

Industry Spotlight

Higher Revenues in First Quarter 2015

The two largest dialysis firms in the US reported higher revenues recently. Fresenius had a first quarter revenue of \$3.96 billion, which was an increase of 11 percent, but its dialysis product revenue of \$778 million remained unchanged compared with the first quarter of 2014, the company reported. Zacks' online investment research experts had predicted total revenue of \$3.92 billion, or about \$40 million less for the enterprise. Fresenius reported that "organic growth" through good performances from all of its regions worldwide was positive during the quarter, outpacing analysts' expectations.

Fresenius saw North America "net dialysis care revenue" increase by 4 percent to \$2.14 billion. Dialysis product revenue increased by 4 percent to \$200 million compared with the first quarter of 2014. Fresenius North America overall revenues rose 16% year over year to \$2.77 billion.

The company reaffirmed its guidance for 2015: it expects revenues to grow at 5 percent to 7 percent. Zacks reported that a strong performance in North America and particularly in the Asia Pacific, "coupled with an encouraging pharma business in North America is expected to help the company, going forward." However, declining margins remain a potential problem, Zacks said.

With business in more than 50 countries around the world, Fresenius has approximately 60,000 em-

ployees in North America, according to its US web site. Fresenius "will lie in wait for an overheated healthcare deal market to cool down" before making additional larger acquisitions, CEO Ulf Schneider said.

DaVita Kidney Care, based in Denver, announced on May 4, 2015, net revenue of \$3.3 billion for the first quarter of 2015, an increase of 10 percent compared with \$3 billion the same three months in 2014.

While revenues were higher, net income was not. DaVita HealthCare Partners' first-quarter income performance was a net loss of \$111 million compared with a year ago, when the kidney care and medical group operator posted net income of \$183.3 million.

As of March 31, 2015, the company had provided dialysis services to approximately 181,000 patients at 2290 outpatient dialysis centers, of which 2197 centers are located in the United States; 93 centers are located in 10 countries outside of the United States. During the first quarter of 2015, DaVita opened a total of 18 new dialysis centers, acquired one dialysis center, and closed two dialysis centers in the United States. The company also



opened two new dialysis centers outside of the United States.

DaVita's first quarter results included a tentative \$495 million settlement for a civil suit brought by private attorneys in 2009, Modern Healthcare reported. The suit alleged DaVita wasted medication and billed Medicare for it. DaVita has invested heavily in compliance programs to avoid any potential problems. ●

Nephrogenex Raising Research Funds

NephroGenex, a drug development firm based in Raleigh, NC, plans to raise \$34.5 million in a secondary public offering, according to the Triangle Business Journal. The goal is to increase the number of clinical trial sites to test the company's drug Pyridorin, a treatment for diabetic nephropathy, commonly stemming from acute kidney injury (AKI) and diabetes.

In its first quarter results, Nephrogenex announced that it aims to expand its Phase 3 clinical trial of Pyridorin to 150 sites worldwide and to file for an Investigational New Drug (IND) Application through the US Food and Drug Administration (FDA). Last February, the company raised \$33 million in an initial public offering.

In late December 2014, NephroGenex, announced it had "successfully completed a thorough QT/QTc

(TQT) cardiac safety study on Pyridorin." This study assessed a drug's risk of QT prolongation and its proarrhythmic potential, and is a standard component of all clinical development programs for new molecular entities. Pyridorin showed no effect on the QT/QTc interval at the expected therapeutic dose of 300 mg and at a quadrupled dose of 1200 mg.

"These are important study results that support the use of Pyridorin in patients with diabetic nephropathy, many of whom suffer from cardiovascular disease," said Chief Executive Officer Pierre Legault. "They are also important given the concerns over cardiac safety seen with other therapies in development for this disease."

In March 2015, the company presented a poster session on preclinical findings in an ischemia-reperfusion model in mice that were administered doses of

Pyridorin before surgically induced AKI. Pyridorin treatment significantly reduced the level of kidney injury, enhanced renal function recovery, and reduced post-injury fibrosis, the company reported. Treatment with a higher dose of Pyridorin was shown to be even more beneficial in the animals.

"We're in discussion with the US FDA regarding design of a clinical program in acute kidney injury and anticipate initiating an AKI Phase 1 study during second half of 2015," Legault said.

In 2014, NephroGenex spent \$11.3 million in research and development and \$5.3 million on general administrative costs. Cash, cash equivalents, and short-term investments were approximately \$28.7 million as of Dec. 31, 2014, compared with approximately \$2.1 million as of Dec. 31, 2013. ●

Greens for CKD

Welcome to the expanding market for factory-produced low-potassium lettuce aimed at people with chronic kidney disease (CKD).

The new lettuce produced by Fujitsu has been selling for about \$4.90 (500 yen) for a 90 gram bag, just over 3 ounces in some locations in Japan. The lettuce has only about 20 percent of the potassium found in typical lettuce, manufacturers say, which makes it a good substitute for people craving salad and who have to closely watch potassium intake. Because the lettuce leaves are grown in the repurposed clean rooms of electronics manufacturers, no pesticides are necessary. So far, the products are available in Asia.

In 2013, Japanese electronics manufacturer Fujitsu converted an old semiconductor plant into the 2000 m² Akisai Plant Factory in Japan. For the vegetable facility, Fujitsu has combined its own and Microsoft's products.

"Fujitsu brought together its Eco-Management Dashboard, the IoT/M2M platform, Microsoft cloud services, and Windows tablets in a way that could enable managers, engineers, and scientists to improve product quality, streamline systems, and enhance functionality while reducing costs," Microsoft reported recently.

SG Greenhouse has constructed a facility that can produce 3500 bunches of low-potassium lettuce per day. The facility is on the Saibu Gas facility grounds in Ki-

takyushu, Japan.

Horiba, another Japanese company that conventionally trades in automotive test systems, semiconductors, and other devices, is also contributing to the production of low-potassium and low-sodium lettuce. Yoshio Miyashita, CEO of Oizumi Yasaikobo Co., Ltd., has opened a lettuce factory in Oizumi-machi, Oura-gun, Gunma Prefecture, to produce and sell lettuce free of insect damage and agricultural chemicals in a completely enclosed factory environment. Oizumi uses the LAQUAtwin compact water quality analyzer from Horiba to manage water quality and nutrient solutions for the new, factory-produced lettuce. ●