RESMED INC
Form 10-K
August 08, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF

THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2014

Commission file number: 001-15317

RESMED INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of incorporation or organization)

98-0152841

(IRS Employer Identification No.)

9001 Spectrum Center Blvd.

San Diego, CA 92123

United States of America

(Address of principal executive offices)

(858) 836-5000

(Registrant s telephone number, including area code)

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

TITLE OF EACH CLASS

Common Stock, $0.004 Par Value

Name of each exchange upon which registered

New York Stock Exchange

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [x] No [ ]

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

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 period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [x] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [x] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulations S-K (§ 229.405 of this Chapter) 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 check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer [x] Accelerated filer [ ] Non-accelerated filer [ ] Smaller reporting company [ ]

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of registrant as of December 31, 2013 (the last business day of the registrant s most recently completed second fiscal quarter), computed by reference to the closing sale price of such stock on the New York Stock Exchange, was $6,605,592,497. All directors, executive officers, and 10% stockholders of registrant are considered affiliates.

At August 1, 2014, registrant had 140,168,442 shares of Common Stock, $0.004 par value, issued and outstanding. This number excludes 36,641,013 shares held by the registrant as treasury shares.

Portions of the registrant s definitive Proxy Statement to be delivered to stockholders in connection with the registrant s 2014 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this report.

CONTENTS

As used in this 10-K, the terms we , us , our and the Company refer to ResMed Inc., a Delaware corporation, and its subsidiaries, on a consolidated basis, unless otherwise stated.

PART I

Cautionary Note Regarding Forward-Looking Statements

This report contains certain forward-looking statements and information that are based on the beliefs of our management as well as estimates and assumptions made by, and information currently available to our management. All statements other than statements regarding historical facts are forward-looking statements. The words believe, expect, anticipate, intend, seek, will, will continue, estimate, plan, future expressions generally identify forward-looking statements, including, in particular, statements regarding the development and approval of new products and product applications, market expansion, pending litigation, and the development of new markets for our products, such as cardiovascular and stroke markets. These forward-looking statements are made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. You are cautioned not to place undue reliance on these forward-looking statements each of which applies only as of the date of this report. Such forward-looking statements reflect the views of our management at the time such statements are made and are subject to a number of risks, uncertainties, estimates and assumptions, including, without limitation, and in addition to those identified in the text surrounding such statements, those identified in Item 1A Risk Factors and elsewhere in this report.

In addition, important factors to consider in evaluating such forward-looking statements include changes or developments in social, economic, market, legal or regulatory circumstances, changes in our business or growth strategy or an inability to execute our strategy due to changes in our industry or the economy generally, the emergence of new or growing competitors, the actions or omissions of third parties, including suppliers, customers, competitors and governmental authorities, and various other factors subject to risks and uncertainties which could cause actual results to materially differ from those projected or implied in the forward-looking statements. Should any one or more of these risks or uncertainties materialize, or the underlying estimates or assumptions prove incorrect, actual results may vary significantly from those expressed in such forward-looking statements, and there can be no assurance that the forward-looking statements contained in this report will in fact occur.

ITEM 1 BUSINESS

General

We are a global leader in the development, manufacturing, distribution and marketing of medical products for the diagnosis, treatment and management of respiratory disorders, with a focus on sleep-disordered breathing, or SDB. SDB includes obstructive sleep apnea, or OSA, and other respiratory disorders that occur during sleep. When we were formed in 1989, our primary purpose was to commercialize a treatment for OSA. This treatment, nasal Continuous Positive Airway Pressure, or CPAP, was the first successful noninvasive treatment for OSA. CPAP systems deliver pressurized air, typically through a nasal mask, to prevent collapse of the upper airway during sleep.

Since the development of CPAP, we have developed a number of innovative products for SDB and other respiratory disorders including airflow generators, diagnostic products, mask systems, headgear and other accessories. Our growth has been fuelled by geographic expansion, our research and product development efforts, and an increasing awareness of SDB and respiratory conditions as a significant health concern among physicians and patients around the world.

We employ approximately 4,100 people and sell our products in approximately 100 countries through a combination of wholly owned subsidiaries and independent distributors.

Our web site address is www.resmed.com. We make our periodic reports, together with any amendments, available on our web site, free of charge, as soon as reasonably practicable after we electronically file or furnish the reports with the Securities and Exchange Commission, or SEC. Information contained on the website is not part of or incorporated into this annual report.

Corporate History

ResMed Inc., a Delaware corporation, was formed in March 1994 as the ultimate holding company for our operating subsidiaries. On June 1, 1995, we completed an initial public offering of common stock and on June 2, 1995 our common stock commenced trading on the NASDAQ National Market. On September 30, 1999 we transferred our principal public listing to the New York Stock Exchange, or NYSE, trading under the ticker symbol RMD. On November 25, 1999, we established a secondary listing of our common stock via Chess Depositary Instruments, or CDI s, on the Australian Stock Exchange (now known as the Australian Securities Exchange), or ASX, also under the symbol RMD. Ten CDI s on the ASX represent one share of our common stock on the NYSE.

Our Australian subsidiary, ResMed Holdings Limited, was originally organized in 1989 by Dr. Peter Farrell to acquire from Baxter Center for Medical Research Pty Limited, or Baxter, the rights to certain technology relating to CPAP treatment as well as Baxter s existing CPAP device business. Baxter acquired the rights to the technology in 1987, and sold CPAP devices in Australia from 1988 until our acquisition of the business.

Since formation we have acquired a number of businesses including distributors, suppliers, developers of medical equipment and related technologies.

Segment Information

We believe that, given the single market focus of our operations in the sleep and respiratory disorders sector of the medical device industry, and the inter-dependence of its products, we operate in a single operating segment. See Note 15 Segment Information of the Notes to Financial Statements (Part II, Item 8) for financial information regarding segment reporting. Financial information about our revenues from and assets located in foreign countries is also included in the Notes to our consolidated financial statements.

The Market

Sleep is a complex neurological process that includes two distinct states: rapid eye movement, or REM, sleep and non-rapid eye movement, or non-REM, sleep. REM sleep, which is about 20-25% of total sleep experienced by adults, is characterized by a high level of brain activity, bursts of rapid eye movement, increased heart and respiration rates, and paralysis of many muscles. Non-REM sleep is subdivided into four stages that generally parallel sleep depth; stage 1 is the lightest and stage 4 is the deepest.

The upper airway has no rigid support and is held open by active contraction of upper airway muscles. Normally, during REM sleep and deeper levels of non-REM sleep, upper airway muscles relax and the airway narrows. Individuals with narrow upper airways or poor muscle tone are prone to temporary collapses of the upper airway during sleep, called apneas, and to near closures of the upper airway called hypopneas. These breathing events result in a lowering of blood oxygen concentration, causing the central nervous system to react to the lack of oxygen or increased carbon dioxide and signaling the body to respond. Typically, the individual subconsciously arouses from sleep, causing the throat

muscles to contract, opening the airway. After a few gasping breaths, blood oxygen levels increase and the individual can resume a deeper sleep until the cycle repeats itself. Sufferers of OSA

typically experience ten or more such cycles per hour. While these awakenings greatly impair the quality of sleep, the individual is not normally aware of these disruptions. In addition, OSA has recently been recognized as a cause of hypertension and a significant co-morbidity for heart disease, stroke and diabetes.

A 2013 epidemiology study estimated that 26% of adults age 30-70 have some form of obstructive sleep apnea. In the United States alone, this represents approximately 46 million people. Despite the high prevalence of OSA, there is a general lack of awareness of OSA among both the medical community and the general public. It is estimated that less than 20% of those with OSA have been diagnosed or treated. Many healthcare professionals are often unable to diagnose OSA because they are unaware that such non-specific symptoms as excessive daytime sleepiness, snoring, hypertension and irritability are characteristic of OSA.

While OSA has been diagnosed in a broad cross-section of the population, it is predominant among middle-aged men and those who are obese, smoke, consume alcohol in excess or use muscle-relaxing and pain-killing drugs. A strong association has been discovered between OSA and a number of cardiovascular diseases. Studies have shown that SDB is present in approximately 83% of patients with drug-resistant hypertension, approximately 72% of patients with type 2 diabetes, approximately 77% of patients with obesity and approximately 76% of patients with congestive heart failure.

Sleep-Disordered Breathing and Obstructive Sleep Apnea

Sleep-disordered breathing encompasses all disease processes that cause abnormal breathing patterns during sleep. Manifestations include OSA, central sleep apnea, or CSA, and hypoventilation syndromes that occur during sleep. Hypoventilation syndromes are generally associated with obesity, chronic obstructive lung disease and neuromuscular disease. OSA is the most common form of SDB.

Sleep fragmentation and the loss of the deeper levels of sleep caused by OSA can lead to excessive daytime sleepiness, reduced cognitive function, including memory loss and lack of concentration, depression and irritability. OSA sufferers also experience an increase in heart rate and an elevation of blood pressure during the cycle of apneas. Several studies indicate that the oxygen desaturation, increased heart rate and elevated blood pressure caused by OSA may be associated with increased risk of cardiovascular morbidity and mortality due to angina, stroke and heart attack. Patients with OSA have been shown to have impaired daytime performance in a variety of cognitive functions including problem solving, response speed and visual motor coordination, and studies have linked OSA to increased occurrences of traffic and workplace accidents.

Generally, an individual seeking treatment for the symptoms of OSA is referred by a general practitioner to a sleep specialist for further evaluation. The diagnosis of OSA typically requires monitoring the patient during sleep at either a sleep clinic or the patient s home. During overnight testing, respiratory parameters and sleep patterns may be monitored, along with other vital signs such as heart rate and blood oxygen levels. Simpler tests, using devices such as our Apnealink, or our automatic positive airway pressure devices, monitor airflow during sleep, and use computer programs to analyze airflow patterns. These tests allow sleep clinicians to detect any sleep disturbances such as apneas, hypopneas or subconscious awakenings.

There are many studies being conducted that provide new evidence that treating SDB and OSA can improve health, quality of life and also mitigate the dangers of sleep apnea in occupational health and safety, especially in the transport industry. Evidence continues to mount supporting the role of SDB therapy for disease prevention, improvement of quality of life and healthcare cost reduction.

Existing Therapies

Before 1981, the primary treatment for OSA was a tracheotomy, a surgical procedure to create a hole in the patient s windpipe. Alternative surgical treatments have involved either uvulopalatopharyngoplasty, or UPPP, in which surgery is performed on the upper airway to remove excess tissue and to streamline the shape of the airway or implanting a device to add support to the soft palate. UPPP alone has a poor success rate; however, when performed in conjunction with multi-stage upper airway surgical procedures, a greater success rate has been claimed. These combined procedures, performed by highly specialized surgeons, are expensive and involve prolonged and often painful recovery periods. Surgical treatments are not considered first line therapy for OSA. Other alternative treatments available today include nasal surgery, mandibular advancement surgery, dental appliances, palatal implants, somnoplasty and nasal devices. Alternative treatments reported to be under development include pharmaceutical therapies and electrical stimulation of the nerves or muscles.

A variety of devices are marketed for the treatment of OSA. Most are only partially effective, but CPAP is a reliable treatment for all severities of OSA and is considered first-line therapy. Use of mandibular advancement devices is increasing as a second-line option in patients unable to use CPAP or those with mild OSA. These devices cause the mandible and tongue to be pulled forward and improve the dimensions of the upper airway. CPAP is a non-invasive means of treating OSA. CPAP was first used as a treatment for OSA in 1980 by Dr. Colin Sullivan, the past Chairman of our Medical Advisory Board and was commercialized for treatment of OSA in the United States in the mid 1980 s. During CPAP treatment, a patient sleeps with a nasal interface connected to a small portable airflow generator that delivers room air at a positive pressure. The patient breathes in air from the flow generator and breathes out through an exhaust port in the interface. Continuous air pressure applied in this manner acts as a pneumatic splint to keep the upper airway open and unobstructed. Interfaces include nasal masks and nasal pillows. Sometimes, when a patient leaks air through their mouth, a full-face mask may need to be used, rather than a nasal interface.

CPAP is not a cure and therefore, must be used on a nightly 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. Patients experienced soreness from the repeated use of nasal masks and had difficulty falling asleep with the CPAP device operating at the prescribed pressure. In more recent years, product innovations to improve patient comfort and compliance have been developed. These include more comfortable patient interface systems; delay timers that gradually raise air pressure allowing the patient to fall asleep more easily; bilevel air flow generators, including Variable Positive Airway Pressure, or VPAP systems, which provide different air pressures for inhalation and exhalation; heated humidification systems to make the airflow more comfortable; and autotitration devices that reduce the average pressure delivered during the night.

Business Strategy

We believe that the SDB market will continue to grow in the future due to a number of factors including increasing awareness of OSA, improved understanding of the role of SDB treatment in the management of cardiac, neurologic, metabolic and related disorders, and an increase in home-based diagnosis. Our strategy for expanding our business operations and capitalizing on the growth of the SDB market consists of the following key elements:

Continue Product Development and Innovation. We are committed to ongoing innovation in developing products for the diagnosis and treatment of SDB. We have been a leading innovator of products designed to treat SDB more effectively, increase patient comfort and encourage compliance with prescribed therapy. For example, in 2011, we introduced the S9 bilevel range of flow generators, the Quattro FX full face mask, the Swift FX for Her nasal pillow mask, the Mirage FX nasal mask,

the Mirage FX for Her nasal mask and the Stellar ventilation device. In 2012, we introduced Swift FX Bella mask, Pixi pediatric mask, Quattro FX for Her and the EasyCare compliance management solution. In 2013, we introduced new products across both our mask and flow generator categories, including the VPAP COPD, Quattro Air, Swift FX Bella, Swift FX Nano and ResMed s SleepSeeker. In 2014, we introduced the AirFit P10 nasal pillows system, AirFit N10 nasal mask, AirFit F10 full-face mask and the Astral platform, our new generation of life support ventilators. We believe that continued product development and innovation are key factors to our ongoing success. Approximately 13% of our employees are devoted to research and development activities. In fiscal year 2014, we invested $118.2 million, or approximately 8% of our net revenues, in research and development.

Expand Geographic Presence. We market our products in more than 100 countries to sleep clinics, home healthcare dealers and third-party payors. We intend to increase our sales and marketing efforts in our principal markets, as well as expand the depth of our presence in other geographic regions.

Increase Public and Clinical Awareness. We intend to continue to expand our existing promotional activities to increase awareness of SDB and our treatment alternatives. These promotional activities target both the population with predisposition to SDB and medical specialists, such as cardiologists, neurologists and pulmonologists. In addition, we also target special interest groups, including the National Stroke Association, the American Heart Association and the National Sleep Foundation. In concert with other industry participants, we sponsor educational programs targeted at the primary care physician community, which should further enlighten both doctors and patients about the relationship between SDB or OSA and co-morbidities such as cardiac disease, diabetes, hypertension and obesity. The programs should also support our efforts to inform the community of the dangers of sleep apnea with regard to occupational health and safety, especially in the transport industry.

Expand into New Clinical Applications. We continually seek to identify new applications of our technology for significant unmet medical needs. Studies have established a clinical association between OSA and both stroke and congestive heart failure, and have recognized SDB as a cause of hypertension or high blood pressure. Research also indicates that SDB is independently associated with glucose intolerance and insulin resistance. We have developed a device for the treatment of Cheyne-Stokes breathing in patients with congestive heart failure. In addition, we maintain close working relationships with a number of prominent physicians to explore new medical applications for our products and technology. In 2007, we received Food and Drug Administration, or FDA, clearance and launched a new product in the United States for the treatment of respiratory insufficiency due to central sleep apnea, mixed apnea and periodic breathing, called the Adapt SV. The Adapt SV uses a technology known as adaptive servo-ventilation which utilizes an advanced algorithm to calculate a patient-specific minute ventilation target and automatically adjusts pressure support to maintain the target. We believe this technology has allowed physicians to successfully treat complex breathing disorders in some patients who had previously tried and failed traditional positive airway pressure therapy.

Leverage the Experience of our Management Team. Our senior management team has extensive experience in the medical device industry in general, and in the field of SDB in particular. We intend to continue to leverage the experience and expertise of these individuals to maintain our innovative approach to the development of products and increase awareness of the serious medical problems caused by SDB.

Products

Our portfolio of products includes airflow generators, diagnostic products, mask systems, headgear and other accessories.

Air Flow Generators

We produce CPAP, VPAP and AutoSet systems for the titration and treatment of SDB. The flow generator systems deliver positive airway pressure through a patient interface, either a small nasal mask, nasal pillows system, or full-face mask. Our VPAP units deliver ultra-quiet, comfortable bilevel therapy. AutoSet systems are based on a proprietary technology to monitor breathing and can also be used in the diagnosis, treatment and management of OSA.

The VS and Elisée range of products complement our VPAP Adapt SV and Autoset CS2 for patients who need ventilatory assistance. During fiscal year 2011, we launched the Stellar 100 and 150 ventilation devices, which provide both invasive and non-invasive ventilation applications for adult and pediatric patients. In 2014, we launched the Astral , our new generation of portable, lightweight, and user-friendly life support ventilators.

Flow generators in total accounted for approximately 54% of our net revenues in each of the fiscal years 2014, 2013 and 2012, respectively.

The tables below provide a selection of products, as known by our trademarks, which have been released during the last five years.

CONTINUOUS POSITIVE AIRWAY PRESSURE PRODUCTS	DESCRIPTION	DATE OF COMMERCIAL INTRODUCTION
S9 Elite	Premium level CPAP device in ResMed s sleek, compact S9 Series. Features Enhanced Easy-Breathe motor, Expiratory Pressure Relief (EPR) and detailed data options. The device also has an optional integrated humidifier (H5i), ClimateLine heated tube and the small, lightweight SlimLine tube.	February 2010
S9 Escape	As the Standard CPAP model of the S9 Series, the S9 Escape features Expiratory Pressure Relief (EPR) and other innovative features including Climate Control and the enhanced Easy-Breathe motor. The device also has an optional integrated humidifier (H5i).	September 2010

VARIABLE POSITIVE AIRWAY PRESSURE PRODUCTS	DESCRIPTION	DATE OF COMMERCIAL INTRODUCTION
VPAP Tx Lab System	VPAP Tx therapy device features all ResMed s sleep therapy modes. Tx Link connection module relays signals from the device to PSG equipment. The system is controlled through the user-friendly EasyCare Tx titration	March 2010

	software.	
S9 VPAP S	Bilevel pressure support therapy device in ResMed s sleek, compact S9 Series. Designed for comfort and compliance with the Easy-Breath waveform in S-mode* and pressures up to 25 cmH2O. The device also has an optional integrated humidifier (H5i), ClimateLine heated tube and the small, lightweight SlimLine tube.	March 2011

VARIABLE POSITIVE AIRWAY PRESSURE PRODUCTS	DESCRIPTION	DATE OF COMMERCIAL INTRODUCTION
S9 VPAP ST	Bilevel pressure support therapy device with pressures up to 25 cmH2O designed for comfort, effective therapy with the assurance of back up rate up to 50 bpm. The device also has an optional integrated humidifier (H5i), ClimateLine heated tube and the small, lightweight SlimLine tube.	March 2011
S9 VPAP Auto	Premium auto-adjusting device with the unique VAuto mode and Easy-Breathe technology designed for patients requiring both higher pressures and pressure relief. VAuto mode features enhanced AutoSet technology with central sleep apnea (CSA) detection. The device may be used with an optional integrated humidifier (H5i), ClimateLine heated tube and the small, lightweight SlimLine tube	March 2011
S9 VPAP Adapt	Adaptive Servo-Ventilator specifically designed to provide a rapid response to periodic breathing for the treatment of central and/or mixed apneas, providing ventilatory support when it is needed packaged in ResMed s sleek, compact S9 Series. The device also offers an optional integrated humidifier (H5i), ClimateLine heated tube and the small, lightweight SlimLine tube.	March 2011
S9 AutoSet CS	Adaptive Servo-Ventilator specifically designed to provide a rapid response to Cheyne-Stokes breathing and periodic breathing associated with Heart Failure for the treatment of central and/or mixed apneas, providing ventilatory support when it is needed. Packaged in ResMed s sleek, compact S9 Series. The device also has an optional integrated humidifier (H5i), ClimateLine heated tube and the small, lightweight SlimLine tube.	March 2011
S9 Auto 25#	Premium auto-adjusting device with the unique VAuto mode and Easy-Breathe technology designed for patients requiring both higher pressures and pressure relief. VAuto mode features enhanced AutoSet technology with central sleep apnea (CSA) detection. The device may be used with an optional integrated humidifier (H5i), ClimateLine heated tube and the small, lightweight SlimLine tube	March 2011

Variable Positive Airway Pressure Products	Description	Date of Commercial Introduction
S9 VPAP ST-A	Bilevel pressure support therapy device with pressures up to 30 cmH2O designed for comfort, effective therapy with the assurance of back up rate up to 50 bpm and alarms. The device also has an optional integrated humidifier (H5i), ClimateLine heated tube and the small, lightweight SlimLine tube.	March 2013
S9 VPAP COPD	Bilevel pressure support up to pressure 30cmH_2O with both fixed and adjustable alarms. This device has been specifically designed for COPD.	April 2013

Automatic Positive Airway Pressure Products	Description	Date of Commercial Introduction
S9 AutoSet	Premium APAP device packaged in ResMed s sleek, compact S9 Series. Features Enhanced AutoSet (with Central Sleep Apnea Detection), Enhanced Easy-Breathe motor, expiratory pressure relief (EPR) and detailed data options. The device also has, an optional integrated humidifier (H5i), ClimateLine heated tube and the small, lightweight SlimLine tube.	February 2010
S9 Escape Auto	The S9 Escape Auto is the Standard APAP device packaged in ResMed s sleek, compact S9 Series. It features an intelligent algorithm with Easy-Breathe expiratory pressure relief (EPR) and delivers whisper-quiet therapy in a smooth waveform. The device also offers an optional integrated humidifier (H5i), Climate Control with the ClimateLine heated tube and the small, lightweight SlimLine tube.	September 2010

Ventilation Products	Description	Date of Commercial Introduction
Stellar 100 and 150	Pressure support ventilator for invasive and non-invasive purposes so it can be used from the hospital to the home.	March 2011
Astral	Pressure support and volume ventilator for invasive and non-invasive purposes so it can be used from the hospital to the home	May 2014

Masks, Accessories, Motors and Diagnostic Products

Masks, accessories, motors and diagnostic products together accounted for approximately 46% of our net revenues in each of the fiscal years 2014, 2013 and 2012, respectively.

Mask Systems and Diagnostic Products

Mask systems are one of the most important elements of SDB treatment systems. Masks are a primary determinant of patient comfort and as such may drive or impede patient compliance with therapy. We have been a consistent innovator in masks, improving patient comfort while minimizing size and weight.

Mask Products	Description	Date of Commercial Introduction
Swift FX	Fourth generation nasal pillows system offering a fully flexible design for comfort and performance	September 2009
Mirage SoftGel	Nasal mask offering a gel cushion, interchangeable with the Activa LT system to improve choice and comfort	October 2009
Quattro FX	Full Face mask offering unobtrusive fit	September 2010
Swift FX for Her	Fourth generation nasal pillows system offering a fully flexible design for comfort and performance with female specific design features	September 2010
Mirage FX	Nasal mask offering auto adjusting forehead support and SoftEdge headgear	October 2010
Mirage FX for Her	Nasal mask offering auto adjusting forehead support and SoftEdge headgear with female specific design features	April 2011
Pixi Pediatric Mask	A pediatric mask designed for children 2 years and older	September 2011
Quattro FX for Her	Full face mask offering unobtrusive fit with female specific design features	October 2011
Swift FX Bella	Fourth generation nasal pillows system with an alternative headgear design	January 2012
Quattro Air	Next Generation lightweight Full Face Mask with improved comfort	June 2013
Swift FX Nano	A compact nasal mask designed to deliver an excellent user experience, without compromising on fit, comfort and ease of use.	June 2013

AirFit P10	A compact, lightweight nasal pillows system that has only three parts, including a new soft and stable QuickFit headgear.	January 2014

Mask Products	Description	Date of Commercial Introduction
AirFit F10	A compact, lightweight full-face mask that delivers comfort, stability, and performance in a simple and elegant design.	April 2014
AirFit N10	A compact nasal mask that stands out with its comfort and visual freedom in a user-friendly design.	April 2014

We market sleep recorders for the diagnosis and titration of SDB in sleep clinics and hospitals. These diagnostic systems record relevant respiratory and sleep data, which can be analyzed by a sleep specialist or physician who can then tailor an appropriate OSA treatment regimen for the patient.

Diagnostic Products	Description	Date of Commercial Introduction
ApneaLink Plus (U.S.)	A portable diagnostic device with oximetry measurement and respiratory effort measurement	June 2009
Apnealink Air	A portable diagnostic device which measures oximetry, respiratory effort, pulse, nasal flow and snoring. Works with EasyCare Online to provide comprehensive diagnostic solution to clinicians.	December 2013

Accessories and Other Products

To assist those professionals diagnosing or managing the treatment of patients there are data communications and control products such as EasyCare, ResLink, ResControl, ResControl II, TxControl, ResScan and ResTraxx modules that facilitate the transfer of data and other information to and from the flow generators. To enhance patient comfort, convenience and compliance, we market a variety of other products and accessories. These products include humidifiers, such as H5i and H4i, which connect directly with the CPAP, VPAP and AutoSet flow generators to humidify and heat the air delivered to the patient, helping to prevent the drying of nasal passages that can cause discomfort. Other optional accessories include cold passover humidifiers, carry bags and breathing circuits.

DATA / PATIENT MANAGEMENT PRODUCTS	DESCRIPTION	DATE OF COMMERCIAL INTRODUCTION
S9 Embletta Adapter	The S9 Embletta Adapter provides a connection between an S9 device and an Embletta Portable Diagnostic System	November 2010
ResScan v3.14	An easy and flexible patient monitoring system providing therapy insights. This version included support for S9 bilevel and cross-patient first 30 days compliance reporting.	April 2011
ResTraxx v17.1	ResMed s web-based compliance monitoring system which introduced several new features to ResTraxx Online reports and enhanced support for S9 VPAP devices.	April 2011
ResTraxx v 18.3	ResMed s web-based compliance monitoring system introducing EasyCare Card online compliance reporting direct from device SD card to ResTraxx Online	November 2011
ResScan V3.16	ResMed s easy and flexible patient monitoring system providing therapy insights and supporting VS and Elise ventilation products (Europe)	November 2011
EasyCare	ResMed s new compliance management solution offers both wireless and card-to-cloud functionality, providing access to patient data anywhere with an internet connection. Intuitive user interface, easy to understand reports and automated compliance notification.	April 2012
U-Sleep	A flexible compliance solution that monitors CPAP device usage and helps HMEs manage their patients during their initial acclimatization and ongoing therapy.	August 2012

Product Development and Clinical Trials

We have a strong track record in innovation in the sleep market. In 1989, we introduced our first CPAP device. Since then we have been committed to an ongoing program of product advancement and development. Currently, our product development efforts are focused on not only improving our current product offerings, but also expanding into new product applications.

We continually seek to identify new applications of our technology for significant unmet medical needs. SDB is associated with a number of symptoms beyond excessive daytime sleepiness and irritability. Studies have established a clinical association between SDB and hypertension, stroke, congestive heart failure and diabetes. We support clinical trials in many countries including the United States, Germany, France, the United Kingdom, Italy, Switzerland, China and Australia to develop new clinical applications for our technology.

We consult with physicians at major sleep centers throughout the world to identify technological trends in the treatment of SDB. New product ideas are also identified by our marketing staff, direct sales force, network of distributors, customers and patients.

In fiscal years 2014, 2013 and 2012 we invested $118.2 million, $120.1 million and $109.7 million, respectively, on research and development.

Sales and Marketing