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Foreword

As is detailed later in this document, in 1981 Colin Sullivan and his colleagues introduced their invention of continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea. In my opinion, the only possible rival for a single product that would produce such an upturn in life expectation and quality of life for humanity was the introduction of penicillin. Although sleep specialists were aware that obstructive sleep apnea was a very serious illness and surprisingly commonplace, it would be more than a decade after the introduction of CPAP before the true and stunningly high prevalence would be documented by Terry Young and her colleagues. Rarely in the history of medicine has an effective treatment for an illness been developed before the true magnitude of the problem was scientifically established.

The next big challenge after 1981 was to convert the Colin Sullivan vacuum cleaner device into a practical, effective, and dependable treatment for the literally millions of apnea victims around the world. Referring again to the penicillin analogy, victims on the verge of dying from pneumonia or wound infections could be miraculously restored to health by the antibiotic if it could be made very widely available. To see individuals who are failing in every aspect of their lives including their cardiovascular function and their daytime alertness restored to high energy and good health is a joy and a miracle.

The next huge challenge facing sleep professionals as well as victims of obstructive sleep apnea is the lack of effective public awareness about the problem. It remains an ongoing process to identify all the victims of sleep disordered breathing and make them aware that there is an effective treatment which will restore their lives and health. ResMed is completely committed to enhancing public awareness.

In conclusion, we must congratulate this pioneering company for its many successes, and we strongly encourage its continuing effort to improve therapeutic approaches and to support vastly expanding public awareness.

William C Dement MD PhD
Stanford University

Preface

ResMed has been conspicuous on the world business scene since it listed on the NASDAQ stock exchange in June 1995, raising US\$24 million. By 2007, market capitalisation exceeded US\$3 billion. Internationally, ResMed markets its products in over 80 countries. In each, it is leader in both market share and in technical excellence. For more than a decade, business assessors in the USA have recognised distinguished achievements. In Australia, its country of origin, ResMed has received accolades for design of its products and it has won awards for export sales. Its Founder has won awards from the community in Australia, and from his peers, in Australia and the USA, for leadership and professional expertise.

ResMed's business is based on devices for diagnosis and treatment of sleep disordered breathing (SDB) and its most extreme manifestation - obstructive sleep apnea (OSA)*. The characteristic feature of OSA is the repeated sequence of increasingly heavy snoring, followed by cessation of breathing, with gasping arousal, and return to sleep. Consequences are insidious, increasing in severity as the disease advances. Consequences arise from mechanical damage to tissues from snoring and psychological disturbances from sleep disruption. Other mechanical effects are produced by highly variable pressure in the thorax that disrupts the heart's control of blood volume to cause nocturia. Pressure variations in the thorax also cause reflux of stomach contents into the esophagus. Frequent intermittent starving of the organs of oxygen combines with stress to cause a range of lethal cardiovascular diseases and metabolic disturbances connected to diabetes.

OSA is a disease of global significance. It is highly prevalent in every society where it has been studied. Symptoms of the disease are so conspicuous that they have been the source of comment for at least 2,000 years, yet it was only in the 1960s that physiologists recognised OSA as a distinct disease entity. Following recognition of OSA, studies of pathophysiology and the extent of its consequences were inhibited by the

absence of an acceptable and successful method of treatment. With no available treatment it was difficult to establish cause and effect between symptoms and consequences.

When a scientist from the University of Sydney announced a treatment, the news was met with incredulity by the medical establishment. The equipment used for the demonstration was improvised and primitive. Theory behind the method had either not been considered by others or had been rejected without experimental testing. It took the genius of a medical scientist who was prepared to experiment and test what others had ignored or argued against, before success of this unlikely treatment was demonstrated.

Invention is only the first stage in the tortuous process of innovation. One successful demonstration is a long way from a marketable product that can be manufactured on an industrial scale. In this example, a great deal of R&D was needed to convert an improvised apparatus into an industrial product. It took determination, persistence, and the proselytising enthusiasm of an evangelist to convince financiers to invest in a R&D project of unproven utility. The requirement then was for engineers, designers, and medical researchers to create a technology that would be cost-effective and patient-acceptable. Finally, the medical profession had to be convinced and then educated, manufacturing plants built, and a global marketing infrastructure established. This gargantuan task was taken on the shoulders of one academic/engineer/industrialist.

The story told here is an acknowledgement of the resounding success of the formation and operation of the ResMed group of companies in filling every need. ResMed stands out conspicuously and favourably as a paragon against the bursting dotcom bubble. That financial disaster arose from innumerable failed attempts by others directed toward a similar goal of industrial success from academic origins. The continuing commercial success of ResMed over a

*Numbers in parenthesis in the text indicate references, identified in the Appendix. Endnotes are indicated by superscript Roman numerals.

period of almost two decades has attracted attention of scholars of business management from the level of the local high school, through government bureaucracy, to the hallowed halls of Harvard (54).

The contrary conventional wisdom of established and conservative professions combined with their innate inertia to create a variety of obstacles to the formation and eventual success of ResMed. This innovation relied heavily on the two key individuals who met and overcame all the challenges of defining an invention and taking innovation through to the global marketplace. Together they led the world into a new era of therapy with products that were commercially viable, and therapeutically effective against one of the major afflictions of humankind. Both had backgrounds that uniquely prepared them for the roles they had to play. How this came about is the main theme of this narrative. The period covered is from antiquity to 2 June 1995, when the company listed on the NASDAQ stock exchange.

The continuing success of ResMed means that this narrative considers only the first episode of a serial story that has no end in sight. This episode is concerned with the struggle to found a global organization. The next episode of growth and consolidation is left for others to cover, for the theme and challenges changed subsequent to the listing. The success of the listing was recognition that ResMed had become a mature operation, taking its place alongside other western industrial companies.

Such success would not have come without the inspired efforts of a small group of dedicated engineers and support staff. Starting as a handful, numbers increased until the organisation chart comfortably filled one page, as shown in the Appendix for 22 July 1994. In this text it is not practical to detail the contribution of each individual. It is a tribute to inspired leadership that staff relationships were harmonious, with significant achievements being made weekly. Over a score of those in Australia who brought the Company to listing are still with ResMed

in 2007, when global staff numbers exceed 3000.

Of those who have left, special gratitude must be expressed to Chris Lynch. He played a critical role in the very early days, and was forced to leave only when struck down by multiple sclerosis. Ken Hely was instrumental in development of successful early masks. He also left for medical reasons. Each made greatly appreciated contributions.

On a happier note, ResMed has operated as a training ground for people seeking career advancement beyond what could be offered in-house. Congratulations to Dr Chris Roberts. With a scientific education, he gained marketing experience in another technology company before joining ResMed. No doubt the management experience he gained will serve him well in his new role as Chief Executive Officer of Cochlear - another Australian medical device success story.

A debt too is owed to Bill Nicklin, who brought the production of product substantially under one roof from a scattering of contractors. He too has moved to a senior management role in another technology start-up company. Wal Flicker worked long and hard as Company Secretary and Director and manager and operator of anything and everything to do with finance and spending and organising this and that. Shirley Sproats joined and remained until December 2005 as a most dedicated accountant, bookkeeper, personnel manager, and odd job person when the term multitasking was invented for ResCare staff activities.

The Company would not have succeeded without the dedicated efforts of these and many others.

Sherill Burden, Colin Sullivan, William Dement, and, Christian Guillemineault are thanked for photographs. Lisa and Lance Hopper and Lucy Bode prepared the design and layout for printer, John Mockridge.

Charles S Barnes PhD FTSE 26 May 2007

OSA in Antiquity to the 20th Century

"You can't cross a chasm in two small leaps"

David Lloyd George, Former British Prime Minister

The symptom of heavy snoring is so obvious that historians had noted extreme examples in documents going back to antiquityⁱ. Notable were members of the Ptolemy dynasty that ruled Egypt for 300 years until Julius Caesar took control of Egypt (and Cleopatra) in 30 BC. Many of the Ptolemys had symptoms that are associated with OSA. Family members were recorded as being hugely obese, with indications of a genetic propensityⁱⁱ to obesity (4). There are many other records of apparent OSA symptoms, such as heavy snoring and obesity, in prominent historical figures. These include Emperor Napoleon Bonaparte (5), Queen Victoria, US President Taft (6, with BMI >40), both Presidents Roosevelt, and Johannes Brahms, composer of a lullaby for infants (7). We can only speculate how the disease affected their reasoning, and what effect treatment would have had on history.

By the early 1800s, medical professionals were taking an interest in the interrelationships between obesity, sleep, and breathing. In those days, diagnosis had to rely on what the physician could see, hear, and feel. In 1816, William Wadd (8), Surgeon Extraordinary to King George III, wrote a critical review of current knowledge in a monograph: *Cursory Remarks on Corpulence; or Obesity Considered as a Disease: With a Critical Examination of Ancient and Modern Opinions Relative to its Causes and Cure*. In it he noted that in the obese, "respiration is performed imperfectly, or with difficulty", and that obese people "could fall asleep at any time".

The most influential description in the 1800s was not from a physician, but from the novelist Charles Dickens. In 1836-7, when he was a young man in his 20s,

Dickens published a novel in serial form with the title *The Posthumous Papers of the Pickwick Club*. This made him famous as a novelist. The book can still be read on the Internet. In his novel, a conspicuous character called Joe was an excessively sleepy, red-faced, loud snoring, cognitively dysfunctional, "wonderfully fat" boy with peripheral edema. Joe's symptoms are reminiscent of OSA. Mr Pickwick himself was obese, and after imbibing too much would drop off to sleep, snoring, with choking sounds. Dickens' impact on the medical profession was substantial. Sir William Osler^{iv}, a Canadian who became Professor of Medicine at Oxford, was one of the most influential persons in medicine around the late 19th and early 20th centuries. Osler adopted the term Pickwickian Syndrome before the condition could be adequately diagnosed.

Scottish physician John Cheyne in 1818 and Irish physician William Stokes in 1854 described abnormal periodic breathing with central apneas, now associated with their names. The London physician, WH Broadbent (9), in 1877, gave the first detailed description by a medical professional of the clinical symptoms of obstructive sleep apnea. He described loud snoring, attributed to resistance in the pharynx, silence through two or three respiratory periods, during which there were ineffectual chest movements, and finally respiration resuming with a loud snort. He recognised the repetition of this cycle "at regular intervals, and the pause was so long as to excite attention, and indeed alarm."

Other physicians made similar observations, associating obesity with excessive sleepiness, apneas due to glottic closure, and snorting arousals. There was still confusion between sleepiness due to apnea and other sources, for example narcolepsy, which had been identified in 1880. The symptoms of narcolepsy include an uncontrollable need for sleep, even when night-time sleep was adequate. The cause of narcolepsy is still not understood, nor is there a cure^v.

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