Industry Spotlight

Amgen Fourth Quarter Profits Drop, Revenue Up for 2012

Amgen finished 2012 with lower fourth-quarter profits—reporting a net income of $788 million—despite an 11 percent increase in revenue for the quarter to $4.42 billion. Increased spending on research and development and other administrative costs led to the 16 percent decline for the quarter compared to 2011.

For 2012, revenues at the biotechnology company also rose 11 percent for the year, totaling $17.3 billion. This performance also reflects the costs of Amgen's acquisition of deCODE Genetics—a biotechnology company based in Iceland that focuses on identifying genetic risk factors for disease development—which was finalized in December of last year.

Amgen's anemia drugs contributed to the weak fourth-quarter performance, with Aranesp (darbepoetin alfa) and Epogen (epoetin alfa) sales falling by 9 percent and 1 percent, respectively. For 2012, Aranesp and Epogen sales declined 11 percent and 5 percent, respectively, driven by changing practice patterns and reduced dosing. Introduction of new drugs to treat anemia in patients receiving dialysis could lead to a more competitive environment for this therapeutic area, and possibly pose additional challenges to sales.

Demand for other medications in Amgen's nephrology portfolio remained strong. Sales of Sensipar (cinacalcet), a treatment for secondary hyperparathyroidism, were up 19 percent in the fourth quarter of 2012 and 18 percent for the year.

Looking ahead to 2013, Amgen's chairman and CEO Robert A. Bradway announced several new phase III trials, including one for AMG 145 for individuals with high LDL cholesterol levels. "We enter 2013 with good momentum, a broad late-stage pipeline, and a continued focus on building our business internationally," he said. However, the company announced plans in January to lay off 160 employees, or 1 percent of its workforce.

New Hyperphosphatemia Treatment Meets Phase III End Points

Keryx Biopharmaceuticals recently announced that the phase III clinical trial of its drug Zerenex (ferric citrate) successfully met its predetermined end points. Conducted under a Special Protocol Agreement, the study assessed the oral ferric iron–based compound for the treatment of hyperphosphatemia in patients with ESRD who are receiving dialysis.

The multicenter, randomized, open-label trial involved 441 patients with ESRD who were undergoing either hemodialysis or peritoneal dialysis. The study was conducted in two stages, a 52-week safety assessment phase and a 4-week efficacy assessment phase, preceded by a 2-week washout interval.

Zerenex met the primary end point of significantly reducing serum phosphorus levels compared to placebo in the efficacy assessment phase. The drug also met all secondary end points during the 52-week safety assessment, including maintenance of serum phosphorus in the normal range (with a noninferiority comparison with Renvela [sevelamer carbonate]), increasing ferritin and transferrin saturation levels, and reducing intravenous iron and erythropoiesis-stimulating agent use compared with the active control.

Based in New York City, Keryx also reported plans to file a New Drug Application for Zerenex with the Food and Drug Administration (FDA) and a Marketing Authorization Application with the European Medicines Agency in the second quarter of 2013.

The results of this trial follow the January 2013 announcement that Zerenex was submitted for approval in Japan by Japanese Tobacco, the company that sublicenses the drug from Keryx.

Current therapies for the treatment of hyperphosphatemia include Renvela and Renagel (sevelamer hydrochloride), both of which are manufactured by Sanofi.

Keryx has also initiated phase II development of Zerenex for the management of phosphorus and iron deficiency in patients with stage III–V CKD who are not receiving dialysis.

Canadian Biotech Merger Puts Focus on Nephrology Drugs

Two Canadian biotechnology firms—the publicly traded Isotechnika Pharma and privately held Aurinia Pharmaceuticals—will combine forces to concentrate on the nephrology therapeutic market. The companies will join together under the Aurinia banner to focus on developing the calcineurin inhibitor voclosporin, an immunosuppressant, for approval.

Although the merger is based in Canada, the deal has international overtones. If approved, the South Korean ILJIN Life Science—which owns the rights to voclosporin—will take a 25 percent ownership stake in the new Aurinia.

Vifor Pharma, the Swiss pharmaceutical company held by the Galenica Group, is also involved. In 2012 it signed a development and commercialization agreement with Isotechnika to market voclosporin for treatment of lupus and all proteinuric nephrology indications in the United States and other countries outside of Canada.

Aurinia itself was spun out from Vifor as a separate entity after the Swiss firm acquired Aspreva in 2008, a company that specialized in immunosuppressive therapies, investigated lupus nephritis treatments, and conducted the Aspreva Lupus Management Study (ALMS).

Previously, voclosporin has been studied in the treatment of chronic noninfectious uveitis. However, the drug was withdrawn from approval for this indication in Europe because of a failure to demonstrate that its benefits outweighed its risks.

Isotechnika recently completed a phase IIb study of voclosporin for use in solid organ transplantation that demonstrated equivalence to tacrolimus in prevention of acute rejection.

"While there have been a number of advances in the treatment of lupus nephritis, there is no question that significant unmet medical need remains," said Neil Solomons, MD, the new company's chief medical officer. "To that end, we expect to launch this phase IIB study of voclosporin in lupus nephritis in 2013," he added.

Based in Edmonton, Alberta, Canada, Isotechnika anticipates completion of the deal by the end of the first quarter of 2013, pending shareholder and regulatory approval.

New Iron Therapy Successful in Reducing ESA Dosing

A novel iron supplement therapy under development at Rockwell Medical significantly reduced erythropoietin-stimulating agent (ESA) dosing by 37 percent over the course of a recent 9-month study. A randomized placebo-controlled phase II clinical trial demonstrated that the drug—soluble ferric pyrophosphate (SFP)—met the primary end point of lowering ESA use in patients with end stage renal disease (ESRD) receiving hemodialysis.

Unlike other iron supplement therapies, which are given intravenously, SFP is mixed into dialysate and administered during dialysis. SFP's unique mechanism simulates the body's delivery of dietary iron, which could contribute to its efficacy. Upon entering the bloodstream, the drug quickly binds to apotransferrin and travels to bone marrow.

The phase II PRIME trial involved 108 patients with ESRD receiving hemodialysis randomized to receive dialysate either with or without SFP. Hemoglobin levels in both the SFP and placebo groups were similar at the beginning and end of the trial. However, the ESA dosing needed to maintain hemoglobin levels was significantly lower in the SFP group. In addition, SFP maintained iron balance without increasing iron stores in other organs and had a safety profile similar to placebo.

"We believe that SFP's unique ability to treat iron deficiency while dramatically reducing the need for ESA, without increasing iron stores, strengthens SFP's potential to become the market leading iron therapy treatment for CKD-HD patients," said Rockwell Medical President and CEO Robert Chioini. "SFP's ability to substantially reduce ESA use in the treatment of anemia should translate into significant cost savings in dialysis care while potentially lowering the serious risks associated with the dosing of ESAs."

Based in Michigan, Rockwell Medical is currently conducting a phase III trial of SFP for use in the treatment of anemia in patients with ESRD who are receiving hemodialysis. At the trial's conclusion, the company anticipates filing a new drug application with the U.S. Food and Drug Administration by the end of 2013.

Abbott Laboratories Spins Off AbbVie, Reports Dip in Fourth-Quarter Profits

Abbott Laboratories announced a 35 percent decrease in profits in the fourth quarter of 2012. Despite an increase in sales of more than 4 percent, net earnings for the quarter were $1.05 billion, down from $1.62 billion in 2011.

Early repayment of debt and costs associated with spinning off Abbott's biopharmaceutical business into a new company called AbbVie contributed to the drop at the end of the last quarter. Finalized at the beginning of 2013, the new multinational will concentrate solely on the development of pharmaceuticals to treat complex diseases that affect broad patient populations.

The *Wall Street Journal's* Market Watch recently reported that Abbott's move to spin off AbbVie was "a bid for a higher market valuation for Abbott Labs' diversified businesses, which are poised for stronger earnings growth in coming years than AbbVie."

Abbott will maintain its stable of diagnostic and endovascular devices, as well as diabetes, vision, and nutritional products.

AbbVie's focus is on drug development in therapeutic areas such as hepatitis C, rheumatoid arthritis, and multiple sclerosis. The new pharmaceutical firm also inherited several products from Abbott's nephrology portfolio, including Calcijex (calcitriol injection) and Zemplar (paricalcitol).

"In 2012, we achieved a significant milestone in Abbott's 125-year history with the creation of AbbVie while delivering another year of strong results," Abbott's chairman and CEO Miles White said. "Abbott's mix of diversified health care businesses and pipeline is favorably aligned with key health care and emerging market trends and well positioned to deliver top-tier growth in 2013."