

RESMED INC  
Form 10-K  
August 07, 2015  
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**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, 2015**

**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)

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(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  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

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  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  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.

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Large accelerated filer  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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of registrant as of December 31, 2014 (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 \$7,803,275,736. All directors, executive officers, and 10% stockholders of registrant are considered affiliates.

At July 28, 2015, registrant had 140,516,403 shares of Common Stock, \$0.004 par value, issued and outstanding. This number excludes 39,186,234 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 2015 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this report.

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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.

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**PART I**

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**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 4,340 people and sell our products in approximately 100 countries through a combination of wholly owned subsidiaries and independent distributors.



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Our web site address is [www.resmed.com](http://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 CDIs, on the Australian Stock Exchange (now known as the Australian Securities Exchange), or ASX, also under the symbol RMD. Ten CDIs 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

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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

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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 been recognized as a cause of hypertension and a significant co-morbidity for heart disease, stroke and diabetes.

A 2013 update to a long-term 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.



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### **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 2012, we introduced Swift FX Bella mask, Pixi pediatric mask, Quattro FX for Her and the EasyCare compliance management solution. In 2013, we



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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. During fiscal year 2015, we released significant new products across our flow generator categories, including the AirSense™ 10, AirCurve™ 10, and Lumis. In 2015, we also released the AirView™, our cloud-based remote monitoring and therapy management system, along with our Air Solutions platform that provides a suite of end-to-end healthcare informatics solutions that address customer business processes from diagnosis to monitoring and patient management and billing. 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 2015, we invested \$114.9 million, or approximately 7% 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. In addition, we maintain close working relationships with a number of prominent physicians to explore new medical applications for our products and technology. In 2014, 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 chronic obstructive pulmonary disease and neuromuscular diseases.

**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**

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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

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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.

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. During fiscal year 2015, we released significant new products across our flow generator categories, including the AirSense™ 10, AirCurve™ 10, and Lumis.

Flow generators in total accounted for approximately 58%, 54% and 54% of our net revenues in fiscal years 2015, 2014, and 2013, respectively.

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

<b>CONTINUOUS POSITIVE AIRWAY PRESSURE PRODUCTS</b>	<b>DESCRIPTION</b>	<b>DATE OF COMMERCIAL INTRODUCTION</b>
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
AirSense 10 Elite	An advanced fixed-pressure therapy device with an integrated humidifier. It is designed to be intuitive and easy-to-use. The device also features built-in wireless connectivity.	August 2014
AirSense 10 CPAP	The AirSense 10 CPAP is a fixed-pressure therapy device. It also provides compliance, AHI and leak data reporting. The device also features built-in wireless connectivity.	August 2014

<b>VARIABLE POSITIVE AIRWAY PRESSURE PRODUCTS</b>	<b>DESCRIPTION</b>	<b>DATE OF COMMERCIAL INTRODUCTION</b>
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





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VARIABLE POSITIVE AIRWAY PRESSURE PRODUCTS	DESCRIPTION	DATE OF COMMERCIAL INTRODUCTION
S9 VPAP ST	Bilevel pressure support therapy device with pressures up to 25 cmH <sub>2</sub> O 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

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VARIABLE POSITIVE AIRWAY PRESSURE PRODUCTS	DESCRIPTION	DATE OF COMMERCIAL INTRODUCTION
S9 VPAP ST-A	Bilevel pressure support therapy device with pressures up to 30 cmH <sub>2</sub> O 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 <sub>2</sub> O with both fixed and adjustable alarms. This device has been specifically designed for COPD.	April 2013
AirCurve 10 S	A bilevel device ideal for patients who need extra pressure support or find it difficult to adjust to therapy on a fixed pressure continuous positive airway pressure device. Features built-in wireless connectivity and works seamlessly with ResMed's AirView patient monitoring software.	December 2014
AirCurve 10 V Auto	An auto-adjusting bilevel device for patients who need greater pressure support to treat their obstructive sleep apnea. Features built-in wireless connectivity and works seamlessly with ResMed's AirView patient monitoring software.	December 2014
AirCurve 10 ST	A bilevel device with backup rate that provides exceptional patient-ventilator synchrony, reducing the work of breathing so patients remain comfortable and well ventilated. Features built-in wireless connectivity and works seamlessly with ResMed's AirView patient monitoring software.	December 2014
AirCurve 10 CS	An adaptive servo-ventilator specifically designed to treat patients exhibiting central sleep apnea (CSA), mixed sleep apnea and periodic breathing, with or without obstructive sleep apnea. The device also features built-in wireless connectivity. Features built-in wireless connectivity and works seamlessly with ResMed's AirView patient monitoring software.	December 2014

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<b>AUTOMATIC POSITIVE AIRWAY PRESSURE PRODUCTS</b>	<b>DESCRIPTION</b>	<b>DATE OF COMMERCIAL INTRODUCTION</b>
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
AirSense 10 Auto	A premium auto-adjusting therapy device featuring AutoRamp with sleep onset detection, expiratory pressure relief (EPR) and Easy-Breathe technology. The device also features built-in wireless connectivity.	August 2014

<b>VENTILATION PRODUCTS</b>	<b>DESCRIPTION</b>	<b>DATE OF COMMERCIAL INTRODUCTION</b>
Stellar 100 and 150	Pressure support ventilators 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
Lumis* 100 and 150	Pressure support noninvasive ventilators that support a variety of therapy modes, built-in wireless connectivity, integrated humidification and intuitive simplicity.	April 2015

\* Sold outside United States only

**Masks, Accessories, Motors and Diagnostic Products**

Masks, accessories, motors and diagnostic products together accounted for approximately 42%, 46% and 46% of our net revenues in fiscal years 2015, 2014, and 2013, respectively.

**Table of Contents****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.

<b>MASK PRODUCTS</b>	<b>DESCRIPTION</b>	<b>DATE OF COMMERCIAL INTRODUCTION</b>
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
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

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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.

<b>DIAGNOSTIC PRODUCTS</b>	<b>DESCRIPTION</b>	<b>DATE OF COMMERCIAL INTRODUCTION</b>
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, helping to prevent the drying of nasal passages that can cause discomfort, carry bags and breathing circuits. With the introduction of our latest generation of flow generators, we are expanding our use of cloud-based patient management and engagement platforms such as AirView and myAir enabling remote monitoring, over-the-air trouble shooting and changing of device settings.

<b>DATA / PATIENT MANAGEMENT PRODUCTS</b>	<b>DESCRIPTION</b>	<b>DATE OF COMMERCIAL INTRODUCTION</b>
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



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<b>DATA / PATIENT MANAGEMENT PRODUCTS</b>	<b>DESCRIPTION</b>	<b>DATE OF COMMERCIAL INTRODUCTION</b>
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
AirView	AirView is a seamless, cloud-based system enabling remote monitoring and changing of patients' device settings. AirView also makes it easier to simplify workflows and collaborate more efficiently across the patient's care network.	August 2014
myAir	A personalized therapy management application for patients with sleep-disordered breathing providing support, education and troubleshooting tools for increased patient engagement and improved compliance.	October 2014
S+	A personalized sleep solution that uses patented bio-motion sensors, designed to measure an individual's sleep stages and environment, and deliver personalized feedback that helps improve sleep.	October 2014

**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 2015, 2014, and 2013 we invested \$114.9 million, \$118.2 million and \$120.1 million, respectively, on research and development.





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### **Sales and Marketing**

We currently market our products in more than 100 countries through a network of distributors and our direct sales force. We attempt to tailor our marketing approach to each national market, based on regional awareness of SDB as a health problem, physician referral patterns, consumer preferences and local reimbursement policies. See Note 15 Segment Information of the Notes to Consolidated Financial Statements (Part II, Item 8) for financial information about our geographic areas.

**North America and Latin America.** Our products are typically purchased by a home healthcare dealer who then sells the products to the patient. The decision to purchase our products, as opposed to those of our competitors, is made or influenced by one or more of the following individuals or organizations: the prescribing physician and his or her staff; the home healthcare dealer; the insurer and the patient. In North and Latin America, our sales and marketing activities are conducted through a field sales organization made up of regional territory representatives, program development specialists and regional sales directors. Our field sales organization markets and sells products to home healthcare dealer branch locations throughout North and Latin America.

We also market our products directly to physicians and sleep clinics. Patients who are diagnosed with OSA or another respiratory condition and prescribed our products are typically referred by the diagnosing physician or sleep clinic to a home healthcare dealer to fill the prescription. The home healthcare dealer, in consultation with the referring physician, will assist the patient in selecting the equipment, fit the patient with the appropriate mask and set the flow generator pressure to the prescribed level.

Sales in North and Latin America accounted for 57%, 54% and 56% of our net revenues for fiscal years 2015, 2014, and 2013, respectively.

**Europe.** We market our products in most major European countries. We have wholly-owned subsidiaries in Austria, Czech Republic, Finland, France, Germany, Ireland, Netherlands, Norway, Poland, Sweden, Switzerland and the United Kingdom. We use independent distributors to sell our products in other areas of Europe. Distributors are selected in each country based on their knowledge of respiratory medicine and a commitment to SDB therapy. In each country in which we sell our products direct, a local senior manager is responsible for direct national sales. In many countries in Europe, we sell our products to home healthcare dealers who then sell the products to the patients. In Germany, we also operate a home healthcare company, in which we provide products and services directly to patients, and receive reimbursement directly from third-party payors.

Sales in Europe accounted for 32%, 36% and 33% of our total net revenues for fiscal years 2015, 2014, and 2013, respectively.

**Asia Pacific.** We have wholly-owned subsidiaries in Australia, China, Hong Kong, India, Japan, Korea, New Zealand, and Taiwan. We use a combination of our direct sales force and independent distributors to sell our products in Asia Pacific. In Australia and New Zealand, we operate a home healthcare business and sell our products and services directly to patients. Sales in Asia Pacific accounted for 11%, 10% and 11% of our total net revenues for the fiscal years 2015, 2014, and 2013, respectively.

### **Market Growth Opportunities**

## Edgar Filing: RESMED INC - Form 10-K

We view the future as having three horizons of growth within the sleep and respiratory disorders sector of the medical device industry. The first horizon includes our existing market in OSA treatment, where telemedicine is becoming an important factor. The use of technologies that allow remote collection and transfer of information may change the current clinical pathways for following

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up patients on our devices and provides an opportunity to improve our services. We are investing in expanding our capabilities in this area.

The second horizon includes the use of our devices for the treatment of respiratory failure both in the hospital and the home. An area of growth is expected to be in the treatment of chronic obstructive pulmonary disease, or COPD, which is an increasingly common chronic disease. Some patients with advanced COPD may benefit from the use of ventilation at night, but until recently only a small number of COPD patients were treated using ventilation on a long term basis. A study published in 2014 has demonstrated a reduction in mortality and an improvement in quality of life and exercise capacity in COPD patients with stable but severe disease using non-invasive ventilation or NIV, nightly for 6 months. The findings from this study and our associated marketing activities may result in an increase in the size of the homecare market for NIV. Additionally, the use of NIV is becoming routine in most acute care hospitals, as guidelines stipulate its use in acute exacerbations and familiarity with the techniques involved increases. The second horizon also includes several initiatives to expand our presence in high growth and emerging markets including China, India and Brazil.

The focus of the third horizon is the cardiology market and respiratory monitoring solutions for heart failure and COPD. There is a growing body of literature documenting the association and interactions between a number of cardiac diseases and SDB. OSA is the most common secondary cause of hypertension and is prevalent in hypertensive populations, particularly those resistant to therapy. Treatment with CPAP tends to lower blood pressure. OSA is prevalent in those with atrial fibrillation and may trigger episodes of fibrillation. Treatment with CPAP appears to improve outcomes. OSA is also known to be a strong risk factor for the development of acute coronary disease and cardiovascular disease in general. Heart failure is also commonly associated with both OSA and CSA, and both forms of SDB are risk factors for poor outcomes. We are undertaking several clinical trials in cardiology to strengthen the knowledge base on the effects of SDB therapy on outcomes. In addition to clinical trials we pursue suitable opportunities with professional and healthcare associations to raise awareness of the importance of SDB in cardiology patients.

We are also continuing our work to raise awareness of SDB in diabetes. OSA is common in diabetic patient populations and those with metabolic syndrome. OSA has a number of deleterious effects in these diseases and importantly raises the risk of cardiovascular disease, if left untreated.

We are also working with occupational health professionals to raise awareness of the issues caused by untreated OSA in the workplace including accidents, absenteeism and reduced productivity, plus increased costs for employers who provide healthcare coverage for employees.

We continue to provide research funding in these strategic areas while at the same time providing educational support to physicians working within these various specialties. We believe that the increasing awareness among physicians supports the efforts and investment we are making in new markets.

## **Manufacturing**

Our manufacturing operations consist primarily of assembly and testing of our flow generators, masks and accessories. Of the numerous raw materials, parts and components purchased for assembly of our therapeutic and diagnostic sleep disorder products, most are off-the-shelf items available from multiple vendors. We also purchase uniquely configured components from various suppliers, including some who are single-source suppliers for us. Any reduction or halt in supply from one of these single-source suppliers could limit our ability to manufacture our products or devices until a replacement supplier is found and qualified. We generally manufacture to our internal sales forecasts



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and fill orders as received. Over the last few years, the manufacturing processes have been transformed along lean manufacturing guidelines to flow lines staffed by dedicated teams. Each team is responsible for the manufacture and quality of their product group and decisions are based on performance and quality measures, including customer feedback.

Our quality management system is based upon the requirements of ISO 9001, ISO 13485, FDA Quality System Regulations for Medical Devices, the Medical Device Directive (93/42/EEC) and other applicable regulations for the markets in which we sell. All of our manufacturing sites are accredited to ISO 13485. These sites are subject to third-party audits, conducted by the ISO notified bodies, at regular intervals.

Details of our main manufacturing facilities are:

<b>Location</b>	<b>Ownership Status (Owned / Leased)</b>	<b>Square footage</b>	<b>Primary Usage</b>
Norwest, Sydney, Australia	Owned	155,000	Primary manufacturing site full product range
Singapore, Singapore	Leased	95,000	Primary manufacturing site full product range
Chatsworth, California	Leased	72,000	Manufacturing facility for motor manufacturing
Paris, France	Leased	43,000	Manufacturing facility for mechanical ventilators and accessories
Freudenstadt, Germany	Owned	43,000	Manufacturing facility for medical humidification products
Johor Bahru, Malaysia	Leased	46,000	Manufacturing facility for headgear and accessories.

**Third-Party Coverage and Reimbursement**

The cost of medical care in many of the countries in which we operate is funded in substantial part by government and private insurance programs. In Germany, we receive payments directly from these payors. Outside Germany, although we do not generally receive payments for our products directly from these payors, our success in major markets is dependent upon the ability of patients to obtain coverage and adequate reimbursement from third-party payors for our products.

In the United States, our products are purchased primarily by home healthcare dealers, hospitals or sleep clinics, which then invoice third-party payors directly for reimbursement. Domestic third-party payors include government payors such as Medicare and Medicaid and commercial health insurance plans. These payors may deny coverage and reimbursement if they determine that a device is not used in accordance with certain covered treatment methods, or is experimental, unnecessary or inappropriate. The long-term trend towards cost-containment, through managed healthcare, or other legislative proposals to reform healthcare, could control or significantly influence the purchase of healthcare services and products and could result in lower prices for our products. In some foreign markets, such as France, Germany and Japan, government reimbursement is currently available for purchase or rental of our products, subject to constraints such as price controls or unit sales limitations. In Australia and in some other foreign markets, there is currently limited or no reimbursement for devices that treat OSA.

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The past decade of legislative reform in the United States, including, by way of example, the 2010 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the PPACA), Medicare Improvement for Patients and Providers Act of 2008 (MIPPA), Deficit Reduction Act of 2005 (DRA), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), has significantly impacted reimbursement for products that we provide. The longer term impact, though not entirely predictable, continues to bring significant changes to the third-party payor landscape.

Beginning in 2005, the MMA established a Medicare competitive acquisition program for HME and imposed quality standards and accreditation requirements for HME suppliers. Effective 2011, the Centers for Medicare & Medicaid Services (CMS) implemented the first round of competitive bidding in 9 competitive bidding areas, or CBAs, and included home medical equipment that we manufacture and develop, specifically, CPAP and respiratory assist devices, and related supplies and accessories. The average reduction from current Medicare payment rates in the first round of competitive bidding implemented was approximately 32% overall and 34% for CPAP and respiratory devices. In 2013, CMS announced the single payment amounts for the second round, which covered a total of 91 CBAs. For CPAP and respiratory devices, the average reduction from current Medicare payment rates in the second round was approximately 47% on a weighted average basis. CMS is required by law to recompetete these contracts at least once every three years. In addition, CMS has announced it will use single payment amounts established by competitive bidding to set payment rates in areas not subject to competitive bidding. New rates will be phased in beginning January 1, 2016, and fully effective July 1, 2016.

The PPACA, which was passed both to expand the number of individuals with healthcare coverage and to develop additional revenue sources, includes, among other things, a deductible excise tax equal to 2.3% of the price for which medical devices are sold in the United States on any entity that manufactures or imports medical devices, with limited exceptions, beginning in 2013. This excise tax is applicable to our products that are primarily used in hospitals and sleep labs, which includes the ApneaLink, VPAP Tx, certain Respiratory Care and dental sleep products. The PPACA also provides for a number of Medicare regulatory requirements, including new face-to-face encounter requirements for durable medical equipment and home health services; and a requirement that by 2016, the competitive bidding process must be rolled-out nationally or prices in non-competitive bidding areas must be adjusted to match competitive bidding prices.

We cannot predict at this time the full impact of the PPACA, or any U.S. legislation enacted in the future will have on our revenues, profit margins, profitability, operating cash flows and results of operations.

## **Service and Warranty**

We generally offer either one-year or two-year limited warranties on our flow generator products. Warranties on mask systems are for 90 days. Our distributors either repair our products with parts supplied by us or arrange shipment of products to our facilities for repair or replacement.

We receive returns of our products from the field for various reasons. We believe that the level of returns experienced to date is consistent with levels typically experienced by manufacturers of similar devices. We provide for warranties and returns based on historical data.

## **Competition**

The markets for our products are highly competitive. We believe that the principal competitive factors in all of our markets are product features, reliability and price. Customer support, reputation and efficient distribution are also important factors.



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We compete on a market-by-market basis with various companies, some of which have greater financial, research, manufacturing and marketing resources than us. Our primary competitors include Philips BV; DeVilbiss Healthcare; Fisher & Paykel Healthcare Corporation Limited; Apex Medical Corporation; BMC Medical Co. Ltd.; and regional manufacturers. The disparity between our resources and those of our competitors may increase as a result of the trend towards consolidation in the healthcare industry. In addition, some of our competitors, such as Weinmann Geräte für Medizin GmbH + Co. KG, are affiliates of customers of ours, which may make it difficult to compete with them. Finally, our products compete with surgical procedures and dental appliances designed to treat OSA and other SDB-related respiratory conditions. The development of new or innovative procedures or devices by others could result in our products becoming obsolete or noncompetitive, which would harm our revenues and financial condition.

Any product developed by us that gains regulatory clearance will have to compete for market acceptance and market share. An important factor in such competition may be the timing of market introduction of competitive products. Accordingly, the speed with which we can develop products, complete clinical testing and regulatory clearance processes and supply commercial quantities of the product to the market are important competitive factors. In addition, our ability to compete will continue to be dependent on successfully protecting our patents and other intellectual property.

## **Patents and Proprietary Rights and Related Litigation**

We rely on a combination of patents, trade secrets, copyrights, trademarks and non-disclosure agreements to protect our proprietary technology and rights.

Through our various subsidiaries, as of the date of this annual report, we own or have licensed rights to approximately 958 issued United States patents (including approximately 380 design patents) and approximately 1,737 issued foreign patents. In addition, there are approximately 458 pending United States patent applications (including approximately 54 design patent applications), approximately 1,003 pending foreign patent applications, approximately 1,180 registered foreign designs and 146 pending foreign designs. Some of these patents, patent applications and designs relate to significant aspects and features of our products.

Of our patents, 168 United States patents and 395 foreign patents are due to expire in the next five years. There are 15 foreign patents due to expire in 2016, 28 in 2017, 109 in 2018, 61 in 2019, and 182 in 2020. There are 5 United States patents due to expire in 2016, 22 United States patents in 2017, 53 United States patents in 2018, 17 United States patents in 2019, and 71 United States patents in 2020. We believe that the expiration of these patents will not have a material adverse impact on our competitive position.

Litigation may be necessary to enforce patents issued to us, to protect our rights, or to defend third-party claims of infringement by us of the proprietary rights of others. The defense and prosecution of patent claims, including pending claims, as well as participation in other inter-party proceedings, can be expensive and time-consuming, even in those instances in which the outcome is favorable to us. Patent laws regarding the enforceability of patents vary from country to country. Therefore, there can be no assurance that patent issues will be uniformly resolved, or that local laws will provide us with consistent rights and benefits.

## **Government Regulations**

*FDA*



Our products are subject to extensive regulation particularly as to safety, efficacy and adherence to FDA Quality System Regulation, and related manufacturing standards. Medical device products are subject to rigorous FDA and other governmental agency regulations in the United States and similar

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regulations of foreign agencies abroad. The FDA regulates the design, development, research, preclinical and clinical testing, introduction, manufacture, advertising, labeling, packaging, marketing, distribution, import and export, and record keeping for such products, in order to ensure that medical products distributed in the United States are safe and effective for their intended use. In addition, the FDA is authorized to establish special controls to provide reasonable assurance of the safety and effectiveness of most devices. Non-compliance with applicable requirements can result in import detentions, fines, civil and administrative penalties, injunctions, suspensions or losses of regulatory approvals, recall or seizure of products, operating restrictions, refusal of the government to approve product export applications or allow us to enter into supply contracts, and criminal prosecution.

Unless an exemption applies, the FDA requires that a manufacturer introducing a new medical device or a new indication for use of an existing medical device obtain either a Section 510(k) premarket notification clearance or a premarket approval, or PMA, before introducing it into the U.S. market. The type of marketing authorization is generally linked to the classification of the device. The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk the FDA determines to be associated with a device and the level of regulatory control deemed necessary to ensure the device's safety and effectiveness.

Our products currently marketed in the United States are marketed in reliance on 510(k) pre-marketing clearances as either Class I or Class II devices. The process of obtaining a Section 510(k) clearance generally requires the submission of performance data and often clinical data, which in some cases can be extensive, to demonstrate that the device is substantially equivalent to a device that was on the market before 1976 or to a device that has been found by the FDA to be substantially equivalent to such a pre-1976 device, a predecessor device is referred to as predicate device. As a result, FDA clearance requirements may extend the development process for a considerable length of time. In addition, in some cases, the FDA may require additional review by an advisory panel, which can further lengthen the process. The PMA process, which is reserved for new devices that are not substantially equivalent to any predicate device and for high-risk devices or those that are used to support or sustain human life, may take several years and requires the submission of extensive performance and clinical information.

Medical devices can be marketed only for the indications for which they are cleared or approved. After a device has received 510(k) clearance for a specific intended use, any change or modification that significantly affects its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, may require a new 510(k) clearance or PMA approval and payment of an FDA user fee. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance; however, the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties. The FDA is currently reviewing its guidance describing when it believes a manufacturer is obligated to submit a new 510(k) for modifications or changes to a previously cleared device. The FDA is expected to issue revised guidance to assist device manufacturers in making this determination. It is unclear whether the FDA's approach in this new guidance will result in substantive changes to existing policy and practice regarding the assessment of whether a new 510(k) is required for changes or modifications to existing devices.

Any devices we manufacture and distribute pursuant to clearance or approval by the FDA are subject to pervasive and continuing regulation by the FDA and certain state agencies. These include product listing and establishment registration requirements, which help facilitate FDA inspections and other regulatory actions. As a medical device manufacturer, all of our manufacturing facilities are subject to

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inspection on a routine basis by the FDA. We are required to adhere to applicable regulations setting forth detailed cGMP requirements, as set forth in the QSR, which require, manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all phases of the design and manufacturing process. Noncompliance with these standards can result in, among other things, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the government to grant 510(k) clearance or PMA approval of devices, withdrawal of marketing approvals and criminal prosecutions. We believe that our design, manufacturing and quality control procedures are in compliance with the FDA's regulatory requirements.

We must also comply with post-market surveillance regulations, including medical device reporting, or MDR, requirements which require that we review and report to the FDA any incident in which our products may have caused or contributed to a death or serious injury. We must also report any incident in which our product has malfunctioned if that malfunction would likely cause or contribute to a death or serious injury if it were to recur.

Labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. Medical devices approved or cleared by the FDA may not be promoted for unapproved or uncleared uses, otherwise known as off-label promotion. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

Sales of medical devices outside the United States are subject to regulatory requirements that vary widely from country to country. Approval for sale of our medical devices in Europe is through the CE mark process. Where appropriate, our products are CE marked to the European Union's Medical Device Directive. Under the CE marketing scheme, our products are classified as either Class I or Class II. Our devices are listed in Australia with the Therapeutic Goods Administration, and in Canada with Health Canada.

### *Other Healthcare Laws*

Even though we do not submit claims or bill governmental programs and other third-party payers directly for reimbursement for our products sold in the United States, we are still subject to a number of laws and regulations that may restrict our business practices, including, without limitation, anti-kickback, false claims, physician payment transparency and data privacy and security laws. The government has interpreted these laws broadly to apply to the marketing and sales activities of manufacturers and distributors like us.

The federal Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes any request or demand for money or property presented to the U.S. government. The civil False Claims



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Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the civil False Claims Act.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.

Also, many states and countries outside the U.S. have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

Under HIPAA, the Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including health care providers, such as us. HIPAA also regulates standardization of data content, codes and formats used in health care transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties. In addition to federal privacy and security regulations, there are a number of state laws governing confidentiality and security of health information that are applicable to our business. New laws governing privacy may be adopted in the future as well. Failure to comply with privacy requirements could result in civil or criminal penalties, which could have a materially adverse effect on our business.

Additionally, there has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. The Physician Payment Sunshine Act was enacted in law as part of PPACA, which imposed new annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties. Certain states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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### Employees

As of June 30, 2015, we had approximately 4,340 employees or full-time consultants, of which approximately 1,660 were employed in warehousing and manufacturing, 570 in research and development and 2,110 in sales, marketing and administration. Of our employees and consultants, approximately 1,360 were located in Australia, 890 in North and Latin America, 1,330 in Europe and 760 in Asia.

We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel.

### ITEM 1A RISK FACTORS

Before deciding to purchase, hold or sell our common stock, you should carefully consider the risks described below in addition to the other cautionary statements and risks described elsewhere, and the other information contained, in this Report and in our other filings with the SEC, including our subsequent reports on Forms 10-Q and 8-K. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business. If any of these known or unknown risks or uncertainties actually occurs with material adverse effects on us, our business, financial condition and results of operations could be seriously harmed. In that event, the market price for our common stock will likely decline, and you may lose all or part of your investment.

**Our inability to compete successfully in our markets may harm our business.** The markets for our SDB products are highly competitive and are characterized by frequent product improvements and evolving technology. Our ability to compete successfully depends, in part, on our ability to develop, manufacture and market innovative new products. The development of innovative new products by our competitors or the discovery of alternative treatments or potential cures for the conditions that our products treat could make our products noncompetitive or obsolete. Current competitors, new entrants, academics, and others are trying to develop new devices, alternative treatments or cures, and pharmaceutical solutions to the conditions our products treat.

Additionally, some of our competitors have greater financial, research and development, manufacturing and marketing resources than we do. The past several years have seen a trend towards consolidation in the healthcare industry and in the markets for our products. Industry consolidation could result in greater competition if our competitors combine their resources, if our competitors are acquired by other companies with greater resources than ours, or if our competitors become affiliated with customers of ours. This competition could increase pressure on us to reduce the selling prices of our products or could cause us to increase our spending on research and development and sales and marketing. If we are unable to develop innovative new products, maintain competitive pricing, and offer products that consumers perceive to be as good as those of our competitors, our sales or gross margins could decrease which would harm our business.

**Our business depends on our ability to market effectively to dealers of home healthcare products and sleep clinics.** We market our products primarily to home healthcare dealers and to sleep clinics that diagnose OSA and other sleep disorders, as well as to non-sleep specialist physician practices that diagnose and treat sleep disorders. We believe that these groups play a significant role in determining which brand of product a patient will use. The success of our business depends on our ability to market effectively to these groups to ensure that our products are properly marketed and sold by these third-parties.

We have limited resources to market to the sleep clinics, home healthcare dealer branch locations and to the non-sleep specialists, most of whom use, sell or recommend several brands of products. In



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addition, home healthcare dealers have experienced price pressures as government and third-party reimbursement has declined for home healthcare products, and home healthcare dealers are requiring price discounts and longer periods of time to pay for products purchased from us. We cannot assure you that physicians will continue to prescribe our products, or that home healthcare dealers or patients will not substitute competing products when a prescription specifying our products has been written.

We have expanded our marketing activities to target the population with a predisposition to sleep-disordered breathing as well as primary care physicians and various medical specialists. We cannot assure you that these marketing efforts will be successful in increasing awareness or sales of our products.

**Consolidation in the health care industry could have an adverse effect on our revenues and results of operations.** Many home health care dealers are consolidating which may result in greater concentration of market power. As the health care industry consolidates, competition to provide goods and services to industry participants may become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for medical devices and components produced by us. If we are forced to reduce our prices because of consolidation in the health care industry, our revenues may decrease and our consolidated earnings, financial condition, and/or cash flows may suffer.

**If we are unable to support our continued growth, our business could suffer.** We have experienced rapid and substantial growth. As we continue to grow, the complexity of our operations increases, placing greater demands on our management. Our ability to manage our growth effectively depends on our ability to implement and improve our financial and management information systems on a timely basis and to effect other changes in our business including, the ability to monitor and improve manufacturing systems, information technology, and quality and regulatory compliance systems, among others. Unexpected difficulties during expansion, the failure to attract and retain qualified employees, the failure to successfully replace or upgrade our management information systems, the failure to manage costs or our inability to respond effectively to growth or plan for future expansion could cause our growth to stop. If we fail to manage our growth effectively and efficiently, our costs could increase faster than our revenues and our business results could suffer.

**If we fail to integrate our recent acquisitions with our operations, our business could suffer.** We continue to integrate our recent acquisitions into our operations and we may find it difficult to integrate the operations as personnel may leave and licensees, distributors or suppliers may terminate their arrangements or demand amended terms to these arrangements. Additionally, our management may have their attention diverted while trying to integrate these businesses. If we are not able to successfully integrate the operations, we may not realize the anticipated benefits of the acquisitions.

**We are subject to various risks relating to international activities that could affect our overall profitability.** We manufacture substantially all of our products outside the United States and sell a significant portion of our products in non-U.S. markets. Sales outside North and Latin America accounted for approximately 43% and 46% of our net revenues in the years ended June 30, 2015 and 2014, respectively. We expect that sales within these areas will account for approximately 45% of our net revenues in the foreseeable future. Our sales and operations outside of the U.S. are subject to several difficulties and risks that are separate and distinct from those we face in the U.S., including:

fluctuations in currency exchange rates;

tariffs and other trade barriers;

compliance with foreign medical device manufacturing regulations;



difficulty in enforcing agreements and collecting receivables through foreign legal systems;

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reduction in third-party payor reimbursement for our products;

inability to obtain import licenses;

changes in trade policies and in U.S. and foreign tax policies;

possible changes in export or import restrictions; and

the modification or introduction of other governmental policies with potentially adverse effects.

Any of the above factors may have a material adverse effect on our ability to increase or maintain our non-U.S sales.

**Government and private insurance plans may not adequately reimburse our customers for our products, which could result in reductions in sales or selling prices for our products.** Our ability to sell our products depends in large part on the extent to which coverage and reimbursement for our products will be available from government health administration authorities, private health insurers and other organizations. These third-party payers are increasingly challenging the prices charged for medical products and services and can, without notice, deny coverage for our products or treatments that may include the use of our products. Therefore, even if a product is approved for marketing, we cannot make assurances that coverage and reimbursement will be available for the product, that the reimbursement amount will be adequate or that the reimbursement amount, even if initially adequate, will not be subsequently reduced. For example, in some markets, such as Spain, France and Germany, government coverage and reimbursement are currently available for the purchase or rental of our products but are subject to constraints such as price controls or unit sales limitations. In other markets, such as Australia, there is currently limited or no reimbursement for devices that treat SDB conditions. As we continue to develop new products, those products will generally not qualify for coverage and reimbursement until they are approved for marketing, if at all.

In the United States, we sell our products primarily to home healthcare dealers, hospitals and to sleep clinics. Reductions in reimbursement to our customers by third-party payers, if they occur, may have a material impact on our customers and, therefore, may indirectly affect our sales to, or the collectability of receivables we have from, those customers. A development affecting reimbursement negatively stems from the Medicare competitive bidding program mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA. Under the program, our customers who provide home healthcare services must compete to offer products in designated competitive bidding areas, or CBAs. Under PPACA, by 2016, the competitive bidding process must either be rolled-out nationally or Medicare prices in non-competitive bidding areas must be reduced to match competitive bidding prices.

We cannot predict at this time the full impact the competitive bidding program and the developments in the competitive bidding program will have on our business and financial condition.

**Healthcare reform, including recently enacted legislation, may have a material adverse effect on our industry and our results of operations.** In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the PPACA ) was signed into law in the United States. The PPACA makes changes that are expected to impact the medical device industry. One of the principal purposes of the PPACA was to expand health insurance coverage to approximately 32 million Americans who were uninsured. The PPACA requires adults not covered by an employer- or government-sponsored insurance plan to maintain health insurance coverage or pay a penalty, a provision commonly referred to as the individual mandate. We cannot predict the impact of these coverage expansions, if any, on the sales of our products.

The PPACA also contains a number of provisions designed to generate the revenues necessary to fund the coverage expansions. This includes new fees or taxes on certain health-related industries,

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including medical device manufacturers. Beginning in 2013, entities that manufacture, produce or import medical devices were required to pay an excise tax in an amount equal to 2.3% of the price for which such devices are sold in the United States. This excise tax is applicable to our products that are primarily used in hospitals and sleep labs, which includes the ApneaLink, VPAP Tx, certain Respiratory Care and dental sleep products. In addition to the competitive bidding changes discussed above, the PPACA also includes, among other things, demonstrations to develop organizations that are paid under a new payment methodology for voluntary coordination of care by groups of providers, such as physicians and hospitals, and the establishment of a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research. The increased funding and focus on comparative clinical effectiveness research, which compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products, may result in lower reimbursements by payers for our products and decreased profits to us.

Other federal legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers, including home healthcare companies, of up to 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012, or the ATRA, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Various healthcare reform proposals have also emerged at the state level within the United States.

The PPACA as well as other federal and/or state healthcare reform measures that may be adopted in the future, singularly or in the aggregate, could have a material adverse effect on our business, financial condition and results of operations.

**Failure to comply with anti-kickback and fraud regulations could result in substantial penalties and changes in our business operations.** Although we do not provide healthcare services, submit claims for third-party reimbursement, or receive payments directly from Medicare, Medicaid or other third-party payors for our products, we are subject to healthcare fraud and abuse regulation and enforcement by federal, state and foreign governments, which could significantly impact our business. In the United States, the laws that may affect our ability to operate include, but are not limited to:

the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers and distributors like us;

federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly

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avoiding or decreasing an obligation to pay or transmit money or property to the federal government. These laws may apply to manufacturers and distributors who provide information on coverage, coding, and reimbursement of their products to persons who do bill third-party payers;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;

the federal Physician Sunshine Act requirements under the PPACA, which impose new reporting and disclosure requirements on device and drug manufacturers for any transfer of value made or distributed by certain manufacturers of drugs, devices, biologics, and medical supplies to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

state and foreign law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA.

The scope and enforcement of these laws are uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. We also are subject to foreign fraud and abuse laws, which vary by country.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

**Complying with Food and Drug Administration, or FDA, and other regulations is an expensive and time-consuming process, and any failure to comply could have a materially adverse effect**



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**on our business, financial condition, or results of operations.** We are subject to extensive U.S. federal, state, local and international regulations regarding our business activities. Failure to comply with these regulations could result in, among other things, recalls of our products, substantial fines and criminal charges against us or against our employees. Furthermore, our products could be subject to recall if the FDA, other regulators or we determine, for any reason, that our products are not safe or effective. Any recall or other regulatory action could increase our costs, damage our reputation, affect our ability to supply customers with the quantity of products they require and materially affect our operating results.

**Product sales, introductions or modifications may be delayed or canceled as a result of FDA regulations or similar foreign regulations, which could cause our sales and profits to decline.** Unless a product is exempt, before we can market or sell a new medical device in the United States, we must obtain FDA clearance or approval, which can be a lengthy and time-consuming process. We generally receive clearance from the FDA to market our products in the United States under Section 510(k) of the Federal Food, Drug, and Cosmetic Act or our products are exempt from the Section 510(k) clearance process. The 510(k) clearance process can be expensive, time-consuming and uncertain. In the 510(k) clearance process, the FDA must determine that a proposed device is substantially equivalent to a device legally on the market, known as a predicate device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. The FDA has a high degree of latitude when evaluating submissions and may determine that a proposed device submitted for 510(k) clearance is not substantially equivalent to a predicate device. After a device receives 510(k) premarket notification clearance from the FDA, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in the intended use of the device, technology, materials, packaging, and certain manufacturing processes may require a new 510(k) clearance or premarket approval. We have modified some of our Section 510(k) approved products without submitting new Section 510(k) notices, which we do not believe were required. However, if the FDA disagrees with us and requires us to submit new Section 510(k) notifications for modifications to our existing products, we may be required to stop marketing the products while the FDA reviews the Section 510(k) notification.

Any new product introduction or existing product modification could be subjected to a lengthier, more rigorous FDA examination process. For example, in certain cases we may need to conduct clinical trials of a new product before submitting a 510(k) notice. We may also be required to obtain premarket approvals for certain of our products. Indeed, recent trends in the FDA's review of premarket notification submissions suggest that the FDA is often requiring manufacturers to provide new, more expansive, or different information regarding a particular device than what the manufacturer anticipated upon 510(k) submission. This has resulted in increasing uncertainty and delay in the premarket notification review process.

For example, the FDA is currently reviewing its guidance describing when it believes a manufacturer is obligated to submit a new 510(k) for modifications or changes to a previously cleared device. The FDA is expected to issue revised guidance to assist device manufacturers in making this determination. It is unclear whether the FDA's approach in this new guidance will result in substantive changes to existing policy and practice regarding the assessment of whether a new 510(k) is required for changes or modifications to existing devices. The FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a manufacturer must submit a new 510(k) for a modification to a previously cleared product, or by applying more onerous review criteria to such submissions. FDA continues to review its 510(k) clearance process which could result in additional changes to regulatory requirements or guidance documents which could increase the costs of compliance, or restrict our ability to maintain current clearances. The requirements of the more

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rigorous premarket approval process and/or significant changes to the Section 510(k) clearance process could delay product introductions and increase the costs associated with FDA compliance. Marketing and sale of our products outside the United States are also subject to regulatory clearances and approvals, and if we fail to obtain these regulatory approvals, our sales could suffer. We cannot assure you that any new products we develop will receive required regulatory approvals from U.S. or foreign regulatory agencies.

**We are subject to substantial regulation related to quality standards applicable to our manufacturing and quality processes. Our failure to comply with these standards could have an adverse effect on our business, financial condition, or results of operations.** The FDA regulates the approval, manufacturing, and sales and marketing of many of our products in the U.S. Significant government regulation also exists in Canada, Japan, Europe, and other countries in which we conduct business. As a device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European Community, we are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Failure to comply with current governmental regulations and quality assurance guidelines could lead to temporary manufacturing shutdowns, product recalls or related field actions, product shortages or delays in product manufacturing. Efficacy or safety concerns, an increase in trends of adverse events in the marketplace, and/or manufacturing quality issues with respect to our products could lead to product recalls or related field actions, withdrawals, and/or declining sales.

**Our products are the subject of clinical trials conducted by us, our competitors, or other third parties, the results of which may be unfavorable, or perceived as unfavorable, and could have a material adverse effect on our business, financial condition, and results of operations.** As a part of the regulatory process of obtaining marketing clearance for new products and new indications for existing products, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations, and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, by our competitors, or by third parties, or the market's or regulatory bodies' perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate, and our business, financial condition, and results of operations.

**Off-label marketing of our products could result in substantial penalties.** The FDA strictly regulates the promotional claims that may be made about FDA-cleared products. In particular, clearance under Section 510(k) only permits us to market our products for the uses indicated on the labeling cleared by the FDA. We may request additional label indications for our current products, and the FDA may deny those requests outright, require additional expensive clinical data to support any additional indications or impose limitations on the intended use of any cleared products as a condition of clearance. If the FDA determines that we have marketed our products for off-label use, we could be subject to fines, injunctions or other penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government



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healthcare programs, and the curtailment of our operations. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

**Disruptions in the supply of components from our single source suppliers could result in a significant reduction in sales and profitability.** We purchase uniquely configured components for our devices from various suppliers, including some who are single-source suppliers for us. We cannot assure you that a replacement supplier would be able to configure its components for our devices on a timely basis or, in the alternative, that we would be able to reconfigure our devices to integrate the replacement part. A reduction or halt in supply while a replacement supplier reconfigures its components, or while we reconfigure our devices for the replacement part, would limit our ability to manufacture our devices, which could result in a significant reduction in sales and profitability. We cannot assure you that our inventories would be adequate to meet our production needs during any prolonged interruption of supply.

**We are subject to potential product liability claims that may exceed the scope and amount of our insurance coverage, which would expose us to liability for uninsured claims.** We are subject to potential product liability claims as a result of the design, manufacture and marketing of medical devices. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates. In addition, we would have to pay any amount awarded by a court in excess of our policy limits. Our insurance policies have various exclusions, and thus we may be subject to a product liability claim for which we have no insurance coverage, in which case, we may have to pay the entire amount of any award. We cannot assure you that our insurance coverage will be adequate or that all claims brought against us will be covered by our insurance and we cannot assure you that we will be able to obtain insurance in the future on terms acceptable to us or at all. A successful product liability claim brought against us in excess of our insurance coverage, if any, may require us to pay substantial amounts, which could harm our business.

**Our intellectual property may not protect our products, and/or our products may infringe on the intellectual property rights of third-parties.** We rely on a combination of patents, trade secrets and non-disclosure agreements to protect our intellectual property. Our success depends, in part, on our ability to obtain and maintain United States and foreign patent protection for our products, their uses and our processes to preserve our trade secrets and to operate without infringing on the proprietary rights of third-parties. We have a number of pending patent applications, and we do not know whether any patents will issue from any of these applications. We do not know whether any of the claims in our issued patents or pending applications will provide us with any significant protection against competitive products or otherwise be commercially valuable. Legal standards regarding the validity of patents and the proper scope of their claims are still evolving, and there is no consistent law or policy regarding the valid breadth of claims. Additionally, there may be third-party patents, patent applications and other intellectual property relevant to our products and technology which are not known to us and that block or compete with our products.

We face the risks that:

third-parties will infringe our intellectual property rights;

our non-disclosure agreements will be breached;

we will not have adequate remedies for infringement;

our trade secrets will become known to or independently developed by our competitors; or

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third-parties will be issued patents that may prevent the sale of our products or require us to license and pay fees or royalties in order for us to be able to market some of our products.

Litigation may be necessary to enforce patents issued to us, to protect our proprietary rights, or to defend third-party claims that we have infringed upon proprietary rights of others. The defense and

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prosecution of patent claims, including these pending claims, as well as participation in other inter-party proceedings, can be expensive and time-consuming, even in those instances in which the outcome is favorable to us. If the outcome of any litigation or proceeding brought against us were adverse, we could be subject to significant liabilities to third-parties, could be required to obtain licenses from third-parties, could be forced to design around the patents at issue or could be required to cease sales of the affected products. A license may not be available at all or on commercially viable terms, and we may not be able to redesign our products to avoid infringement. Additionally, the laws regarding the enforceability of patents vary from country to country, and we cannot assure you that any patent issues we face will be uniformly resolved, or that local laws will provide us with consistent rights and benefits.

**We are subject to tax audits by various tax authorities in many jurisdictions.** From time to time we may be audited by tax authorities in various jurisdictions. Any final assessment resulting from such audits could result in material changes to our past or future taxable income, tax payable or deferred tax assets, and could require us to pay penalties and interest that could materially adversely affect our financial results.

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

the introduction of new products by us or our competitors;

the geographic mix of product sales;

the success and costs of our marketing efforts in new regions;

changes in third-party payor reimbursement;

timing of regulatory clearances and approvals;

timing of orders by distributors;

expenditures incurred for research and development;

competitive pricing in different regions;

the effect of foreign currency transaction gains or losses; and

other activities of our competitors.

Fluctuations in our quarterly operating results may cause the market price of our common stock to fluctuate.

**If a natural or man-made disaster strikes our manufacturing facilities, we will be unable to manufacture our products for a substantial amount of time and our sales and profitability will decline.** Our facilities and the manufacturing equipment we use to produce our products would be costly to replace and could require substantial lead-time to repair or replace. The facilities may be affected by natural or man-made disasters and in the event they were affected by a disaster, we would be forced to rely on third-party manufacturers. Although we believe we possess adequate insurance for the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

**Delaware law and provisions in our charter and could make it difficult for another company to acquire us.** Provisions of our certificate of incorporation may have the effect of delaying or preventing changes in control or management which might be beneficial to us or our security holders. In particular, our board of directors is divided into three classes, serving for staggered three-year terms. Because of this classification, it will require at least two annual meetings to elect directors

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constituting a majority of our board of directors. Additionally, our board of directors has the authority to issue up to 2,000,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without further vote or action by the stockholders. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control, may discourage bids for our common stock at a premium over the market price of our common stock and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock.

**You may not be able to enforce the judgments of U.S. courts against some of our assets or officers and directors.** A substantial portion of our assets are located outside the United States. Additionally, some of our directors and executive officers reside outside the United States, along with all or a substantial portion of their assets. As a result, it may not be possible for investors to enforce judgments of U.S. courts relating to any liabilities under U.S. securities laws against our assets, those persons or their assets. In addition, investors may not be able to pursue claims based on U.S. securities laws against these assets or these persons in Australian courts, where most of these assets and persons reside.

**We are increasingly dependent on information technology systems and infrastructure.** Our technology systems are potentially vulnerable to breakdown or other interruption by fire, power loss, system malfunction, unauthorized access and other events. Likewise, data privacy breaches by employees and others with both permitted and unauthorized access to our systems may pose a risk that sensitive data may be exposed to unauthorized persons or to the public, or may be permanently lost. While we have invested heavily in the protection of data and information technology and in related training, there can be no assurance that our efforts will prevent significant breakdowns, breaches in our systems or other cyber incidents that could have a material adverse effect upon the reputation, business, operations or financial condition of the company. In addition, significant implementation issues may arise as we continue to consolidate and outsource certain computer operations and application support activities.

**Our results of operations may be materially affected by global economic conditions generally, including conditions in the financial markets.** Recently, concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, and the ability of sovereign nations to pay their debts have contributed to increased volatility and diminished expectations for the economy and the financial markets going forward. These factors, combined with volatile commodity prices, declining business and consumer confidence and increased unemployment, have precipitated an economic slowdown. It is difficult to predict how long the current economic conditions will continue and whether the economic conditions will continue to deteriorate. If the economic climate in the United States or outside the United States continues to deteriorate or there is a shift in government spending priorities, customers or potential customers could reduce or delay their purchases, which could impact our revenue, our ability to manage inventory levels, collect customer receivables, and ultimately decrease our profitability.

## **ITEM 1B UNRESOLVED STAFF COMMENTS**

We have received no written comments regarding our periodic or current reports from the staff of the Securities and Exchange Commission that were issued 180 days or more preceding the end of our fiscal year 2015 that remain unresolved.

**Table of Contents****ITEM 2 PROPERTIES**

We conduct our operations in both owned and leased properties. Our principal executive offices and U.S. sales facilities, consisting of approximately 230,000 square feet, are located on Spectrum Center Boulevard in San Diego, California, in a building we own. We have our research and development and office facilities and manufacturing facilities at our owned site in Norwest, Sydney, Australia. Warehousing and distribution facilities are leased in Atlanta, Georgia, and Moreno Valley, California, U.S.A.; Abingdon, England; Munich, Bremen, Hochstadt, Germany; Lyon, Paris, France; Basel, Switzerland; Stockholm, Sweden; Helsinki, Finland; Oslo, Norway; New Delhi, India; Tokyo, Japan and Dublin, Ireland, Beijing, China; the Czech Republic and Poland.

We believe that our facilities are adequate to meet the needs of our current business operations. At June 30, 2015, our principal owned and leased properties were as follows:

<b>Location</b>	<b>Ownership Status (Owned / Leased)</b>	<b>Square footage</b>	<b>Primary Usage</b>
San Diego, California	Owned	230,000	Corporate headquarters, sales and administration
Norwest, Sydney, Australia	Owned	224,000	Manufacturing, engineering, research and development
Chatsworth, California	Leased	72,000	Motor manufacturing, engineering, research and development
Atlanta, Georgia	Leased	470,000	Warehouse and distribution
Moreno Valley, California	Leased	130,000	Warehouse and distribution
Singapore, Singapore	Leased	95,000	Manufacturing facility
Munich, Germany	Leased	119,000	Sales and distribution, research and development
Lyon, France	Leased	52,000	Sales and distribution
Paris, France	Leased	43,000	Manufacturing facility, field service
Freudenstadt, Germany	Owned	43,000	Manufacturing facility
Johor Bahru, Malaysia	Leased	46,000	Manufacturing facility

**ITEM 3 LEGAL PROCEEDINGS**

We are involved in various legal proceedings and claims. Litigation is inherently uncertain. Accordingly, we cannot predict the outcome of these matters. But we do not expect the outcome of these matters to have a material adverse effect on our consolidated financial statements when taken as a whole.

In 2013, we filed actions in the U.S. and Germany against Chinese manufacturer BMC Medical Co., Ltd and its U.S. distributor, 3B Medical, Inc. to stop the infringement of several ResMed patents. The



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U.S. International Trade Commission initiated an investigation, and in December 2014, ruled that certain of BMC's masks infringed ResMed's patents and should be excluded from importation or sale in the US. BMC subsequently notified the Commission that it discontinued US sales of the mask products affected by the Commission's order. The International Trade Commission also ruled that the claims of the patent against BMC's humidifier patent were anticipated by prior art, invalidated those claims, and declined to exclude BMC's humidifier products from importation or sale. Each party has appealed the International Trade Commission's ruling. A companion case in the United States District Court for the Southern District of California remains stayed pending those appeals. In 2013, we obtained preliminary injunctions prohibiting BMC from marketing and selling certain flow generators and mask assemblies accused of patent infringement in Germany. The preliminary injunction against BMC's mask assemblies remains in effect, but in November 2014 the court dissolved the preliminary injunction against the sale of BMC's flow generators, and the court's action dissolving that preliminary injunction was affirmed on appeal. ResMed continues to pursue the underlying German patent infringement action against BMC's flow generators and mask assemblies.

In 2015, BMC's U.S. distributor, 3B Medical, Inc., filed suit in the United States District Court for the Middle District of Florida against ResMed Inc. and ResMed Corp. for alleged federal and state antitrust violations. Specifically, 3B Medical alleges that in addition to enforcing its patents, ResMed has entered into exclusive dealing arrangements with customers, tied sales of masks to sales of flow generators, and spread false information that 3B would go out of business due to ResMed's patent infringement action. 3B Medical seeks damages and an injunction. ResMed Inc. has been dismissed from the case, and ResMed Corp. has denied the allegations.

**ITEM 4 MINE SAFETY DISCLOSURES**

Not Applicable.



**Table of Contents****PART II****ITEM 5 MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTER AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock is traded on the NYSE under the symbol RMD . The following table sets forth for the fiscal periods indicated the high and low closing prices for the common stock as reported by the NYSE.

	2015		2014	
	High	Low	High	Low
Quarter One, Ended September 30	\$ 53.35	\$ 48.65	\$ 54.36	\$ 43.26
Quarter Two, Ended December 31	57.39	46.25	57.11	45.36
Quarter Three, Ended March 31	72.44	56.65	47.82	42.03
Quarter Four, Ended June 30	74.82	55.44	53.76	44.43

At July 28, 2015, there were 26 holders of record of our common stock, although many of these holders of record own shares as nominees on behalf of other beneficial owners. During fiscal years 2015 and 2014, we paid dividends totaling \$157.3 million and \$141.5 million, respectively. On July 30, 2015, we announced an increase in the quarterly dividend from \$0.28 per share to \$0.30 per share. We pay the dividend in U.S. currency to holders of our common stock trading on the NYSE. Holders of CDIs trading on the ASX will receive an equivalent amount in Australian currency based on the exchange rate on the record date and reflecting the 10:1 ratio between CDIs and NYSE shares. We expect the dividend will continue to be unfranked for Australian tax purposes. We expect to fund our dividend commitments with our operating cash flows and existing loan facilities.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The information included under Item 12 of Part III of this Report, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, is hereby incorporated by reference into this Item 5 of Part II of this Report.

**Table of Contents****Purchases of Equity Securities**

The following table summarizes purchases by us of our common stock during the fiscal year ending June 30, 2015:

<b>Period</b>	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased<sup>(1)</sup></b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Programs<sup>(1)</sup></b>
July 1 - 31, 2014	182,579	\$ 49.50	36,625,074	18,090,939
August 1 - 31, 2014	257,986	51.65	36,883,060	17,832,953
September 1 - 30, 2014	394,922	51.93	37,277,982	17,438,031
October 1 - 31, 2014	416,982	48.16	37,694,964	17,021,049
November 1 - 30, 2014	75,000	53.40	37,769,964	16,946,049
December 1 - 31, 2014	175,000	53.93	37,944,964	16,771,049
January 1 - 31, 2015	0	-	37,944,964	16,771,049
February 1 - 28, 2015	92,500	65.03	38,037,464	16,678,549
March 1 - 31, 2015	207,500	68.91	38,244,964	16,471,049
April 1 - 30, 2015	165,000	64.45	38,409,964	16,306,049
May 1 - 31, 2015	438,571	58.15	38,848,535	15,867,478
June 1 - 30, 2015	337,699	58.62	39,186,234	15,529,779
<b>Total</b>	<b>2,743,739</b>	<b>\$ 55.63</b>	<b>39,186,234</b>	<b>15,529,779</b>

<sup>1</sup>. On February 21, 2014, our board of directors approved a new share repurchase program, authorizing us to acquire up to an aggregate of 20 million shares of our common stock. The program allows us to repurchase shares of our common stock from time to time for cash in the open market, or in negotiated or block transactions, as market and business conditions warrant and subject to applicable legal requirements. There is no expiration date for this program, and the program may be accelerated, suspended, delayed or discontinued at any time at the discretion of our board of directors. All share repurchases after February 21, 2014 have been executed under this program. Since the inception of the share buyback programs, we have repurchased 39.2 million shares at a total cost of \$1.4 billion.

**Table of Contents****PERFORMANCE GRAPH**

This performance graph is furnished and shall not be deemed filed with the SEC or subject to Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any of our filings under the Securities Act of 1933, as amended.

The following graph compares the cumulative total stockholders return on our common stock from June 30, 2010 through June 30, 2015, with the comparable cumulative return of the S&P 500 index, the S&P 500 Health Care index, and the Dow Jones US Medical Devices index. The graph assumes that \$100 was invested in our common stock and each index on June 30, 2010. In addition, the graph assumes the reinvestment of all dividends paid. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

The following table shows total indexed return of stock price plus reinvestments of dividends, assuming an initial investment of \$100 at June 30, 2010, for the indicated periods.

Index	June 2010	June 2011	June 2012	June 2013	June 2014	June 2015
ResMed Inc	100	102	103	150	170	191
S&P 500	100	128	132	156	190	200
S&P 500 Health Care	100	126	135	169	216	263
Dow Jones US Medical Devices	100	126	124	149	194	229

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**Table of Contents****ITEM 6      SELECTED FINANCIAL DATA**

The following table summarizes certain selected consolidated financial data for, and as of the end of, each of the fiscal years in the five-year period ended June 30, 2015. The data set forth below should be read in conjunction with Item 7 of Part II of this annual report, Management's Discussion and Analysis of Financial Condition and Results of Operations and Item 8 of Part II of this annual report, Consolidated Financial Statements and Supplementary Data, and related Notes included elsewhere in this annual report. The consolidated statement of income data for the years ended June 30, 2015, 2014 and 2013 and the consolidated balance sheet data as of June 30, 2015 and 2014 are derived from our audited consolidated financial statements included elsewhere in this annual report. The consolidated statement of income data for the years ended June 30, 2012 and 2011 and the consolidated balance sheet data as of June 30, 2013, 2012 and 2011 are derived from our audited consolidated financial statements not included herein. Historical results are not necessarily indicative of the results to be expected in the future, and the results for the years presented should not be considered indicative of our future results of operations.

<b>Consolidated Statement of Income Data (In thousands, except per share data):</b>	<b>Years Ended June 30,</b>				
	<b>2015</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>
Net revenues	\$ 1,678,912	\$ 1,554,973	\$ 1,514,457	\$ 1,368,515	\$ 1,243,148
Cost of sales (excluding amortization of acquired intangible assets)	667,516	565,187	573,800	547,780	501,822
Gross profit	1,011,396	989,786	940,657	820,735	741,326
Selling, general and administrative expenses	478,627	450,414	430,802	402,621	372,249
Research and development expenses	114,865	118,226	120,124	109,733	92,007
Restructuring expenses	-	6,326	-	-	-
Education, research and settlement charge	-	-	24,765	-	-
Amortization of acquired intangible assets	8,668	9,733	10,142	13,974	10,146
Total operating expenses	602,160	584,699	585,833	526,328	474,402
Income from operations	409,236	405,087	354,824	294,407	266,924
Other income:					
Interest income, net	20,430	25,107	32,486	29,080	26,043
Other, net	6,250	884	(2,191)	8,458	10,740
Total other income, net	26,680	25,991	30,295	37,538	36,783
Income before income taxes	435,916	431,078	385,119	331,945	303,707
Income taxes	83,030	85,805	77,986	77,095	76,721
Net income	\$ 352,886	\$ 345,273	\$ 307,133	\$ 254,850	\$ 226,986
Basic earnings per share	\$ 2.51	\$ 2.44	\$ 2.15	\$ 1.75	\$ 1.49
Diluted earnings per share	\$ 2.47	\$ 2.39	\$ 2.10	\$ 1.71	\$ 1.44
Dividends per share	\$ 1.12	\$ 1.00	\$ 0.68	\$ -	\$ -
Weighted average:					
Basic shares outstanding	140,468	141,474	142,954	145,901	152,471
Diluted shares outstanding	142,687	144,359	146,410	149,316	157,195

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<b>Consolidated Balance Sheet Data (In thousands):</b>	<b>As of June 30,</b>				
	<b>2015</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>
Working capital	\$ 1,176,923	\$ 1,286,651	\$ 874,800	\$ 1,108,299	\$ 1,083,612
Total assets	2,184,260	2,360,962	2,210,721	2,137,869	2,068,922
Long-term debt, less current maturities	300,594	300,770	769	250,783	100,000
Total stockholders' equity	\$ 1,587,307	\$ 1,758,248	\$ 1,610,516	\$ 1,607,627	\$ 1,730,737

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### ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### Overview

Management's discussion and analysis of financial condition and results of operations is intended to help the reader understand the results of operations and financial condition of ResMed Inc and subsidiaries. It is provided as a supplement to, and should be read in conjunction with the selected financial data and consolidated financial statements and notes included elsewhere in this Report.

We are a leading developer, manufacturer and distributor of medical equipment for treating, diagnosing, and managing sleep-disordered breathing ( SDB ) and other respiratory disorders. During the fiscal year, we continued our efforts to build awareness of the consequences of untreated SDB and to grow our business in this market. In our efforts, we have attempted to raise awareness through market and clinical initiatives and by highlighting the increasing link between the potential effects SDB can have on co-morbidities such as cardiac disease, diabetes, hypertension and obesity.

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.

We are committed to ongoing investment in research and development and product enhancements. During fiscal year 2015, we invested approximately \$114.9 million on research and development activities, which represents approximately 7% of net revenues. Since the development of CPAP, we have developed a number of innovative products for the treatment of SDB and other respiratory disorders including airflow generators, diagnostic products, mask systems, headgear and other accessories. During fiscal year 2015, we released significant new products across our flow generator categories, including the AirSense™ 10, AirCurve™ 10, AirView™ and Lumis as well as the AirView™, our cloud-based remote monitoring and therapy management system. The release of these products as well as the release of AirFit™ P10, AirFit N10 and AirFit F10 masks and the Astral™, in fiscal 2014, and a robust product pipeline, will continue to provide us with a strong platform for future growth.

Net revenue in fiscal year 2015 increased to \$1,678.9 million, an increase of 8% compared to fiscal year 2014. Gross profit increased for the year ended June 30, 2015 to \$1,011.4 million, from \$989.8 million for the year ended June 30, 2014, an increase of \$21.6 million or 2%. Our net income for the year ended June 30, 2015 was \$352.9 million or \$2.47 per diluted share compared to net income of \$345.3 million or \$2.39 per diluted share for the year ended June 30, 2014.

Total operating cash flow for fiscal year 2015 was \$383.2 million and at June 30, 2015, our cash and cash equivalents totaled \$717.2 million. At June 30, 2015, our total assets were \$2.2 billion and our stockholders' equity was \$1.6 billion. During fiscal year 2015, we repurchased 2.7 million shares at a cost of \$152.6 million under our share repurchase program, compared to 4.4 million shares at a cost of \$208.1 million during fiscal year 2014. We paid a quarterly dividend of \$0.28 per share during fiscal 2015 with a total amount of \$157.3 million paid to stockholders.

In order to provide a framework for assessing how our underlying businesses performed, excluding the effect of foreign currency fluctuations, we provide certain financial information on a constant currency basis, which is in addition to the actual financial information presented. In order to calculate our constant currency information, we translate the current period financial information using the foreign currency exchange rates

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that were in effect during the previous comparable period. However, constant currency measures should not be considered in isolation or as an alternative to

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U.S. dollar measures that reflect current period exchange rates, or to other financial measures calculated and presented in accordance with U.S. generally accepted accounting principles.

**Fiscal Year Ended June 30, 2015 Compared to Fiscal Year Ended June 30, 2014**

**Net Revenues.** Net revenue increased for the year ended June 30, 2015 to \$1,678.9 million from \$1,555.0 million for the year ended June 30, 2014, an increase of \$123.9 million or 8% (a 13% increase on a constant currency basis). The increase in net revenue was attributable to an increase in unit sales of our flow generators, masks and accessories, partially offset by a decline in average selling prices. Movements in international currencies against the U.S. dollar negatively impacted net revenues by approximately \$74.5 million for the year ended June 30, 2015.

Net revenue in North and Latin America increased for the year ended June 30, 2015 to \$962.7 million from \$839.1 million for the year ended June 30, 2014, an increase of \$123.6 million or 15%. The increase in net revenue is primarily attributable to an increase in unit sales of our flow generators, masks and accessories, partially offset by a decline in average selling prices.

Net revenue in markets outside North and Latin America increased for the year ended June 30, 2015 to \$716.2 million from \$715.8 million for the year ended June 30, 2014, an increase of \$0.4 million or 0% (a 10% increase on a constant currency basis). The constant currency increase in sales outside North and Latin America predominantly reflects an increase in unit sales of our flow generators, masks and accessories, partially offset by a decline in average selling prices.

Net revenue from flow generators for the year ended June 30, 2015 totaled \$975.9 million from \$846.7 million for the year ended June 30, 2014, an increase of 15%, including an increase of 33% in North and Latin America and an increase of 2% outside North and Latin America (a 12% increase on a constant currency basis). Net revenue from masks and other accessories for the year ended June 30, 2015 totaled \$703.0 million from \$708.3 million for the year ended June 30, 2014, a decrease of 1%, including an increase of 1% in North and Latin America and a decrease of 4% outside North and Latin America (a 6% increase on a constant currency basis). Excluding the impact of foreign currency movements, flow generator sales for the year ended June 30, 2015 increased by 21%, and masks and accessories sales increased by 3%, compared to the year ended June 30, 2014.

The following table summarizes the percentage movements in our net revenue for the year ended June 30, 2015 compared to the year ended June 30, 2014:

	North and Latin America	International	Total	International (Constant Currency)*	Total (Constant Currency)*
Flow generators	33%	2%	15%	12%	21%
Masks and other accessories	1%	-4%	-1%	6%	3%
Total	15%	0%	8%	10%	13%

\* Constant currency numbers exclude the impact of movements in international currencies.



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**Gross Profit.** Gross profit increased for the year ended June 30, 2015 to \$1,011.4 million from \$989.8 million for the year ended June 30, 2014, an increase of \$21.6 million or 2%. Gross profit as a percentage of net revenue was 60.2% for the year ended June 30, 2015, compared with the 63.7% for the year ended June 30, 2014. The decline in gross margins was primarily due to declines in our average selling prices, an unfavorable product mix as sales of our lower margin products represented a higher proportion of our sales, an unfavorable impact from exchange rate movements as a result of the decline in the Euro currency relative to U.S. dollar, and an unfavorable geographic mix.

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**Selling, General and Administrative Expenses.** Selling, general and administrative expenses increased for the year ended June 30, 2015 to \$478.6 million from \$450.4 million for the year ended June 30, 2014, an increase of \$28.2 million or 5%. The selling, general and administrative expenses were favorably impacted by the movement of international currencies against the U.S. dollar, which decreased our expenses by approximately \$29.6 million, as reported in U.S. dollars. Excluding the impact of foreign currency movements, selling, general and administrative expenses for the year ended June 30, 2015 increased by 13% compared to the year ended June 30, 2014. As a percentage of net revenue, selling, general and administrative expenses for the year ended June 30, 2015 was 28.5%, compared to 29.0% for the year ended June 30, 2014.

The increase in selling, general and administrative expenses was primarily due to additional personnel to support our commercial activities, higher marketing expenditure associated with our recent product releases, an increase in our variable employee compensation costs, the impact of recent acquisitions, donations to the University of California San Diego and ResMed Foundation, and the release of contingent consideration in the prior year.

**Research and Development Expenses.** Research and development expenses decreased for the year ended June 30, 2015 to \$114.9 million from \$118.2 million for the year ended June 30, 2014, a decrease of \$3.4 million or 3%. The research and development expenses were favorably impacted by the depreciation of the Australian dollar against the U.S. dollar, which decreased our expenses by approximately \$11.0 million, as reported in U.S. dollars. Excluding the impact of foreign currency movements, research and development expenses for the year ended June 30, 2015 increased by 6% compared to the year ended June 30, 2014. As a percentage of net revenue, research and development expenses were 6.8% for the year ended June 30, 2015 compared to 7.6% for the year ended June 30, 2014.

The increase in research and development expenses in constant currency terms was primarily due to an increase in the number of research and development personnel and an increase in materials and tooling costs incurred to facilitate development of new products.

**Amortization of Acquired Intangible Assets.** Amortization of acquired intangible assets for the year ended June 30, 2015 totaled \$8.7 million compared to \$9.7 million for the year ended June 30, 2014. The reduction in amortization expense was mainly attributable to certain acquired intangibles reaching the end of their useful life and therefore being fully amortized.

**Total other income, net.** Total other income, net for the year ended June 30, 2015 was \$26.7 million, compared with \$26.0 million for the year ended June 30, 2014. The increase in total other income, net, was due primarily due to gains on foreign currency transactions, partially offset by lower interest income resulting from lower interest rates on cash balances held and the depreciation of the Australian dollar against the U.S. dollar.

**Income Taxes.** Our effective income tax rate decreased to 19.0% for the year ended June 30, 2015 from 19.9% for the year ended June 30, 2014. Our effective income tax rate is affected by the geographic mix of our taxable income, including lower taxes associated with our Singapore and Malaysia manufacturing operations. Our Singapore and Malaysia operations operate under certain tax holidays and tax incentive programs which will expire in whole or in part at various dates through June 30, 2020. As of June 30, 2015, we have not provided for U.S. income taxes for the undistributed earnings of our foreign subsidiaries. We intend for these earnings to be permanently reinvested outside the United States.

**Net Income and Earnings per Share.** As a result of the factors above, our net income for the year ended June 30, 2015 was \$352.9 million compared to net income of \$345.3 million for the year ended June 30, 2014, an increase of 2% over the year ended June 30, 2014. As a result of the increase in our



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net income and lower share count due to our stock repurchases, our earnings per share for the year ended June 30, 2015 was \$2.47 per diluted share compared to \$2.39 per diluted share for the year ended June 30, 2014, an increase of 3% over the year ended June 30, 2014.

**Fiscal Year Ended June 30, 2014 Compared to Fiscal Year Ended June 30, 2013**

**Net Revenues.** Net revenue increased for the year ended June 30, 2014 to \$1,555.0 million from \$1,514.5 million for the year ended June 30, 2013, an increase of \$40.5 million or 3%. The increase in net revenue was attributable to an increase in unit sales of our flow generators, masks and accessories, partially offset by a decline in average selling prices. Movements in international currencies against the U.S. dollar positively impacted net revenues by approximately \$17.0 million for the year ended June 30, 2014. Excluding the impact of foreign currency movements, sales for the year ended June 30, 2014 increased by 2% compared to the year ended June 30, 2013.

Net revenue in North and Latin America decreased for the year ended June 30, 2014 to \$839.1 million from \$851.6 million for the year ended June 30, 2013, a decrease of \$12.5 million or 1%. The decrease in net revenue was primarily attributable to increased competitor activity and a decline in average selling prices, partially offset by an increase in unit sales of our flow generators, masks and accessories.

Net revenue in markets outside North and Latin America increased for the year ended June 30, 2014 to \$715.8 million from \$662.8 million for the year ended June 30, 2013, an increase of \$53.0 million or 8%. Movements in international currencies against the U.S. dollar favorably impacted international revenues by approximately \$17.0 million during the year ended June 30, 2014. Excluding the impact of foreign currency movements, international sales for the year ended June 30, 2014 increased by 5%, compared to the year ended June 30, 2013. The increase in sales outside North and Latin America predominantly reflected an increase in unit sales of our flow generators, masks and accessories.

Net revenue from flow generators for the year ended June 30, 2014 totaled \$846.7 million from \$823.5 million for the year ended June 30, 2013, an increase of 3%, including an increase of 7% outside North and Latin America and a decrease of 2% in North and Latin America. Net revenue from masks and other accessories totaled \$708.3 million, an increase of 3%, including an increase of 10% outside North and Latin America and a 1% decrease in North and Latin America, for the year ended June 30, 2014, compared to the year ended June 30, 2013.

The following table summarizes the percentage movements in our net revenue for the year ended June 30, 2014 compared to the year ended June 30, 2013:

	<b>North and Latin America</b>	<b>International</b>	<b>Total</b>	<b>International (Constant Currency)*</b>	<b>Total (Constant Currency)*</b>
Flow generators	-2%	7%	3%	5%	1%
Masks and other accessories	-1%	10%	3%	7%	2%
Total	-1%	8%	3%	5%	2%

\* Constant currency numbers exclude the impact of movements in international currencies.

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**Gross Profit.** Gross profit increased for the year ended June 30, 2014 to \$989.8 million from \$940.7 million for the year ended June 30, 2013, an increase of \$49.1 million or 5%. Gross profit as a percentage of net revenue was 63.7% for the year ended June 30, 2014, compared with 62.1% for the year ended June 30, 2013. The improvement in gross margins was primarily due to cost savings attributable to manufacturing and supply chain improvements, favorable change in product mix as sales of our higher margin products represented a higher proportion of our sales, positive foreign

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currency impact due to the depreciation of the Australian dollar against the U.S. dollar and Euro, and a favorable geographic mix of sales, partially offset by declines in our average selling prices.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses increased for the year ended June 30, 2014 to \$450.4 million from \$430.8 million for the year ended June 30, 2013, an increase of \$19.6 million or 5%. The selling, general and administrative expenses were favorably impacted by the movement of international currencies against the U.S. dollar, which decreased our expenses by approximately \$4.6 million, as reported in U.S. dollars. Excluding the impact of foreign currency movements, selling, general and administrative expenses for the year ended June 30, 2014 increased by 6% compared to the year ended June 30, 2013. As a percentage of net revenue, selling, general and administrative expenses for the year ended June 30, 2014 was 29.0%, compared to 28.4% for the year ended June 30, 2013.

The increase in selling, general and administrative expenses was primarily due to an increase the number of sales and administrative personnel to support our growth and other expenses related to the increase in our sales including activities targeted at increasing the awareness and diagnosis of SDB, as well as an increase in our patent litigation expenses.

**Research and Development Expenses.** Research and development expenses decreased for the year ended June 30, 2014 to \$118.2 million from \$120.1 million for the year ended June 30, 2013, a decrease of \$1.9 million or 2%. The research and development expenses were favorably impacted by the depreciation of the Australian dollar against the U.S. dollar, which decreased our expenses by approximately \$9.0 million, as reported in U.S. dollars. Excluding the impact of foreign currency movements, research and development expenses for the year ended June 30, 2014 increased by 6% compared to the year ended June 30, 2013. As a percentage of net revenue, research and development expenses were 7.6% for the year ended June 30, 2014 compared to 7.9% for the year ended June 30, 2013.

The increase in research and development expenses in constant currency terms was primarily due to an increase in the number of research and development personnel, consulting and contractor expenses and an increase in materials and tooling costs incurred to facilitate development of new products.

**Amortization of Acquired Intangible Assets.** Amortization of acquired intangible assets for the year ended June 30, 2014 totaled \$9.7 million compared to \$10.1 million for the year ended June 30, 2013.

**Restructuring expenses.** During the year ended June 30, 2014 we completed a reorganization of our commercial and research and development teams. As a result of this reorganization we terminated the employment of approximately 1% of our employees at a total cost of \$6.3 million.

**Total other income, net.** Total other income, net for the year ended June 30, 2014 was \$26.0 million, a decrease of \$4.3 million compared with \$30.3 million for the year ended June 30, 2013. The decrease in total other income, net, was due primarily to lower interest income resulting from lower interest rates on cash balances held, and the depreciation of the Australian dollar against the U.S. dollar, partially offset by gains on foreign currency transactions.

**Income Taxes.** Our effective income tax rate was 19.9% for the year ended June 30, 2014 compared to 20.2% for the year ended June 30, 2013. Our effective income tax rate is affected by the geographic mix of our taxable income, including lower taxes associated with our Singapore and Malaysia manufacturing operations. Our Singapore and Malaysia operations operate under certain tax holidays and tax incentive

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programs which will expire in whole or in part at various dates through June 30, 2020. As of June 30, 2014, we had not provided for U.S. income taxes for the undistributed earnings of our foreign subsidiaries. We intend these earnings to be permanently reinvested outside the United States.

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**Net Income and Earnings per Share.** As a result of the factors above, our net income for the year ended June 30, 2014 was \$345.3 million compared to net income of \$307.1 million for the year ended June 30, 2013, an increase of 12% over the year ended June 30, 2013. As a result of the increase in our net income and lower share count due to our stock repurchases, our earnings per share for the year ended June 30, 2014 was \$2.39 per diluted share compared to \$2.10 per diluted share for the year ended June 30, 2013, an increase of 14% over the year ended June 30, 2013.

## **Liquidity and Capital Resources**

As of June 30, 2015 and June 30, 2014, we had cash and cash equivalents of \$717.2 million and \$905.7 million, respectively. Working capital was \$1.2 billion and \$1.3 billion, at June 30, 2015 and June 30, 2014, respectively.

As of June 30, 2015 and June 30, 2014, our cash and cash equivalent balances held within the United States amounted to \$32.0 million and \$29.0 million, respectively. Our remaining cash and cash equivalent balances at June 30, 2015 and June 30, 2014, of \$685.2 million and \$876.7 million, respectively, were held by our non-U.S. subsidiaries, indefinitely invested outside the United States. Our cash and cash equivalent balances are held at highly rated financial institutions.

As of June 30, 2015, the cumulative amount of undistributed earnings from our foreign subsidiaries was approximately \$1.4 billion, and those undistributed earnings are considered permanently reinvested. We intend to reinvest the cash and cash equivalents of those entities whose undistributed earnings are permanently reinvested in our international operations. We reassess our reinvestment assertions each reporting period and currently believe that we have sufficient sources of liquidity to support our assertion that the undistributed earnings held by foreign subsidiaries may be considered to be reinvested permanently. If these earnings had not been permanently reinvested, deferred taxes of approximately \$364 million would have been recognized in our consolidated financial statements.

We repatriated \$130 million and \$191 million to the U.S. in fiscal years 2015 and 2014, respectively, from earnings generated in each of those years. The amount of the current year foreign earnings that we have repatriated to the U.S. in the past has been determined, and the amount that we expect to repatriate during fiscal year 2016 will be determined, based on a variety of factors, including current year earnings of our foreign subsidiaries, foreign investment needs and the cash flow needs we have in the U.S., such as for the repayment of debt, dividend distributions, and other domestic obligations. The majority of our repatriation of foreign subsidiaries' earnings to the U.S. has historically occurred at year-end, although we may repatriate funds earlier in the year based on our business needs. When we repatriate funds to the U.S., we are required to pay taxes in the U.S. on these amounts based on applicable U.S. tax rates, net of any foreign tax that would be allowed to be deducted or taken as a credit against U.S. income tax. We paid \$17.1 million and \$10.7 million in additional U.S. federal income taxes in fiscal years 2015 and 2014, respectively, as a result of repatriation of foreign earnings generated in those years.

Inventories at June 30, 2015 increased by \$81.4 million or 49% to \$246.9 million compared to June 30, 2014 inventories of \$165.4 million. The increase in inventories was due mainly to new product introductions and an increase in inventories held to support the increase in unit sales.

Accounts receivable, net of allowance for doubtful accounts, at June 30, 2015 were \$362.6 million, an increase of \$3.0 million or 1% over the June 30, 2014 accounts receivable balance of \$359.6 million. Accounts receivable days sales outstanding of 69 days at June 30, 2015 decreased by 7 days compared to 76 days at June 30, 2014. Our allowance for doubtful accounts as a percentage of total accounts receivable at June 30, 2015 and 2014 was 3.3% and 3.0%, respectively. The credit quality of our customers remains broadly consistent with our past experience.





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During the year ended June 30, 2015, we generated cash of \$383.2 million from operations. This was slightly lower than the cash generated from operations for the year ended June 30, 2014 of \$391.3 million, which was primarily the result of the increase in our inventory balance. Movements in foreign currency exchange rates during the year ended June 30, 2015 had the effect of decreasing our cash and cash equivalents by \$172.8 million, as reported in U.S. dollars. During fiscal years 2015 and 2014, we repurchased 2.7 million and 4.4 million shares at a cost of \$152.6 million and \$208.1 million, respectively. During fiscal years 2015 and 2014, we also paid dividends totaling \$157.3 million and \$141.5 million, respectively.

Details of contractual obligations at June 30, 2015 are as follows:

In \$000 s	Total	Payments Due by Fiscal Year					Thereafter
		2016	2017	2018	2019	2020	
Long Term Debt	\$ 300,594	\$ -	\$ -	\$ -	\$ 300,000	\$ -	\$ 594
Interest on Long Term Debt	14,066	4,199	4,199	4,199	1,419	29	21
Operating Leases	59,737	16,915	12,910	8,453	5,349	3,817	12,293
Purchase Obligations	134,140	133,984	156	-	-	-	-
Total	\$ 508,537	\$ 155,098	\$ 17,265	\$ 12,652	\$ 306,768	\$ 3,846	\$ 12,908

Details of other commercial commitments at June 30, 2015 are as follows:

In \$000 s	Total	Amount of Commitment Expiration Per Fiscal Year					Thereafter
		2016	2017	2018	2019	2020	
Standby Letter of Credit	\$ 7,713	\$ -	\$ -	\$ 6,942	\$ -	\$ -	\$ 771
Guarantees*	\$ 9,122	\$ 179	\$ 127	\$ -	\$ 2	\$ 68	\$ 8,746
Total	\$ 16,835	\$ 179	\$ 127	\$ 6,942	\$ 2	\$ 68	\$ 9,517