RESPIRONICS INC
Form 10-K
September 13, 2006
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

FORM 10-K

(Mark One)

x Annual Report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended June 30, 2006

or

¨ Transition Report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____ to _____

Commission File No. 000-16723

RESPIRONICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**25-1304989**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
1010 Murry Ridge Lane	
Murrysville, Pennsylvania	**15668-8525**
(Address of principal executive offices)	**(Zip Code)**

(Registrant s Telephone Number, including area code) 724-387-5200

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

Title of each class	Name of each exchange on which registered
Common Stock, par value $.01 per share	**The NASDAQ Stock Market**

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

(Title of Class)

None

Indicate by check mark 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 periods that the registrant was required to file such reports) and (2) has been subject to such filing requirements for at least the past 90 days. Yes x No ¨

Indicate by check mark 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 the 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 check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes x No ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of December 31, 2005, the aggregate market value of the registrant s voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter was approximately $2,628,298,000. (All directors, executive officers, and 10% shareholders of the registrant are considered affiliates).

As of August 31, 2006, there were 79,869,297 shares of Common Stock of the registrant outstanding, of which 6,990,315 were held in treasury.

Documents incorporated by reference: Portions of the Proxy Statement for the registrant s Annual Meeting of Shareholders to be held on November 14, 2006 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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PART I

CAUTIONARY STATEMENT FOR PURPOSES OF THE SAFE HARBOR PROVISIONS OF THE PRIVATE SECURITIES REFORM ACT OF 1995.

The statements contained in this Annual Report on Form 10-K, including those contained in Item 1 Business and Item 7 Management s Discussion and Analysis of Results of Operations and Financial Condition, and statements incorporated by reference in this Form 10-K from the 2006 Annual Report to Shareholders, along with statements in other reports filed with the Securities and Exchange Commission, external documents and oral presentations which are not historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21B of the Securities Exchange Act of 1934, as amended. These forward-looking statements represent the Company s present expectations or beliefs concerning future events. The Company cautions that such statements are qualified by important factors that could cause actual results to differ materially from the expected results included in the forward-looking statements. Those factors include, but are not limited to, the following: developments in the healthcare industry; the success of the Company s marketing, sales, and promotion programs; future sales, acceptance and quality of the Company s products and programs; the timing and success of new product introductions; new product development; anticipated cost savings; U.S. Food and Drug Administration (FDA) and other regulatory requirements; enforcement actions, product recalls or related field actions; future results from acquisitions and strategic investments; growth rates in foreign markets; regulations and other factors affecting operations and sales outside the United States; foreign currency fluctuations; the effects of a major earthquake, cyber-attack or other catastrophic event that results in the destruction or disruption of any critical business or information technology systems; customer consolidation and concentration; increasing price competition and other competitive factors in the manufacture, distribution, and sale of products; interest rate fluctuations; expiration of intellectual property rights; intellectual property and related litigation; other litigation; future levels of earnings and revenues; the number of equity awards granted to employees and changes in the Company s stock price; and third party reimbursement; all of which are subject to change.

Item 1. Business

Respironics, Inc. was incorporated in Delaware in 1984. Its executive offices are located at 1010 Murry Ridge Lane, Murrysville, PA 15668-8525. Unless the context indicates otherwise, reference in this Annual Report to the Company or Respironics refers to Respironics, Inc. and its domestic and foreign subsidiaries. Unless the context indicates otherwise, reference in this Annual Report to fiscal year refers to the twelve-month period ending on June 30 of the year indicated.

Respironics maintains an internet website at the following address: www.respironics.com. The information on the Company s website is not incorporated by reference in this Annual Report on Form 10-K.

Copies of the Company s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and all amendments to these reports as filed with the Securities and Exchange Commission (SEC) are available on or through the Company s website without charge as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. Copies are also available, without charge, upon written request to Dorita Pishko, Corporate Secretary, Respironics, Inc., 1010 Murry Ridge Lane, Murrysville, PA 15668-8525.

General

Respironics is a leading provider of innovative solutions for the global sleep and respiratory markets. Respironics designs, develops, manufactures and markets medical devices used primarily for the treatment of patients suffering from sleep and respiratory disorders. The Company s products are designed to reduce costs while improving the effectiveness of patient care and are used primarily in homes, hospitals, alternative care facilities and emergency medical settings. The Company s primary product lines are:

(i) Sleep and Home Respiratory products:

a. Sleep Disordered Breathing The sleep market is one of the cornerstones of Respironics business strategy. Recognized as a global leader and innovator in the sleep-disordered breathing marketplace, Respironics goal is to leverage its core expertise in treating Obstructive Sleep Apnea (OSA) to develop innovative solutions for the diagnosis, treatment and monitoring of other sleep disorders. OSA is a serious disorder characterized by the repeated cessation of breathing during sleep. The Company s sleep therapy products are designed to encourage patients acceptance of OSA therapy through increased comfort. The end result is improved sleep and, ultimately, improved quality of life. Sleep therapy products include continuous positive airway

pressure (CPAP) devices and bi-level positive airway pressure electro-mechanical devices (and related patient interfaces and accessories) used in the home for the treatment of OSA. The Company also offers a wide range of technologically advanced clinical products for use in sleep laboratories that are used to diagnose sleep disorders.

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b. Home Respiratory Care Respironics Home Respiratory Care business is expanding the Company s solutions for patients who suffer from chronic respiratory diseases. With a broad range of oxygen, ventilation, and monitoring products, Home Respiratory Care offers an array of solutions to help clinicians manage respiratory diseases in a transitional care or home environment. Home Respiratory Care is dedicated to improving today s respiratory technologies, while leading research and development of emerging therapies to assist homecare providers and healthcare professionals in addressing patients needs. Home Respiratory Care products include (a) noninvasive ventilation products that provide positive airway pressure by mask to supplement the patient s own breathing; (b) portable life support ventilators used in the home on patients requiring continuous support; (c) and home oxygen delivery products and; (d) oximetry products

c. Sleep Well Ventures Sleep Well Ventures moves Respironics beyond its core OSA business into the broader sleep market, which encompasses the millions of people who suffer from undiagnosed and untreated sleep and sleep-related movement disorders such as insomnia, circadian rhythm disorders, or restless legs syndrome. Sleep Well Ventures also works to identify and provide solutions for millions of problem sleepers who may not have a specific sleep disorder like chronic snorers or people who have difficulty falling asleep only occasionally. Through products like Actiwatch, a device designed to monitor sleep/wake patterns over time and help assess multiple sleep disorders, Sleep Well Ventures seeks to offer sleep professionals, clinicians and their patients solutions that help to improve quality of life through improving the patients quality sleep.

(ii) Hospital Products:

a. Critical Care Respironics Critical Care business offers a unique platform for managing respiratory patients in a variety of medical environments. Through its Total Ventilation Solutions program, Critical Care gives healthcare providers a diverse and innovative portfolio of invasive and noninvasive ventilators; patient masks; accessories and patient monitoring technologies to help treat, monitor and manage respiratory-impaired patients throughout their diseases. Total Ventilation Solutions comprehensive offerings are designed to provide patients with the best care available while focusing on economical and efficient treatment solutions for healthcare providers. From prehospital admission to long-term acute treatment, Respironics leverages its core expertise and leadership in noninvasive ventilation to assist caregivers in avoiding intubation whenever possible, seeking to reduce the patient s risk of infection and to shorten the length of hospitalization. Critical Care offers therapeutic devices that assist or control a patient s ventilation. These include bi-level noninvasive ventilation products and critical care ventilation products that can deliver both noninvasive and invasive ventilation and cardiorespiratory monitoring products that provide information about a patient s condition, including the effectiveness of ventilation. All of these products are used in hospital or institutional settings.

b. Respiratory Drug Delivery Reflecting its commitment to emerging market needs and providing valued solutions for patients, clinicians and healthcare providers, Respironics is expanding its presence in the respiratory market space through its Respiratory Drug Delivery business. The Company is exploring enhanced methods of delivering drugs via the respiratory pathway to help treat chronic obstructive pulmonary disease, asthma, pulmonary arterial hypertension, cystic fibrosis and conditions beyond respiratory ailments that would benefit from direct, aerosol delivery methods. Respironics unique proprietary technology Adaptive Aerosol Delivery is being integrated into products released in both the European and U.S. markets and offers potential for effective and reliable patient treatment.

c. Children s Medical Ventures Children s Medical Ventures focuses on improving developmental care outcomes for some of the smallest and most fragile patients. Children s Medical Ventures is a leading provider of developmentally supportive products for premature babies and ill infants in the hospital or home. Children s Medical Ventures also offers apnea monitors and recorders, state-of-the-art diagnostic and treatment tools for jaundice, and a line of specialty products designed to enhance infant growth and development. The business promotes education and hands-on programs for neonatal nurses, and works with parents and caregivers to understand the unique requirements of premature and ill infants. Products and programs are developed to meet the needs of this dynamic market. The business helps extend the Company s reach in hospital Neonatal Intensive Care Units (NICUs).

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Respironics markets its products through sleep and home respiratory, hospital, and international sales organizations. These consist of direct and independent sales representatives and sales management personnel who sell to a network of over 5,000 medical product service providers (commonly referred to as homecare providers) and distributors and, in some cases, directly to hospitals and other institutions. The Company also rents certain of its products to dealers and, in limited cases, directly to end-users. Respironics believes that it is well positioned to take advantage of the growing preference for in-home treatment of patients suffering from respiratory disorders.

With an appreciation for the diversity of the global markets it serves, Respironics is committed to a deep understanding of each country s distinctive business environment. International growth and expansion are key components of Respironics strategic plan. Targeted international acquisitions, investments in the Company s international sales and marketing infrastructure, and strong distribution channels have increased Respironics presence in the global sleep and respiratory markets. As of June 30, 2006, Respironics maintains a country specific infrastructure in Germany, France, the United Kingdom (UK), Italy, Switzerland, Japan and China with expansion initiatives in place to increase this direct presence even further.

Recent Acquisitions

Fiscal Year Ended June 30, 2006

OxyTec On April 21, 2006, the Company purchased 100% of the outstanding stock of OxyTec Medical Corporation (OxyTec) for a cash purchase price of $10,400,000 (including transaction costs), with provisions for up to $30,000,000 of additional payments to be made based on the acquired company s operating performance in future years. OxyTec, located in Anaheim Hills, California, developed an innovative portable oxygen concentrator that has the potential to provide ambulatory oxygen patients greater freedom to be mobile while reducing homecare providers costs associated with the delivery of oxygen to these patients.

Omni Therm On May 15, 2006, the Company purchased certain assets and liabilities of Omni Therm, Inc. (Omni Therm) for a cash purchase price of $2,510,000 (including transaction costs). Omni Therm, located in St. Louis, Missouri, is an original equipment manufacturer, supplier, and wholesaler of infant heel warmers, infant warming mattresses, and hospital thermometer products. Prior to the acquisition, Omni Therm was the Company s supplier of these products through Children s Medical Ventures.

Other On October 6, 2005, Respironics acquired an oxygen generation technology company. The acquired technology has the potential to be used as a basis for a cost effective oxygen generation device. The total cash purchase price approximated $8,400,000 (including transaction costs), with provisions for uncapped additional payments to be made based on the acquired company s operating performance in future years through 2010.

The results of operations of these acquired companies are included in the Company s Consolidated Statement of Operations beginning on their respective acquisition dates.

The acquisitions did not have a material impact to the Company s financial condition or results of operations, individually or in the aggregate, during the year ended June 30, 2006.

Fiscal Year Ended June 30, 2005

Mini-Mitter On April 1, 2005, the Company acquired 100% of the outstanding shares of Mini-Mitter Company, Inc. (Mini-Mitter). The base cash purchase price (including $500,000 scheduled to be paid after a three-year retention period) approximated $10,500,000, with provisions for up to $7,500,000 of additional payments to be made based on Mini-Mitter s operating performance through March 31, 2007. Mini-Mitter, located in Bend, Oregon, develops and sells sleep and physiological monitoring products to commercial sleep laboratories and other medical, pharmaceutical and health research institutions involved in clinical trials. The acquisition of Mini-Mitter broadens the Company s presence in the sleep market beyond its core OSA business through innovative technologies that will enable the Company to expand its current position and access new markets that have been identified as key in the broader sleep market. The results of operations of Mini-Mitter are included in the Company s Consolidated Statement of Operations beginning on the acquisition date, April 1, 2005.

Profile On July 1, 2004, the Company s offer to acquire 100% of the outstanding shares of Profile Therapeutics plc (Profile) was declared unconditional, and the Company paid 50.9 British Pence for each share of Profile, representing a total purchase price of 26,309,000 British Pounds (or approximately $43,524,000 net of $4,675,000 of cash acquired in the

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transaction). Profile, which is based in the UK, distributes, develops and commercializes specialty products to improve the treatment of sleep and respiratory patients. The acquisition of Profile expands the Company s presence in the global sleep and respiratory markets, and enhances the breadth of its products and services with Profile s new innovative technologies for respiratory drug delivery. Prior to the acquisition, Profile was a distributor of the Company s sleep and ventilation products in the UK; the acquisition therefore expands the Company s distribution channel in the UK. Profile s core respiratory drug delivery system is an innovative platform that utilizes intelligent inhalation technology called Adaptive Aerosol Delivery (AAD). This delivery system is designed to automatically respond to individual patients breathing patterns to deliver a precise dose synchronized with a patient s inhalation cycle. The technology has the potential to benefit patients by ensuring a uniform drug dose and reproducible therapy, and in addition, allows for smaller fill volumes of drug to be used compared to conventional nebulizers. The results of operations of Profile are included in the Company s Consolidated Statement of Operations beginning on the acquisition date, July 1, 2004.

During the year ended June 30, 2005, the Company also acquired distribution channels in Italy and Switzerland as well as an independent sales organization that previously sold the Company s products in certain U.S. territories. These acquisitions did not materially affect the Company s financial condition or results of operations, individually or in the aggregate.

Fiscal Year Ended June 30, 2004

Caradyne On February 27, 2004, the Company acquired 100% of the outstanding capital stock of Western Biomedical Technologies (WBT), an Ireland-based company, which owns 100% of the outstanding capital stock of Caradyne Limited, now known as Respironics (Ireland) Limited , for a base purchase price of $5,970,000 (including transaction costs), of which $4,470,000 was paid at closing and $1,500,000 was paid on March 2, 2006 upon the conclusion of a two-year retention period. The Company was also required to make up to $2,500,000 of additional future payments based on the achievement of various performance milestones following the acquisition through March 31, 2006 (as amended). The Company paid $2,000,000 as of December 31, 2005, and $500,000 on May 1, 2006, as a result of the successful achievement of performance milestones. The total purchase price, including the additional payments was $8,470,000.

WBT and Caradyne Limited are collectively referred to herein as Caradyne. Caradyne is involved in the development, manufacturing, and marketing of unique technologies that are complementary with the Company s ventilation product portfolio, primarily used in hospital settings and pre-hospital applications.

See Note R to the Consolidated Financial Statements for more information about these acquisitions.

Products

The following are registered trademarks of the Company as used in this document: Respironics, REMstar, Encore, Encore SmartCard, Smart Monitor, ePOD, Wallaby, Inspiration, Esprit, BiPAP, BiPAP Vision, PLV, Synchrony, Alice, Stardust, BiliChek, AAD, Flow-TRAK, NICO, WhisperFlow, Actiwatch and I-neb. The following are trademarks of the Company as used in this document: Respironics Millennium, Profile Lite, Comfort Series, ComfortSelect, ComfortClassic, ComfortLite, ComfortGel, ComfortFull, BiPAP Focus, Cadence, LoFlo, Auto-TRAC, Promixin and NeoPAP.

The trademark C-Flex is used under license.

The Company s principal products can be divided into two categories: sleep and home respiratory products and hospital products, both of which are used in the diagnosis and treatment of patients suffering from sleep and respiratory disorders.

Sleep and Home Respiratory Products

The Company s sleep and home respiratory products can be separated into the following major subcategories: Sleep Disordered Breathing products; Home Respiratory Care products; and Sleep Well Ventures products.

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Sleep Disordered Breathing

Sleep Apnea Products. Respironics is a worldwide leader in OSA therapy devices. The Company s primary OSA products include the new M Series REMstar and legacy REMstar family of CPAP devices and the BiPAP Series of bi-level devices, as well as related accessories such as humidifiers, masks, tubing, filters and headgear.

The Company s CPAP devices consist of a small, portable air pressurization device, an air pressure control and a mask worn by the patient at home during sleep.

During the 2006 fiscal year, the Company initiated the transition from its prior REMstar family of CPAP devices to the new M Series. With three settings, patients have the ability to select the level of pressure relief that is right for them, without altering the benefits of prescribed therapy. The M Series small size, three primary control buttons and more lifestyle-oriented design are aimed at improving the patient s acceptance of therapy. Other comfort features, such as ramp and integrated humidification, are also incorporated into the design. The REMstar M Series has also been designed with an improved monitoring system to make data management more efficient. Some models are also equipped with an Encore Pro SmartCard accessory module to record information for the homecare provider, and the self-management feature allows the proactive user to monitor and verify the effectiveness of therapy. As of June 30, 2006, the M Series was available in limited quantities on all versions of CPAP, including the REMstar, REMstar Auto, Pro, and Plus. The Company plans to complete the M Series launch in the first half of fiscal year 2007 by releasing the new platform in all major international markets, releasing the M Series BiPAP platform, and increasing production capacity to meet global demand on the new platform.

C-Flex technology provides OSA sufferers with a more comfortable treatment for sleep apnea when compared to traditional CPAP treatment by tracking the patient s breathing to ensure the optimal amount of pressure is delivered at exhalation. C-Flex tracks and reacts to every breath throughout the night. This gives the device the ability to make breath-by-breath adjustments to ensure a more reduced level of pressure relief during exhalation.

The REMstar Series CPAP systems (REMstar Plus, REMstar Pro and REMstar Auto) are cost effective, innovative OSA therapy devices that meet the Company s strategy of offering units that provide high-quality treatment options at an economical price.

The REMstar Auto CPAP system utilizes innovative technology to monitor the patient s airway and adjust output automatically in order to deliver the appropriate pressure. The REMstar Pro and REMstar Auto also feature built-in memory to record patient usage and quality of life data. The Company s Encore SmartCard is a device used to retrieve this patient data, update air pressure settings, and change modes of operations for certain of the Company s CPAP and bi-level devices by utilizing specially developed data management software that is programmed onto the credit card sized Encore SmartCard.

BiPAP Pro2, BiPAP Plus and BiPAP Auto are the Company s primary bi-level OSA units. These units sense the patient s breathing cycle and adjust the pressure accordingly. BiPAP Pro also contains advanced leak-sensing technology, which improves the unit s pressure adjustment capability. Bi-level units are used to treat severe OSA and are useful in improving acceptance of therapy by patients as an alternative to CPAP.

The Company also offers both integrated and stand-alone humidifiers as accessories to support its strategy of enhancing patient adherence to prescribed therapy. Humidified air provides more comfortable therapy for certain patients.

The Company also provides masks used with CPAP and bi-level devices, primarily from its Comfort Series including the Respironics ComfortFull 2 and ComfortLite 2, Profile Lite, ComfortSelect, ComfortClassic, and ComfortGel. The Company s nasal mask products are designed to enhance patient comfort by utilizing a variety of shapes and designs and a variety of cushion materials to create a comfortable mask seal around the contours of the face while delivering effective CPAP and bi-level therapy. The ComfortLite 2, released in fiscal year 2006, is a uniquely designed mask for patients. It offers three interchangeable cushion options and a unique headgear system that leaves no pressure points on the face. Full face masks address the needs of specific patient groups for whom CPAP and bi-level therapy is delivered most effectively and comfortably through masks that cover the mouth and nose.

Respironics also manufactures and distributes a wide range of technologically advanced computer-based products for use in the diagnosis of sleep related disorders. The Company provides advanced, technically proficient clinical products for use in sleep labs. The Company also provides products for patient testing in the home that allow clinicians to expand the number of patients who can be served by a traditional sleep lab.

The Company s primary sleep diagnostic product is the Alice Polysomnography System (Alice). Alice is a computer-based system for use in sleep labs and other clinical settings. Alice 5, released during the 2005 fiscal year, is capable of recording up to 25 channels of physiological

data, which are stored on either a desktop or portable computer prior to permanent storage

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on optical cartridges. In addition to acquiring and storing the patient s physiological data, the Alice System utilizes physician input and internal algorithms to provide a comprehensive range of reports for clinical analysis. Alice can be used on infants or adults, and separate software programs were developed specifically for each type of patient.

The Company also manufactures and markets Stardust II. This palm-sized portable sleep system monitors up to seven channels of physiological data for up to ten hours per patient and features pre-programmed host software that simplifies data analysis. Among other factors, Stardust is distinguished by its physiological sensors specifically designed for use in the home. These sensors record a variety of patient data and the information is subsequently sent to the sleep lab or other clinical setting where it is reviewed by a trained clinician.

The Synchrony Sleep Lab System, consisting of the Synchrony pressure support ventilator and a palm-sized remote control unit, is used by clinicians in determining the appropriate level of therapy for the treatment of adult OSA once a diagnosis has been made.

The Company estimates that in the U.S. there are currently more than 3,500 sleep labs located at hospitals, other medical centers and freestanding sites. Pulmonologists, technicians and other medical professionals diagnose sleep disorders and then prescribe the appropriate treatment. Sleep labs provide the most frequent source of patient introductions to the Company s sleep disordered breathing products.

OSA patients can purchase or rent the Company s OSA therapy products from home medical equipment service provider and dealer locations throughout most of the world. These providers and dealers are generally equipped to train the patient in the product s use and to maintain and service the product. See Sales, Distribution, and Marketing. The suggested retail price for a CPAP unit ranges from $1,200 to $1,700, depending on the type of unit, geographical market and whether certain accessories are purchased. The retail price for a bi-level OSA unit generally ranges from $2,400 to $3,000, depending on which model is purchased. The Company s sleep diagnostic products are sold through dealers and directly to clinical sites.

Home Respiratory Care

Noninvasive Ventilation Products. The Company believes it is the leading manufacturer and marketer of noninvasive ventilation products in the U.S. These products are intended to augment the ventilation of a spontaneously breathing patient, but are not intended to satisfy the total ventilation requirements of the patient.

The Company s principle noninvasive ventilation product for home use is the BiPAP Synchrony Ventilatory Support System. This device is a low-pressure, electrically-driven flow generator with an electronic pressure control designed to augment patient breathing by supplying pressurized air to the patient. This device senses the patient s breathing and adjusts its output to assist in inhalation and exhalation. Additionally, the device compensates for mask leaks, which often occur in the delivery of ventilatory support to the patient. This provides what the Company believes is a more efficient and consistent noninvasive therapy than offered by competing ventilators. The face masks described above are also used with the noninvasive ventilatory support units.

The BiPAP S/T System is a compact and lightweight home noninvasive ventilator that is simple to operate offering a straight forward user interface and an integrated heated humidifier for easier set-up and patient comfort. The unit also is the first noninvasive device to combine Respironics proven BiPAP technology with SmartCard for use with Encore Pro and includes features such as Digital Auto-Trak Sensitivity, adjustable RiseTime, and integrated alarms.

The Company believes that its noninvasive ventilation products have the potential for increasing patient comfort by adapting to the patient s breathing cycles as opposed to requiring the patient to adapt his or her breathing to the ventilator cycles. Noninvasive ventilation delivers therapy effectively with a patient mask rather than requiring a tracheotomy for support. Noninvasive ventilation products are generally less expensive than invasive ventilators.

Invasive Portable Volume Ventilation Products. The Company manufactures and markets invasive portable volume ventilators that are used in the home by individuals who are typically dependent on ventilators for continuous life support.

The Company s principal invasive portable volume ventilator is the PLV-100, a microprocessor-controlled, electrically powered unit specifically designed for long-term use in the home. It is suitable for transport, short-term and institutional use. The PLV-100 can be used to ventilate a wide range of patients. The small, lightweight unit delivers volume ventilation through the operation of a piston inside the unit. This ventilator can be powered by normal AC or DC battery power and can be operated in three different ventilation modes depending on the patient s needs. The unit features a variety of alarms and displays that alert clinicians and caregivers to changes in the patient s pulmonary status or to possible unit malfunction. The Company manufactures and distributes different versions of the PLV-100 for international markets based on language

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differences, and it also manufactures and distributes a variety of accessories for use with the PLV-100. The PLV-100 unit and related accessories reach end-user patients primarily through the Company s network of medical product dealers who purchase or rent the unit from the Company and resell or rent it to end-users. In certain limited cases, the Company rents these units directly to end-users. The Company s next generation invasive portable volume ventilator, the PLV-Continuum (PLV-C), was released on a limited basis in August 2005. The PLV-C offers adult and pediatric patients, their physicians, and healthcare providers options in treating respiratory diseases. This advanced, new portable ventilator is designed with the capability to program a primary and alternate set of parameters that provide patients with a distinct ventilation prescription for daytime and nighttime breathing comfort. With an easy-to-read, easy-to-navigate graphic user interface, users should find the PLV-C easy to set up, monitor and use. In May 2006, the Company announced that it voluntary recalled 269 PLV-C ventilators representing all models and serial numbers of the PLV-C. Respironics identified a problem after an analysis of returned units revealed the potential for failure of an internal flow valve, which could result in the ventilator suddenly stopping to provide mechanical ventilation. The Company has received no reports of adverse events or injuries resulting from this problem. Respironics notified the FDA of its decision to voluntarily recall the product in April 2006. The Company plans to re-release the PLV-C in fiscal year 2007.

Oxygen Products. The Company s principle oxygen products are oxygen concentrators. These products provide a continuous flow of oxygen by separating Oxygen from room air with a molecular sieve composed of an inorganic silicate. Oxygen concentrators are generally used in the home by patients who require supplemental oxygen. Supplemental oxygen is prescribed for people with a variety of chronic pulmonary disorders, such as lung cancer, emphysema, bronchitis or acute pneumonia. These individuals generally rent an oxygen delivery system from a home medical equipment dealer.

The Company s primary oxygen concentrator product is the Respironics Millennium. This unit is suitable for chronic patients in the advanced stages of illness as well as for the less severe respiratory patient. The Company offers the Respironics Millennium 5 LPM (liters per minute) and 10 LPM concentrator. The Respironics Millennium 5 LPM is a lightweight mobile concentrator. The Millennium 10 LPM (M10) concentrator delivers up to 10 LPM of oxygen reducing the delivery costs associated with 5 LPM-and-above oxygen patients. The M10 is engineered to reduce the cost of providing oxygen at higher liter flow.

The Company s recent acquisitions of OxyTec and other oxygen delivery technology support the Company s strategy of providing treatment solutions to the growing number of ambulatory patients reliant on long-term oxygen therapy, such as those people with Chronic Obstructive Pulmonary Disease (COPD). OxyTec s recently developed portable oxygen concentrator is a highly efficient portable oxygen concentrator that lasts up to eight hours before the patient must recharge the unit s internal batteries or connect to a conventional power source. Additionally, the 900 milliliter per minute oxygen output is exceptional among portable oxygen concentrators weighing less than ten pounds and is intended to serve as an alternate to traditional portable oxygen tanks and liquid reservoirs. Respironics will introduce the OxyTec product to the U.S. market in fiscal year 2007, with international release to follow.

The Company also offers an electronic pulse oxygen conserving device (ePOD), which combines the durability and ease-of-use of pneumatic conservers and the pulse dose capability of electronic conservers.

The Company also manufactures and markets oximeter products for use in the home. The units, which allow the caregiver to take readings of the patient s blood oxygen levels and pulse rate, feature the capability to store up to 18 hours of data. This data can be later downloaded via the Company s software, which prints reports for oximetry analysis. Additionally, VirtuOx is the latest generation of overnight oximetry testing service that is designed to meet the Centers for Medicare and Medicaid Services (CMS) guidelines for testing and oxygen qualification. It was designed to be an easy to use software application available to homecare providers. VirtuOx is compatible with various versions of the Company s oximeters, and it does not require additional hardware or software. It is the only web-based platform that is hosted on a secure server. Physicians will be able to view home oximetry test results instantly, and auto-faxing software sends the physician a copy of the report within minutes.

Sleep Well Ventures

Sleep Well Ventures. Sleep Well Ventures was established to become the worldwide leader at providing innovative and highly valued sleep and wake solutions beyond OSA. Sleep Well Ventures gained several active product lines and development initiatives with the acquisition of Mini-Mitter on April 1, 2005.

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Current products support the field of actigraphy, and include devices used to determine energy expenditure, sleep/wake patterns, and sleep quality and also to evaluate circadian rhythms. Additionally, biotelemetry products are used to monitor body temperature, heart rate and variability and stress responses.

Hospital Products

The Company s hospital products can be separated into the following major subcategories: Critical Care, Respiratory Drug Delivery, and Children s Medical Ventures.

Critical Care

Ventilation Therapy Products. The Company s primary therapeutic products are the BiPAP Vision and the Esprit. The BiPAP Vision is a noninvasive ventilatory support device designed specifically for hospital use which features an oxygen module, provides higher flow and pressure functions than the Company s other noninvasive units, and is designed to be easily upgraded. The BiPAP Vision also includes integrated airway pressure monitoring, an integrated display screen, a disposable circuit and a mounting stand, all of which are designed to allow the unit to be used more easily in delivering noninvasive ventilation support in the hospital environment.

The Company also manufactures and markets the Esprit, a ventilator designed for use in the hospital and other institutional settings. Esprit is designed to deliver both invasive and noninvasive ventilation effectively, eliminating the need to use two separate ventilators for one patient and allowing it to be used throughout the continuum of patient care. With invasive ventilation, the ventilator delivers a mixture of room air and oxygen into a patient s lungs via a tube inserted into the patient s airway. These patients are typically dependent on the ventilator for life support. Esprit features a graphic user interface with an infrared touch screen; alarm and status indicators designed to allow rapid assessment of alarm conditions and patient status; volume and pressure control; and is designed to be easily upgraded. The Company developed and released several software and other product enhancements to the Esprit ventilator, including a neonatal option, Flow-TRAK and Trending, all aimed at increasing its capabilities and ease of use. The neonatal option allows the ventilator to be used for all patient ranges. Flow-TRAK provides a new breathing mode for the Esprit, whereby the volume of gas delivery can be increased or decreased based on the patient s requirements. Trending provides the clinician with the ability to review patient data, alarm occurrences and ventilator settings from the previous seventy-two hour period. The Esprit has a graphics option available, designed to provide clinicians with immediate, real time feedback in order to optimize ventilator settings. A color screen option is also available and is designed to enhance the clinicians ability to identify displays and facilitate the Esprit s easy-to-use graphic user interface.

The Company also provides innovative noninvasive devices for use in hospitals and pre-hospital applications. The WhisperFlow product line provides a comprehensive noninvasive ventilation treatment solution effective for treating a wide range of adult and pediatric respiratory conditions. Most notably, it is designed to reduce the patient s work of breathing, improve oxygen uptake and is portable and easy to use.

The Company also manufactures, distributes and rents several other hospital ventilation products, including a version of the PLV-100 designed more specifically for institutional use, and a variety of masks, tubing and headgear similar to those used in the sleep and home respiratory market described above along with certain other accessories specifically designed for hospital and institutional use. Additionally, the Company offers the BiPAP Focus Noninvasive Ventilator, which is a basic bi-level delivery system designed specifically for the institutional setting. Ventilatory assistance is provided to stable, lower acuity patients with respiratory insufficiency or failure. Compact and lightweight, the BiPAP Focus System provides features that make delivery of noninvasive ventilation easy and effective. The Company s Cadence Self-Breathing Technology offers a minimally invasive approach to self-breathing trials. It is designed for prolonged mechanical ventilator patients who have undergone a tracheotomy and who are candidates for self-breathing trials. In contrast to other self-breathing methods, the Cadence Self-Breathing System provides oxygen-enriched, heated and humidified gas directly to the patient s lungs through the proprietary Cadence Transtracheal Catheter.

Cardiorespiratory Monitoring Products. The Company manufactures and markets cardiorespiratory monitors, sensors and related disposable accessories. These electronic devices provide the measurements and continuous display of a patient s cardiac output, carbon dioxide, oxygen saturation and respiratory mechanics parameters. The sensors for the Company s devices are designed so that this patient data can be gathered noninvasively. Noninvasive monitoring offers advantages over invasive monitoring, including a reduced likelihood of infection and other associated complications that can result from invasive monitoring. The NICO Cardiopulmonary Management System measures cardiac output based on changes in respiratory carbon dioxide concentration caused by a brief period of rebreathing. The measurement of cardiac output is accomplished by interpreting data collected by sensors that measure flow, airway pressure, and carbon dioxide concentration, and then combining these signals to calculate carbon dioxide elimination. Using these variables, a technique known as Fick

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partial rebreathing is applied to calculate cardiac output. The NICO monitor can be used with mechanically ventilated patients in the operating room, intensive care, or emergency departments. The Company s cardiorespiratory monitoring devices are used in hospital operating rooms, intensive care units, emergency departments, and while transporting patients to or within hospitals. The technology behind Respironics Cardio-Monitoring product line is also packaged for and sold as an OEM module to the major monitoring companies.

Respiratory Drug Delivery

Adaptive Aerosol Delivery (AAD). Through its July 1, 2004 acquisition of Profile, the Company added Profile s core respiratory delivery technology, an intelligent inhalation platform, AAD. Respironics AAD technology is an intelligent inhalation technology that continually monitors and automatically adapts to an individual patient s breathing pattern to deliver a precise medication dose during the patient s inhalation phase. This delivery system is designed to automatically respond to individual patients breathing patterns to deliver a precise dose synchronized with the patient s inhalation cycle. The technology has the potential to benefit patients by ensuring a uniform drug dose and reproducible therapy, and in addition, allows for smaller fill volumes of drug to be used and faster treatment times compared to conventional nebulizers.

The I-neb AAD System is Respironics third generation AAD System and is smaller, quieter and more portable than earlier product generations. It also provides audible and visual feedback to the patient informing them that the treatment is complete. The device is cleared for use by the patient in the homecare, nursing home, sub-acute institution, or hospital environments. During the 2005 fiscal year, the Company reached agreement with a customer to supply the AAD system for delivery of the pulmonary arterial hypertension drug, Ventavis (iloprost) Inhalation Solution, which had previously received FDA approval for marketing in the U.S. The Company also provides, via a third party contract manufacturer, its own branded antibiotic, Promixin, which treats chronic infections associated with cystic fibrosis. Promixin, launched by Profile in 2003 in the UK and marketed in the European Community primarily in combination with the Company s AAD device, is a branded generic antibiotic designed to be delivered directly to the site of infection in the lungs.

Traditional Respiratory Drug Delivery Products. The Company provides respiratory drug delivery products that are used in both the home and hospital settings, including nebulizers, peak flow meters, and spacers. The Company distributes several models of nebulizers which dispense medication in a fine mist for inhalation deep into the lungs, under the trade name Inspiration. The primary uses for nebulizers have been in the treatment of respiratory diseases, such as emphysema and chronic bronchitis, and conditions such as asthma. The Company s models utilize a compressor to direct a flow of air through the nebulizer chamber that contains medication in liquid form. An increase in the number of available respiratory medications in recent years, coupled with the cost and efficacy of aerosol delivery methods, has contributed to the growth of this market. A peak flow meter provides an objective measure of lung function and is used by the patient at home to assist in the management of asthma. A spacer, when used with a Metered Dose Inhaler (MDI), facilitates the delivery of asthma medications.

Children s Medical Ventures

Infant Management and Developmental Care Products. Children s Medical Ventures is a leading provider of developmentally supportive products for premature babies, healthy newborns and older hospitalized infants. The Company s primary infant management products are monitoring devices designed for infants at risk for Sudden Infant Death Syndrome or (SIDS). SIDS is the sudden unexpected death of an infant that remains unexplained after investigation. It is one of the leading causes of death in the U.S. of infants between one month and one year of age. Despite extensive research, the causes of SIDS remain unknown. High-risk infants who are prescribed home monitors include infants with low birth weight, those who are premature, those who survive serious cardiorespiratory episodes and those born to a family with a history of SIDS. A limited number of alternative monitoring technologies are generally available.

The Company s primary infant monitor is the Smart Monitor, a fifth-generation microprocessor-based design that incorporates many aspects of a physiological recorder into the traditional monitor. In addition to sounding an alarm to alert the infant s caregiver when the infant stops breathing, the Smart Monitor documents patient episodes with an internal electronic memory system, enabling physicians to study up to six channels of patient waveforms in order to assess the medical significance of the alarm episodes and determine the need for continued monitoring or possible hospitalization. The data collected by the Smart Monitor can be transmitted from the home to a clinical center over phone lines or can be extracted from the Smart Monitor using a memory transfer device such as a computer.

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Children s Medical Ventures also manufactures and markets the Wallaby 3 Phototherapy System, a cost-effective, home-based alternative to conventional overhead phototherapy lights for treating newborn jaundice, a condition which is caused by elevated levels of bilirubin in the blood and which, in severe cases, can result in brain damage.

The Company also manufactures and markets the BiliChek Noninvasive Bilirubin Analyzer, a noninvasive device that measures the level of bilirubin in the blood of infants. The historical method of measuring bilirubin levels to diagnose jaundice in infants, the heel stick, involves drawing blood from the infant and is a painful, costly and time consuming procedure. BiliChek replaces the heel stick by analyzing reflected light shined on an infant s forehead to generate immediate and painless test results at a low cost.

Children s Medical Ventures also markets developmental care products designed to meet the unique needs of premature infants. Developmental care products are used in the home and in neonatal and pediatric intensive care units of hospitals. These products include appropriately sized infant care products, safety equipment and specialty feeding and skin care products. The Company also offers educational products and programs to teach caregivers how to address the specific needs of premature and ill infants.

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Sales of Sleep and Home Respiratory products and all related accessories and replacement parts accounted for 73% (domestic 51%; international 22%), 73% (51%; 22%) and 74% (56%; 18%), of the Company s net sales for its fiscal years 2006, 2005, and 2004, respectively. Sales of hospital products and accessories accounted for 27% (domestic 18%; international 9%), 27% (18%; 9%), and 26% (19%, 7%) of the Company s net sales for fiscal years 2006, 2005, and 2004, respectively.

Manufacturing and Properties

The Company owns or leases its manufacturing, office and warehouse facilities. The Company s major facilities and their primary uses are summarized below:

	Square Feet	Owned/Leased
United States:		
Murrysville, Pennsylvania (offices)	55,000	Owned
Murrysville, Pennsylvania (offices)	23,000	Leased
Murrysville, Pennsylvania (offices and manufacturing)	127,000	Owned
Monroeville, Pennsylvania (offices)	138,000	Owned
Plum Borough, Pennsylvania (offices and warehouse)	26,000	Leased
Kennesaw, Georgia (offices and manufacturing)	129,000	Leased
Carlsbad, California (offices and manufacturing)	85,000	Leased
Wallingford, Connecticut (offices and manufacturing)	53,000	Leased
Cedar Grove, New Jersey (offices)	10,000	Leased
Youngwood, Pennsylvania (warehouse)	104,000	Leased
Edison, New Jersey (warehouse)	6,800	Leased
Houston, Texas (warehouse)	6,000	Leased
Concord, California (warehouse)	6,400	Leased
La Mirada, California (warehouse)	6,400	Leased
Bend, Oregon (offices and manufacturing)	13,000	Leased
Thornton, Colorado (offices and warehouse)	9,000	Leased
International:		
Hong Kong (offices)	10,000	Leased
Shenzhen, China (manufacturing)	100,000	Leased
Subic Bay, Philippines (manufacturing)	6,800	Leased
Laguna, Philippines (offices and manufacturing)	19,600	Leased
Tokyo, Japan (offices)	5,400	Leased
Saitama City, Japan (warehouse)	26,300	Leased
Herrsching, Germany (offices and warehouse)	19,000	Leased
Nantes, France (offices and warehouse)	7,800	Leased
Paris, France (offices)	3,400	Leased

Galway, Ireland (offices and manufacturing)	14,000	Leased
West Sussex, United Kingdom (offices and manufacturing)	36,000	Leased
Zofingen, Switzerland (offices)	600	Leased
Desio, Italy (offices)	1,200	Leased

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The Company also has approximately 85 sales and service centers throughout Japan, each of which is approximately 950 square feet in size and is leased.

On May 11, 2006 the Company announced it would be closing the Galway, Ireland manufacturing facility. The Company expects this facility to close by October 31, 2006. The manufacturing activities previously conducted at the Galway facility will be transferred to three manufacturing sites within the U.S.

Operations in the Far East and Europe are subject to the risks normally associated with foreign operations including, but not limited to, foreign currency fluctuations, possible changes in export or import restrictions and the modification or introduction of governmental policies with potentially adverse effects.

The Company believes that its present facilities are suitable and adequate for its current and presently anticipated future needs. While several facilities are extensively utilized, additional productive capacity is available through a variety of means including, rental space near each current location that the Company believes is readily available and reasonably priced and production capacity at other existing locations that are less extensively utilized. The Company also owns undeveloped land near its existing Murrysville, Pennsylvania facilities that can be used for future expansion, if needed. The Company s current and prior year acquisitions did not create any material excess or unused capacity.

The Company generally performs all major assembly work on all of its products. It manufactures many of the plastic components for its face mask products and uses subcontractors to supply certain other components. The Company purchases the component parts for its major products from a number of different suppliers. The raw materials used in the Company s components have historically been readily available. However, the loss of a key supplier, quality issues associated with a vendor supplied component, or the loss of access to certain raw materials could have a material adverse impact on the Company.

Sales, Distribution and Marketing

The Company sells and, in some cases, rents its products primarily to homecare providers and distributors. These parties in turn resell and rent the Company s products to end-users. The Company also sells certain of its products directly to hospitals. The Company initiated a change in the third quarter of fiscal year 2005 related to the distribution of its BiPAP Vision Noninvasive Ventilation System for hospital applications. Effective July 1, 2005 the Company began selling the Vision ventilator directly to its domestic hospital customers, replacing the previous distributor-based sales model.

The Company s products reach its customers in the United States through the direct sales force, comprised of national account and regional sales managers that direct the activities of sales representatives and sales support specialists, as well as independent manufacturers representatives. The Company s sales management team includes leadership positions across all major product groups and geographical regions, including the U.S., Canada, South and Central America, Europe and Middle East, and Far East and Asia Pacific. The Company s international sales organization sells products from both the Sleep and Home Respiratory and Hospital product groups. International sales accounted for approximately 31%, 31%, and 25% of the Company s net sales for fiscal years 2006, 2005, and 2004, respectively.

The Company s solutions-oriented approach to doing business with customers incorporates specific products with a package of diagnostic tools and other educational materials. This approach is designed to support a customer s desire to offer the finest care possible while assisting the customer in growing its business.

The Company s marketing organization is currently staffed by Global Product Managers, who are assigned to each of the Company s principal product groups. The Product Managers stay abreast of changes in the marketplace, with an emphasis on product use specifications, features, price, promotions, education, training and distribution.

The Company has relationships with a variety of key customers. Some of these relationships are based on written supply agreements, while others are not. The Company extended its supply agreements with several key customers during the 2006 fiscal year. These agreements generally represent the right to sell to customers, often at stated prices and terms. However, often this access is shared and the Company (and its competitors) must compete for new business. Most of these relationships are terminable at will or upon short notice periods. Maintaining positive relationships with these customers is a key element of the Company s sales and marketing strategy. Failure to maintain customer relationships could adversely affect the Company s future results of operations.

The Company s U.S. homecare provider customer base (which ranges in size from large, publicly held companies with several hundred branch locations to small, owner-operated companies with one location) continues to undergo consolidation, particularly among companies specializing in homecare products. The impact on the Company of this customer consolidation is likely to continue to be reduced selling prices for the

Company s products as a result of greater purchasing power and market dominance enjoyed by larger customers.

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During the fiscal years ended June 30, 2006, 2005, and 2004, no individual customer accounted for 10% or more of the Company s net sales. However, in the aggregate sleep and home respiratory dealer customers constitute an important market for the Company s products.

The Company offers leasing programs to certain of its customers through arrangements with independent leasing companies. In some cases, these arrangements make the Company contingently liable, in the event of a customer default, to the leasing companies for certain unpaid installment receivables initiated by or transferred to the leasing companies. The Company s total exposure for unpaid installment receivables under these leasing programs was approximately $15,718,000 and $16,835,000 at June 30, 2006 and 2005, respectively. Approximately 9% of the Company s net sales were made under these financing arrangements during the year ended June 30, 2006 and 8% of the Company s net sales for the years ended June 30, 2005 and 2004. A portion of these sales were made with recourse. The Company is not dependent on these off-balance sheet arrangements. See Note L to the Consolidated Financial Statements for additional information.

The majority of the Company s revenue in Japan is derived from renting devices to hospitals that in turn provide these devices to patients for use in their homes, with the Company providing product service and support to these patients. The hospital pays monthly fees under month-to-month rental contracts for the patients product use and other services and support the Company provides. In these cases, the hospitals receive reimbursement from the Japanese government for providing devices to the patients. The Company also sells products to hospitals and to a network of distributors in Japan, who resell to other distributors.

Competition

The Company believes that the principal competitive factors in all of its markets are product and service breadth, performance, innovation, quality, strong sales channels with thought leaders, sleep labs and homecare providers, efficient distribution, and competitive price. Price competition has become more intense in the last several years. In the case of a number of the Company s and its competitors products, patent protection is becoming more prevalent and of increasing competitive importance. The Company competes on a product-by-product basis with various other companies, some of which have significantly greater financial and marketing resources and broader product lines than the Company.

The Company believes that it maintains a strong market presence in several of the major markets and product groups in which it competes. However, other manufacturers, including other larger and more experienced manufacturers of home healthcare products, are active in these markets and the Company expects competition to increase. In its major product lines, the Company competes with two principal competitors, divisions of Tyco International Ltd. (Tyco) and ResMed, Inc. (ResMed). Tyco, which is the Company s largest major competitor and has the greatest financial resources of the Company s competitors, offers an array of products that compete with many of the Company s major products. ResMed competes with the Company in OSA and noninvasive ventilation. The Company also competes with Invacare Corp., Viasys Healthcare Inc., Dräger AG, Getinge AG, Vital Signs, Inc., Monaghan Medical Corp., Fisher & Paykel Healthcare Corp. Ltd., and with divisions of Sunrise Medical, Inc. Additionally, the Company competes with a number of smaller medical device manufacturers and healthcare providers, primarily in local overseas markets and, to a lesser extent, in the U.S.

The Company s customer base and the medical device manufacturing industry are undergoing consolidation. Several of the Company s competitors have been involved in acquisitions. The impact on the Company of this competitor consolidation is likely to be greater competition from medical device manufacturers that can utilize the financial and technical resources that may be made available as a result of the consolidation.

Research and Development

The Company believes that its ability to identify product opportunities, to respond to the needs of physicians, healthcare providers, and their patients in the treatment of sleep and respiratory and other disorders and to incorporate the latest technological innovations into its products has been and will continue to be important to its success. The Company s research and development efforts are focused on understanding the problems faced by physicians and healthcare providers and their patients needs and on maintaining the Company s technological leadership in its core product areas. The Company maintains both formal and informal relationships with physician practitioners and researchers to supplement its research and development efforts. The Company s research and development efforts enable it to capitalize on opportunities in the sleep and respiratory medical product market by upgrading its current products as well as developing new products. In addition to the ongoing research and development work in the Company s existing product areas and existing sleep and respiratory markets, the Company continues to invest in research and development to identify opportunities, and potential solutions to other patient needs, in the sleep and respiratory markets. In April 2006, the Company announced that effective May 1, 2006 David P. White, M.D. joined the Company as Chief Medical Officer. Dr. White is a physician and leading researcher in sleep disorders and will lead the Company s clinical research strategies and programs in the sleep and respiratory markets.

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The Company conducts the vast majority of its research and development for existing and potential new products in the U.S. Through the acquisition of Profile, the Company also conducts certain research and development activities in the UK. The research and development staff performs overall conceptual design work for all products and the design work related to the manufacturing, engineering and tooling for products manufactured by the Company. The Company spent approximately $58,966,000 (6% of net sales) in fiscal 2006, $45,625,000 (5% of net sales) in fiscal year 2005, and $29,478,000 (4% of net sales) in fiscal year 2004 to support product enhancement and new product development.

The Company introduced new products in many of its core product areas during fiscal years 2006, 2005, and 2004. New product introductions in 2006 included:

Sleep and Home Respiratory Group

Sleep Disordered Breathing: The Company s most significant new product introduction during 2006 is the new platform of CPAP devices, the REMstar M Series sleep therapy device system, which was available on the REMstar, REMstar Auto, Pro, and Plus by the end of the year. The new M Series was available with the Company s C-flex technology, heated humidification, and Encore SmartCard technology. Also during the year the BiPAP Auto was introduced. This product represents the Company s first auto titrating bilevel device. The Company also introduced two new patient interface products, the ComfortFull 2 and ComfortLite 2. Additionally, the Stardust II portable sleep diagnostic device and software enhancements for the Alice lab-based sleep diagnostic device were released during the year.

Home Respiratory Care: The Company released the Synchrony II noninvasive ventilator internationally and the Virtuox overnight oximetry testing software in 2006.

Hospital Group

Critical Care: The Company continued to add various enhancements and software options to the Esprit invasive ventilation system, including the Respri-link and neonatal options. Additionally, the Company released the Esprit NICO interface in the international markets, as well as an Esprit unit designed for the Chinese market. The Company launched the Cadence Self-Breathing System and began shipping the LoFlo C5 Engine to OEM customers in 2006.

Respiratory Drug Delivery: The I-neb next generation Adaptive Aerosol Delivery (AAD) System for the aerosolization of liquid medication was launched in 2006.

Significant product development efforts are ongoing and new product launches in certain of the Company s major product lines are scheduled for the next six to eighteen months. Additional development work and clinical trials are being conducted in certain product areas and markets outside the Company s current core products and patient groups.

In addition to its development efforts in its core product areas, the Company is actively pursuing product development activities in a variety of emerging markets. The Company continues to invest in research and development related to other sleep disorders, including insomnia, and in respiratory drug delivery applications. The Company continues to explore the area of congestive heart failure (CHF) and the potential co-morbidities that exist between CHF and sufferers of OSA. An additional related opportunity is the use of positive airway pressure to improve cardiovascular function.

Patents, Trademarks and Licenses

The Company seeks protection for certain of its products through the acquisition of patents and exclusive licensing arrangements. In addition, the Company aggressively defends its patents and other rights when infringed by other companies. The Company currently has approximately 624 U.S. and foreign patents (compared to 471 as of June 30, 2005) and has additional U.S. and foreign patent applications pending. Some of these patents and patent applications relate to significant aspects and features of the Company s products. 106 of these patents expire in the next five years as follows: 15 expire in fiscal year 2007, 10 expire in fiscal year 2008, 12 expire in fiscal year 2009, 23 expire in fiscal year 2010, and 46 expire in fiscal year 2011. The Company has an increasingly diverse portfolio of products that should help to mitigate the impact that expiring patents could have on its business. However, the expiration of the Company s intellectual property rights may have a future adverse impact on the Company.

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The Company also has approximately 263 registered U.S. and foreign trademarks (compared to 279 as of June 30, 2005) and has additional U.S. and foreign trademark applications pending.

Regulatory Matters

The Company s products are subject to regulation by, among other governmental entities, the FDA and corresponding foreign agencies. The FDA regulates the introduction, manufacture, advertising, labeling, packaging, marketing and distribution of and recordkeeping for such products in the U.S. The Company must comply with statutory requirements and FDA regulations and is subject to various FDA recordkeeping and reporting requirements and to inspections by the FDA. The testing for and preparation of required applications can be expensive, and subsequent FDA review can be lengthy and the results uncertain. The FDA also regulates the clinical testing of medical devices. Moreover, FDA clearance or approval, if granted, can include significant limitations on the indicated uses for which a product may be marketed. Failure to comply with applicable FDA requirements can result in fines, civil penalties, suspensions or revocation of clearances or approvals, recalls or product seizures, operating restrictions or criminal penalties. Delays in receipt of, or failure to receive, FDA clearances or approvals for the Company s products for which such clearances or approvals have not yet been obtained would adversely affect the marketing of such products in the U.S. and could adversely affect the results of future operations.

The Company must obtain FDA or foreign regulatory approval or clearance for marketing the Company s new devices prior to their release for commercial distribution. There are two primary means by which the FDA permits a medical device to be marketed in the U.S. A manufacturer may seek clearance for the device by filing a 510(k) premarket notification with the FDA. To obtain such clearance, the 510(k) premarket notification must establish that the device is substantially equivalent to a predicate device that has been legally marketed under a 510(k) notification or was marketed before May 28, 1976. In some situations, a device also may be cleared by a 510(k) premarket notification through de novo classification even though there is no predicate device. The manufacturer may not place the device into commercial distribution in the U.S. until a substantial equivalence determination notice is issued by the FDA. The FDA, however, may determine that the proposed device is not substantially equivalent, or require further information, such as additional test data or clinical data, or require the Company to modify its product labeling, before it will make a finding of substantial equivalence. The process of obtaining FDA clearance of a 510(k) premarket notification, including testing, preparation of the 510(k) premarket notification and subsequent FDA review, can take a number of years and require the expenditure of substantial resources.

If a manufacturer cannot establish, to the FDA s satisfaction, that a new device is substantially equivalent to a legally marketed device, it will have to seek approval to market the device through the premarket approval application (PMA) process. This process involves preclinical studies and clinical trials. The process of completing clinical trials, submitting a PMA and obtaining FDA clearance takes a number of years and requires the expenditure of substantial resources. In addition, there can be no assurance that the FDA will approve a PMA. The Company s export activities and clinical investigations also are subject to the FDA s jurisdiction and enforcement.

Foreign regulatory approvals vary widely depending on the country. The Company s business in Japan is subject to government regulation generally similar to that in the U.S. The Japanese Ministry of Health requires registration and review of new products prior to granting approval to distribute such products in Japan and also requires product recalls and corrective actions when circumstances warrant. The Company has received ISO 13485:2003 certification for its Wallingford, Connecticut, Galway, Ireland, Bognor Regis, UK, and Subic Bay, Philippines facilities and ISO 9001:2000 certification for its Nantes, France facility. The Company has received both ISO 9001:2000 and ISO 13485:2003 certifications for its Murrysville, Pennsylvania, Kennesaw, Georgia, Bend, Oregon, Carlsbad, California, Cedar Grove, New Jersey, Herrsching, Germany, and Shenzhen, Peoples Republic of China, facilities. ISO Certification is based on criterion developed by the International Organization for Standardization, a quality standards organization with headquarters in Geneva, Switzerland. The Company has also received authorization for the same facilities, under the European Union s Medical Devices Directive, to affix the CE Mark to the Company s products marketed throughout the world. The primary component of the certification process was an audit of the facilities quality systems conducted by an independent agency authorized to perform conformity assessments under I