consolidated Financial Statements

VITAL SIGNS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF INCOME

	For the Year Ended September 30,		
	2005	**2004**	**2003**
	(In thousands except per share amounts)		
Revenue: (Note 1)			
Net sales	$ 160,581	$ 151,794	$ 145,879
Service revenue	33,456	32,197	36,284
	194,037	183,991	182,163
Cost of goods sold and services performed:			
Cost of goods sold	77,381	73,449	71,887
Cost of services performed	18,126	17,925	19,721
	95,507	91,374	91,608
Gross profit	98,530	92,617	90,555
Operating expenses:			
Selling, general and administrative	51,025	50,115	51,338
Research and development	7,011	7,036	5,871
Impairment charge for China operations (Note 11)			133
Other (income) expense net (Notes 1 and 10)	(78)	612	717
Restructuring charge (Note 9)	213	539	
	58,171	58,302	58,059
Operating income	40,359	34,315	32,496
Interest (income) expense:			
Interest income	(1,672)	(824)	(654)
Interest expense	36	26	910
	(1,636)	(798)	256
Income from continuing operations before provision for income taxes and minority interest	41,995	35,113	32,240
Provision for income taxes (Note 15)	15,093	12,498	12,802
Income from continuing operations before minority interest	26,902	22,615	19,438
Minority interest in net income of subsidiary	602	447	248
Income from continuing operations	26,300	22,168	19,190
Income (loss) from discontinued operations (Note 2):	89	(115)	(4,968)
Net income	$ 26,389	$ 22,053	$ 14,222
Earnings (loss) per common share:			
Basic income per share from continuing operations	$ 2.08	$ 1.73	$ 1.49
Discontinued operations	$ 0.01	$ (0.01)	$ (0.39)
Basic net earnings per share	$ 2.09	$ 1.72	$ 1.10
Diluted income per share from continuing operations	$ 2.06	$ 1.72	$ 1.48
Discontinued operations	$ 0.00	$ (0.01)	$ (0.38)
Diluted net earnings per share	$ 2.06	$ 1.71	$ 1.10
Basic weighted-average number of shares outstanding	12,616	12,793	12,905
Diluted weighted-average number of shares outstanding	12,789	12,907	12,985
Dividends declared and paid per common share	$ .27	$ .24	$ .19

See Notes to Consolidated Financial Statements

VITAL SIGNS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

	Common Stock		Accumulated Other Comprehensive	Retained	Stockholders	Comprehensive
	Shares	Amount	Income (Loss)	Earnings	Equity	Income
	(Dollars in thousands except per share amounts)					
Balance at September 30, 2002	12,938,002	$ 30,812	$ (1,189)	$ 158,192	$ 187,815	
Comprehensive income						
Net income				14,222	14,222	$ 14,222
Repurchase of common stock	(100,300)	(2,579)			(2,579)	
Common stock issued under various incentive plans	77,864	1,936			1,936	
Tax benefit from employees and directors stock option plans (Note 15)		298			298	
Adjustment for aggregate unrealized gain on marketable securities			3		3	3
Foreign currency translation gain			3,013		3,013	3,013
Dividends paid ($.19 per share)				(2,486)	(2,486)	
Balance at September 30, 2003	12,915,566	30,467	1,827	169,928	202,222	
Comprehensive income						$ 17,238
Net income				22,053	22,053	$ 22,053
Repurchase of common stock	(274,600)	(8,143)			(8,143)	
Common stock issued under various incentive plans	74,277	1,695			1,695	
Tax benefit from employees and directors stock option plans (Note 15)		260			260	
Foreign currency translation gain			1,232		1,232	1,232
Dividends paid ($.24 per share)				(3,096)	(3,096)	
Balance at September 30, 2004:	12,715,243	24,279	3,059	188,885	216,223	
Comprehensive income						