RESMED INC
Form 8-K
May 13, 2015

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Under Section 13 or 15(d) of

the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):

May 13, 2015

ResMed Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-15317**	**98-0152841**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

9001 Spectrum Center Blvd.

San Diego, California 92123

(Address of Principal Executive Offices)

(858) 836-5000

(Registrant s telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On May 13, 2015 we issued the press release attached as Exhibit 99.1. It is incorporated into this report by reference. The press release provides an update on the SERVE-HF clinical trial, which studied adaptive servo-ventilation (ASV) therapy in patients with symptomatic chronic heart failure and predominant central sleep apnea.

The study did not show a statistically significant difference, between patients treated with ASV therapy and those in the control group, in the primary endpoint of time to all-cause mortality or unplanned hospitalization for worsening heart failure.

A preliminary analysis of the data identified a statistically significant 2.5 percent absolute increased risk of cardiovascular mortality for those patients in the trial who received ASV therapy per year compared to those in the control group. Based on the data, we are working with global regulatory authorities to proactively revise the labels and instructions for use for ResMed ASV devices to include a contraindication for people with symptomatic chronic heart failure with reduced left ventricular ejection fraction (LVEF≤45%).

Revenue from our ASV flow generators, during the twelve-month period ended March 31, 2015, represented less than 7% of our total revenue. We estimate that approximately 25% of those ASV flow generators were prescribed for patients with symptomatic chronic heart failure with reduced left ventricular ejection fraction.

ASV devices represent less than 2% of flow generator devices that we have shipped to customers. So we estimate that approximately 98% of our flow generator field population will not include this contraindication.

We expect to incur costs associated with the field safety notification during our fourth quarter of fiscal year 2015. We expect to provide more detail when we release our earnings for the fourth quarter of fiscal year 2015.

Statements contained in this 8-K and the attached press release that are not historical facts are forward-looking statements as contemplated by the Private Securities Litigation Reform Act of 1995. These forward-looking statements including statements regarding subsequent analyses of existing data and new data received from past, ongoing and future studies, the nature and scope of the impact that study results may have on the current or future markets for ResMed ASV devices, and the nature and timing of regulatory and other legal action are subject to risks and uncertainties, which could cause actual results to materially differ from those projected or implied in the forward-looking statements. Additional risks and uncertainties are discussed in ResMed s periodic reports on file with the U.S. Securities & Exchange Commission. ResMed does not undertake to update its forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibits:	Description of Document
99.1	Press Release dated May 13, 2015 regarding update on Phase III SERVE-HF study

SIGNATURES

We have authorized the person whose signature appears below to sign this report on our behalf, in accordance with the Securities Exchange Act of 1934.

Date: May 13, 2015

RESMED INC.
(registrant)

By: /s/ Brett Sandercock
Name: Brett Sandercock
Its: Chief Financial Officer

EXHIBIT INDEX

Exhibits:	Description of Document
99.1	Press Release dated May 13, 2015 regarding update on Phase III SERVE-HF study