VITAL SIGNS INC
Form 10-K
December 12, 2006

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

S **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2006.**

£ **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. £ Yes S No

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

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

Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer". Rule 12b-2 of the Exchange Act. Large Accelerated Filer £ Accelerated Filer S Non-Accelerated Filer £

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) £ Yes S 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, 2006), was approximately $431,365,345.

Number of shares of Common Stock outstanding as of December 8, 2006: 13,218,850

Documents incorporated by reference: Definitive Proxy Statement for the 2007 Annual Meeting of Shareholders (Part III).

VITAL SIGNS, INC.
TABLE OF CONTENTS

In this Annual Report, references to "Vital Signs," "we," "us" and "our" refer to Vital Signs, Inc. and its subsidiaries. Actar™, Actar D-Fib™, Babysafe™, Breas®, Breas HA50™, Breas PV10™ , Breas PV10i™, Breas PV101™, Breas PV102™, Breas PV403™, Breas PV501™, Breas SC20™, Broselow®, Broselow-Hinkle™, Broselow-Luten™, C-Cap™, Code Blue II™, CUFF-ABLE™, iMask™, iSleep™, INFUSABLE®, Limb-O-Pedi Blue II™, Misty O2®, SURE-LOK™, TurboHeater™, 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 30th 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 single use 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 innovative 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 laboratories and centers that we operate. We also operate an interventional cardiology/radiology business through our Thomas Medical Products subsidiary and provide technology services to FDA regulated companies.

We categorize our product and service offerings within five business segments: anesthesia, respiratory/critical care, sleep disorder, interventional cardiology/radiology and pharmaceutical technology services. Previously, we included our interventional cardiology/radiology business within our anesthesia segment. 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 over 30 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 now being broken out as a separate segment, interventional cardiology/radiology (see below), and as a result, the historical financial information presented in this Annual Report with respect to our anesthesia segment excludes Thomas Medical for all years presented. For fiscal 2005 and 2006, our anesthesia segment contributed 35.0% and 36.2%, respectively, to our net revenue.

Respiratory/critical care

We have been supplying single use products to the respiratory/critical care market for over 26 years. Our primary respiratory products are arterial blood gas, or ABG, 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 2005 and 2006, our respiratory/critical care segment contributed 21.9% and 21.8%, respectively, to 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, 2006, we operated 56 sleep diagnosis laboratories and

centers in seven states in the United States and in Washington D.C. At these sleep laboratories and centers, we conduct sleep

studies to determine whether the patients referred to us suffer from sleep disorders and if so the severity of their condition. If a patient is determined to suffer from obstructive sleep apnea, we can offer the patient and the patient's referring physician a comprehensive sleep program. This includes diagnosis, titration procedure (that is, the process of determining the optimal pressure to prescribe for the Continuous Positive Airway Pressure, or CPAP device), and the therapeutic intervention. This offering provides a one-stop-shop approach to servicing our patient's needs. Our principal sleep disorder products, currently marketed primarily outside of the United States, are personal non-invasive ventilation support systems, which are used in the treatment of obstructive sleep apnea to prevent temporary airway closure during sleep. For fiscal 2005 and fiscal 2006, sleep disorder and personal ventilation products and services accounted for 21.4% and 21.9%, respectively, of our net revenue.

Interventional Cardiology/Radiology

Our interventional cardiology/radiology business, which operates as Thomas Medical Products, has been included as part of our anesthesia segment since being acquired by Vital Signs, Inc. in 1992. Given the extent of the growth of that business, and the differences between the manner in which that business operates and the manner in which our anesthesia business operates, we have concluded that it is appropriated to report that business as its own segment, which we refer to as "Interventional Cardiology/Radiology".

Our interventional cardiology/radiology business is primarily in vascular access, delivery, and closure. The business operates as a high end OEM that designs, develops, and manufactures precision devices that facilitate access to the cardiovascular system by medical professionals in the electrophysiology, cardiology, radiology, critical care, and anesthesia markets. We provide percutaneous valved introducers, peelaway valved introducers, guiding sheaths, and delivery sheaths. Other products include guide wires, needles, over-the-needle catheters, hemostasis valves, obturators, dilators, transvalvular insertion tools, and contamination shields.

Generally, the business makes finished sterile medical devices and bulk non-sterile products based on our customers' specifications, however, we can also design, develop and manufacture proprietary finished medical devices that are distributed by our customers under their private label. As an OEM, the business depends on its customers for distribution of the medical devices we produce. Our customers include C.R. Bard, Guidant, St. Jude Medical, and Boston Scientific. For fiscal 2005 and 2006, our interventional cardiology/radiology business segment contributed 13.1% and 12.5% respectively, to 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, IT infrastructure, research and development, facilities, 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 2005 and fiscal 2006, pharmaceutical technology services accounted for 8.6% and 7.5%, 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:

- *improved patient care*, by reducing the risk of contracting infections from reusable products, thereby reducing the risk of additional post-operative patient care;

- *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, and procedures.

- *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 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 endotracheal 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 acute care.

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 associated with 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 Heart, Lung and Blood Institute of the National Institutes of Health, approximately 80 percent of people in the United States who suffer from sleep apnea remain undiagnosed. We believe that a substantial portion of those remain undiagnosed. Increased awareness of OSA among doctors and patients in recent years is expected to continue fueling growth of the OSA diagnostic and treatment market at a rate of 15 to 20 percent.

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 indicated that by 2003, there were approximately 2,800 sleep laboratories and centers in the United States. We believe

that this represents a

significant expansion over the number of such laboratories 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, CPAP therapy actually reduces or eliminates 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 or dramatically reduced.

CPAP is generally not a cure but a therapy for managing the chronic condition of 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.

Interventional cardiology/radiology

Our interventional cardiology/radiology business participates in its market as an OEM supplier, and as such deals with a number of substantial medical device companies on an ongoing manufacturing basis as well as an R&D project basis. It is a highly competitive business that can have major technology shifts. Products are sold to other health care product providers either as a component of a kit or as a finished product.

Interventional cardiology is a subspecialty of cardiology that deals specifically with catheter based treatment of structural heart diseases, while interventional radiology is a subspecialty of radiology in which minimally invasive procedures are performed using image guidance, either for diagnostic or treatment purposes. We believe that the long term prospects for this business segment are good as less invasive procedures increase in order to minimize the risk, cost, trauma, aftercare and procedure time of surgery.

Our statements regarding prospects for this segment represent "Forward-Looking Statements" under the Private Securities Litigation Reform Act of 1995. Actual results could differ materially from our projections as a result of a number of risks and uncertainties, including the risk factors identified in Item 1A of this Annual Report.

Pharmaceutical technology services

Pharmaceutical, diagnostic, biotechnology and medical device companies are regulated by the United States Food and Drug Administration or FDA. 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. 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 five segments: anesthesia, respiratory/critical care, sleep disorder, interventional cardiology/radiology, 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 all anesthesia machines. Our anesthesia segment accounted for 35.0% of our net revenue in fiscal 2005 and 36.2% of our net revenue in fiscal 2006.

Our primary anesthesia products and systems include:

- *Anesthesia breathing* circuits are single-patient use devices used to ventilate and carry oxygen and anesthetic gases 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 face mask provides a better seal on most patients than other face masks, thereby improving the delivery of anesthetic gases and oxygen to the patient. A clear face mask 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 face masks. 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.

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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.

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.

Respiratory/critical care

Our respiratory/critical care segment accounted for 21.9% of our net revenue in fiscal 2005 and 21.8% of our net revenue in fiscal 2006.

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 face mask CPAP systems provide a less invasive and more comfortable way of providing oxygen to certain patients than conventional ventilator-based systems. Our face mask CPAP systems eliminate the need to insert an endotracheal tube into the patient's trachea and then attach the patient to a ventilator. Our face mask 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 or weight 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 outside of the United States. We received FDA clearance for our first

8

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 service 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 21.4% of our net revenue in fiscal 2005 and 21.9% of our net revenue during fiscal 2006.

Our primary sleep disorder and personal ventilation products are listed below. Some of these products are offered for sale only outside the United States. Our sleep disorder and personal ventilation products that have been cleared for sale in the United States include the *Breas PV10*™, *PV10i*™, *HA50*™, *iMask*™, *iSleep 10*™, *iSleep 20*™, *iSleep 20+*™, *HAO 30*™, *and VIVO 40*™.

- *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 full range of products to be easy to use, lightweight, small and quiet, making them relatively unobtrusive at the bedside. Our *Breas iSleep 10*™ is a basic low cost CPAP. Our *Breas PV10*™ and our latest generation *iSleep 20*™ are premium CPAP devices for obstructive sleep apnea treatment. Our *iSleep 20+*™ is a premium CPAP device with additional refinement. Our Breas *PV10i*™ and latest generation *iSleep 20*™ products are self-adjusting CPAP devices that use our patented pattern recognition *i-technology* to respond to changes in breathing patterns,

as individual patient needs change, to proactively minimize apneic events. 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*™ and *iSleep 20*™, the mean treatment pressure is lower as airway pressure is adjusted automatically. Clinical studies have demonstrated that patients prefer the lower pressure provided by these units to other available devices.

- *Bilevel CPAPs* are electromechanical devices which allow inspiratory and expiratory pressures to be independently adjusted. Our *iSleep 22*™ and premium *iSleep 25*™ devices are used to treat more severe obstructive sleep apnea. These devices are designed to be especially 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, 2006, we operated 56 sleep laboratories 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 healthcare.

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 any sleep related problem.

Over the past two years, we have eliminated several free standing sleep diagnostic laboratories and hospital contracts that had marginal profitability and have focused our efforts on laboratories (4-12 beds) and centers affiliated with hospitals, such as Doctors Hospital, Johns Hopkins, the University of Maryland, University of Connecticut and Westchester University Medical Center. Hospital compensations are free of support services and lease expenses. The operation of these laboratories and centers provides us with direct access to patients at the point of diagnosis. We believe that the knowledge derived from our laboratories and centers 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 our sleep laboratories and centers 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 laboratories or centers, we are prohibited by federal regulations from substituting our own product.

Interventional Cardiology/Radiology

Through our Thomas Medical subsidiary we sell precision medical devices that provide vascular access, delivery, and closure. Produced on an OEM basis, our products include percutaneous valved introducers, peelaway valved introducers, guiding sheaths, and delivery sheaths. Other products include guide wires, needles, over-the-needle catheters, hemostasis valves, obturators, dilators, transvalvular insertion tools, and contamination shields.

Our interventional cardiology/radiology business segment accounted for 13.1% of our net revenue in fiscal 2005 and 12.5% of our net revenue in fiscal 2006.

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, 2006 our pharmaceutical technology services staff consisted of 97 professionals. Our range of consulting services includes computer systems validation, IT governance, process validation, equipment qualification, development and implementation of

10

quality control programs, regulatory auditing, development of software for regulated environments, and customized training programs.

In addition, through our Vital Path subsidiary, we have developed and currently market proprietary software products to help clients comply with FDA regulations.

Our pharmaceutical technology services segment accounted for 8.6% of our net revenue in fiscal 2005 and 7.5% of our net revenue in fiscal 2006.

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 and Marketing. At September 30, 2006, our United States sales force consisted of 56 sales representatives and six regional sales managers.

We market our anesthesia and respiratory/critical care products primarily to hospitals and other health care providers. While we utilize national distributors to deliver a portion of our anesthesia and respiratory/critical care products in the 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, Healthtrust, MedAssets, 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 2005 and fiscal 2006, 34% and 33%, 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 periodic training sessions for all of our sales people and conduct additional training as we deem appropriate.

Sleep disorder. Sales of the sleep therapeutic 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 our developing a different strategy than 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 and centers, and providing the products direct.

As of September 30, 2006, the sales and marketing department of our SSA subsidiary focused on increasing the patient volumes at existing laboratories and centers and negotiate contracts with new sleep laboratories 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 *a la carte* selection of services, increasing the number of beds and improving the utilization of existing beds.

Interventional Cardiology/Radiology. Generally, our interventional cardiology/radiology business makes finished sterile medical devices and bulk non-sterile products based on our customers' specifications, however, we can also

design, develop and manufacture proprietary finished medical devices that are distributed by our customers under their private label. As an OEM, our business depends on the customers of this segment for distribution of the medical devices we produce. Our customers include C.R. Bard, Guidant, St. Jude Medical and Boston Scientific.

Pharmaceutical technology services. We sell our pharmaceutical technology services through our Stelex subsidiary which, at September 30, 2006 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 2005 and 2006, international sales accounted for approximately 24.1% and 23.5%, 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 terminate the distributor agreement, effective as of November 30, 2005. During the past year, we have transitioned from our three year alliance with Teleflex (Rusch) to distributors in each of the ten countries covered under the Teleflex (Rusch) distribution agreement. Even with this transition, international sales in our anesthesia and respiratory/critical care segments have increased $913,000 (4.2%) for the twelve months ended September 30, 2006 over the twelve months ended September 30, 2005.

We operate a wholly-owned subsidiary in the United Kingdom which is responsible for distributing and selling our anesthesia, and respiratory/critical care products throughout the United Kingdom and Ireland. It employs nineteen individuals, including six 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' 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, 2006, Breas' sales force consisted of 36 professionals.

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, 2006 we employed 42 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 2006 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 face mask through a collaboration arrangement with Respironics, Inc. Face masks are used in a variety of our anesthesia circuits and manual resuscitators and are sold individually to customers. We purchase our face masks from Respironics, a single source which manufactures the face mask in the People's Republic of China. Our supply agreement with Respironics requires Respironics to supply air-filled cushion face masks of various specifications to us on an exclusive basis for anesthesia purposes, and obligates us to purchase all of our anesthesia face masks from Respironics as long as Respironics is the low cost supplier. We have had a series of supply agreements with Respironics for many years. Our current exclusive supply agreement with Respironics extends through June 2012, unless either party provides notice of termination prior to January 1, 2007. We expect that we and/or Respironics may seek to negotiate modifications in our agreement prior to January 1, 2007.

If the supply of face masks from Respironics should be interrupted or should cease for any reason, we would seek to find alternative suppliers of face masks. In such event, we may experience disruption in our business. While there are one or more alternate suppliers that could supply us with face masks if our relationship with Respironics were interrupted or ceased for any reason, no assurance can be given that, in the event of such an interruption or cessation, we could, in fact, maintain our required supply of face masks 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 face masks 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 and continued during fiscal 2006. We believe that this supply issue has now been adequately resolved.

13

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, withdrawal of clearances 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 clearance 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 clearance 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.

14

Most of our products are either Class I or Class II devices. 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 cleared medical devices for uncleared uses.

After clearance 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 clearance, 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 Conformit Europene, 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-13485-2003. Failure to obtain and retain these licenses would preclude us from selling our products into 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.

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

15

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, even if it is not 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 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 laboratories 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 laboratories and 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, 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 laboratories and 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, 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	Bespak 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
Sleep disorder	Fisher & Paykel Healthcare Resmed Respironics Tyco International Various hospital and locally maintained sleep centers
Interventional cardiology/radiology	Enpath Medical Teleflex
Pharmaceutical technology services	Day & Zimmerman Taratec The Washington Group Numerous regional consulting companies.

Employees

As of September 30, 2006, we had 1,163 full-time employees and 48 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, 2006 were:

Department	Number of Employees
Manufacturing and quality control	628
Sales and marketing	149
Sleep Center technical personnel	122
Regulatory consultants	61
Research and development	42
Administration	161
Total	1,163

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 the 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 clearances from the FDA and we cannot assure you that we will always obtain such clearances. 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 are subject to pervasive and continuing regulation 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 for devices, withdrawal of marketing clearances 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, 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.

20

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 2006, sales of our anesthesia and respiratory/critical care products related to our group purchasing arrangements amounted to $32.0 million, representing 33.2% of our net revenue from United States hospital sales. In 2007, 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 2006, we had net revenues of $5.3 million under the contracts subject to termination or renewal in fiscal 2007. 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

22

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 or an alternate supplier, 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 15.7% of our net revenue during our fiscal year ended September 30, 2006. Our current exclusive supply agreement with Respironics extends through June 2012, unless either party provides notice of termination prior to January 1, 2007. We expect that we and/or Respironics may seek to negotiate modifications in our agreement prior to January 1, 2007. 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. Although we believe that there may be one or more alternate suppliers that could supply us with face masks if our relationship with Respironics were interrupted or ceased for any reason, we have not as yet qualified any other supplier or made any determination as to whether any alternate supplier would have the 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 dependent 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 switching business to alternate 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. Mr. Wall is 65 years of age and has recommended to our Board of Directors that it plan on naming a successor chief executive officer by December 2009. 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 2009 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.

Barry Wicker, formerly our executive vice president and chief operating officer, retired at the beginning of the 2007 fiscal year, although he has confirmed his 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 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 may 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 legal proceedings. In one instance, former shareholders of Vital Pharma, a subsidiary currently classified as a discontinued operation, had been 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, were presented to an arbitrator for determination. While we believed that we had meritorious defenses, in August 2006 the arbitrator found in favor of the plaintiffs and gave them an award of $915,000, or approximately $300,000 more than we initially reserved. We have sought judicial relief to set that award aside. However, we cannot assure you that we will be successful in that regard; or in the event that we are successful that a subsequent arbitrator will find in our favor.

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 $20.0 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 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 23.5% of our net revenue during fiscal 2006. 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.

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 2006, approximately 27% of our net revenue 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 operations 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 and laboratories in the United States that diagnose obstructive sleep apnea and other sleep disorders. Our ability to sell our Breas products in our sleep centers and laboratories 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 and laboratories, 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 and laboratories. 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 laboratories and our sleep disorder 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 products and our sleep centers and laboratories.

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 four 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 Securities and Exchange Commission, or 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, 2006, goodwill represented 25.9% 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 insiders, and, as a result, the trading market for our common stock is less liquid and our stock price can be volatile.

As of December 1, 2006, we had 13,218,850 shares of common stock outstanding. Approximately 16.6% of such shares are beneficially owned by Terry D. Wall, our chief executive officer, and his wife and an additional 11.9% of such shares are beneficially owned by trusts established for the benefit of the Walls' children and an additional 9.7% of such shares are beneficially owned by an estate planning trust established by Terry D. Wall. Such trusts are administered by trustees who have 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.

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

As of December 1, 2006, Terry D. Wall, our chief executive officer, and his wife beneficially owned 16.6% of our outstanding common stock. In addition, the trusts established for the benefit of the Walls' children beneficially owned 11.9% of our outstanding common stock and an estate planning trust established by Terry D. Wall beneficially owned 9.7% of our outstanding common stock. 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 influence 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 10,000,000 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 by-laws 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 Glenn Burnie, Maryland properties which relate to our sleep segment, Malvern, Pennsylvania, which relates to our interventional cardiology/radiology business 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	33,561

office space)	
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)	16,516
Glen Burnie, Maryland (Sleep Services of America office space)	9,980
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 response to the lawsuit, we filed a seven count counterclaim against the plaintiffs. In August 2000, the court ordered the plaintiffs to submit their claims relating to the earnout calculation to binding arbitration and stayed all other proceedings pending the outcome of the arbitration. The arbitration hearing commenced on January 26, 2004. In August 2006, the arbitrator issued a decision awarding the plaintiffs $915,000. Plaintiffs originally claimed damages in the pre- interest amount of approximately $8.0 million. Subsequently, 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 the amount of $915,000.

The lawsuit was stayed during the pendency of the arbitration. On October 20, 2006, the stay was lifted and our counterclaim as well as plaintiff's one remaining claim were restored to the court's calendar. While plaintiffs assert that several of their claims were also restored, we believe that except for one limited claim by one of the named plaintiffs, all of plaintiffs original claims were adjudicated through the arbitration proceedings.

On November 11, 2006, plaintiffs filed their motion in the Federal Court to confirm the arbitrator's award and we filed our motion to vacate that award. The court has not yet ruled on either motion.

Intergel litigation

Beginning at the end of our 2003 fiscal year and running through our 2005 fiscal year, a number of negligence and product liability lawsuits were filed against our Vital Pharma, Inc. subsidiary, 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, packaged the Intergel product into plastic containers.

Vital Pharma provided the packaging pursuant to a written contract with Lifecore which contained express provisions requiring that Lifecore indemnify Vital Pharma in the event Lifecore was responsible for injuries resulting from the product. After extensive discovery, retention of experts and pre-trial motions, a global settlement was reached in connection with all of the then pending cases, and settlement procedures were agreed upon for settling all of the cases. Prior to the settlement, several cases had been resolved, either through settlement or dismissal. The settlement procedure entailed the establishment of a settlement fund with monies to be held in escrow pending the allocation to the individual plaintiffs. All of the Intergel related actions have been dismissed.

While the terms of the settlement agreement are confidential, the resolution of all of these matters required no out of pocket payment by Vital Pharma or Vital Signs and only an immaterial and token payment by our insurance carrier.

Lifecore, through its insurer, reimbursed a significant portion of Vital Pharma's legal fees and costs for all of the litigation relating to Intergel in which Vital Pharma had been involved. Notwithstanding this reimbursement, Vital Signs has incurred a substantial amount of legal fees and expenses which were not reimbursed. Therefore, we and our insurance carrier have begun a lawsuit against Lifecore and its insurer Federated Insurance for legal fees and other expenses which were not reimbursed pursuant to the written agreement.

Shore Medical Litigation

In fiscal 2004 we initiated a lawsuit in California against a former employee and the company he owns. We asserted that the employee misappropriated our trade secrets and breached his

obligation of loyalty to us. We negotiated a settlement with the defendants, where the defendants agreed to pay us $1 million in July 2006, and if they did not pay at that time the settlement amount would increase to $2 million. The defendants did not pay in July 2006 and we were required to go back to court to enforce our judgment. On November 8, 2006 the court entered a judgment in our favor for $1 million, and we preserved our rights to appeal and seek a judgment for the full $2 million. We cannot tell you how much we will actually recover from the defendants because as a defensive measure to forestall or prevent paying the judgment the former employee filed for bankruptcy for his corporation. We are continuing to press the matter through the courts and through further negotiations.

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	65	President, Chief Executive Officer and Director
William Craig	50	Executive Vice President and Chief Financial Officer
Alex Chanin	38	Executive Vice President and Chief Information Officer
Anthony P. Martino	60	Vice President, Quality and Regulatory Affairs

* As of September 30, 2006.

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.

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 Master of Science in Computer Engineering from Princeton University.

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.

Anthony P. 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. Prior to joining us, Mr. Martino spent 26 years with Becton Dickinson, a medical products manufacturer holding management positions in research and development, engineering and quality assurance and regulatory affairs. He holds a BSME degree from the New Jersey Institute of Technology.

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, 2005:			
Quarter ended December 31, 2004:	$		