ResMed recalling sleep apnea air generators

by Terri Somers

SAN DIEGO - ResMed said Monday that it is recalling 300,000 air generators that people use to treat sleep apnea because there is a "remote potential for a short circuit in the power supply connector."

Although the problem has been reported in only seven of the company's S8 flow generators, chief executive Peter Farrell said Poway-based ResMed decided to voluntarily recall all the devices manufactured between July 2004 and May 15, 2006, and replace them with new ones.

The company said it estimates the recall will cost $59.7 million, which it treated as a charge in its fiscal third quarter, which ended March 31. The company Monday reported a loss for that quarter of $15.4 million, or 20 cents a share, compared with net income of $26.4 million a year earlier.

ResMed shares fell $6.69, or 14 percent, to hit $41.95 in after-hours trading Monday.

"The irony is that overall the reliability of this product line is better than (the earlier generation) S7 line, and that was relatively excellent," Farrell said.

The generators pump out an adjustable stream of air that goes through a mask the sleep apnea patient wears. The airflow keeps the user's airway from closing.

Recently the company learned that in the past two years, seven of its generators had a problem with the power connection that resulted in some kind of thermal damage to the unit, he said.

The problem stems from a part that is manufactured by a third-party supplier, with whom ResMed has done business for several years and bought more than 4 million power supplies from, he said.

This is the first time there has been a problem with that company's parts, Farrell said. There have been no reports of significant damage to other property as a result, he said.

The company's internal experts and external consultants investigated the cause, and their conclusion was that there was a remote possibility of an adverse event, Farrell said.

Looking at the results of their investigation and the data regarding problems with the unit, there was a statistical possibility that the rate of problems could accelerate over time, he said.

"Three, four or five years down the pike we didn't want to be left with an embarrassment and dissatisfied customers and patients," he said. "We had faced nothing like this before, but we decided to bite the bullet ... we decided the right thing to do was a complete product recall."

Patients can continue to use their S8 flow generators until they receive a replacement device. But people should discontinue use of the device if there is any sign of an electrical problem, such as intermittent power, cracking sounds, sparking or a charred smell. And patients also should not use supplemental oxygen with an affected device.

ResMed has advised the Food and Drug Administration and other regulatory authorities of the recall.

The company has about 100,000 new devices on hand, and it does not expect a problem rolling out the replacement generators and filling new orders, Farrell said.

This is ResMed's first global recall and the second in its history. Previously the company recalled about 1,400 air generators because of a software glitch. Not all of those had been distributed.

The company had not reported a loss since the third quarter of fiscal 2001, when a $10.2 million loss was driven by a write-down association with the acquisition of a German company.

For this year's third quarter, the company said revenue grew 13 percent to $183.0 million.

ResMed recalling sleep apnea air generators by Terri Somers