Pfizer Nets Slice of Biologics Pie with Wyeth Acquisition

The Pfizer-Wyeth union began as a rumor in The Wall Street Journal, which suggested New York-based Pfizer might buy its rival Wyeth, based in Madison, New Jersey, for >$60 billion. This would represent the most expensive merger in the United States since the $67 billion merger in 2006 between AT&T and BellSouth. The article said Pfizer and Wyeth had been in talks for months, but cautioned a deal was nowhere near completion and the chaotic state of the world economy could thwart a merger at any time. Just the prospect of such a major merger constituted major news.

Facing the loss in November 2011 of patent protection for Lipitor (atorvastatin), which accounts for at least a quarter of Pfizer’s revenue, and the failure of its hoped-for successor torcetrapib, Pfizer essentially bowed out of the cardiology sector last fall. At that time, the company announced that it would narrow research efforts primarily to oncology.

Exacerbating matters, investors became disgruntled when Pfizer’s share price declined to barely one-third of its July 2000 peak of $48. Pfizer recently reported a 90% plunge in quarterly net profit and a slight drop in fourth-quarter revenue. Pfizer made modest changes in an attempt to adapt to the harsh economic atmosphere. For example, it made staffing cuts, closed a few plants, and trimmed its research portfolio. In January 2009, the company announced it was cutting another 8000 jobs.

Despite such efforts, investors and analysts continued to push Pfizer to make a bold move. In a press conference announcing the pending $68 billion merger with Wyeth, Jeffrey B. Kindler, chairman and CEO of Pfizer, seemed to acknowledge the need to pull out all the stops, saying, “We’re going to do everything we can to improve on our revenues and maximize our performance.”

The cash-and-stock deal values Wyeth shares at $50.19 each, a nearly 15% premium over the closing price of Wyeth stock the day before the deal was announced. For each Wyeth share, Pfizer has agreed to pay $33 in cash and a 0.985 share in Pfizer stock. Pfizer said the deal would be financed through a combination of cash, debt, and stock. The company is borrowing $22.5 billion from a consortium of banks; some controversy has arisen because most of the banks have received TARP funds from the government. The board of directors also decided to halve Pfizer’s quarterly dividend, to 16 cents a share.

Why Wyeth?
Wyeth’s footprint in the healthcare arena is huge, and a merger would transform Pfizer from a top-tier pharmaceutical player into a healthcare behemoth with a diversified portfolio. Wyeth derives considerable revenue from biotech drugs like the arthritis/psoriasis drug Enbrel (etanercept), vaccines (including Prevnar, a pneumococcal vaccine), and a gamut of over the counter products, including Advil, Chapstick, Centrum vitamins, Dristan, Preparation H, and Robitussin.

Bernard J. Poussot, CEO of Wyeth, speculated that his decision to steer Wyeth away from small-molecule drugs—which always face stiff competition after patent expiration—toward molecular biologics may account for Pfizer’s interest. “We became very attractive to a company like Pfizer,” he told the New York Times, “because you cannot be the No. 1 pharmaceutical company in the world and have not yet started in biotech.”
Making the Giant Manageable

Kindler noted that the Wyeth acquisition would increase Pfizer by nearly 50%, and he plans to establish independent divisions to help manage the various areas of business. Kindler said some of the specialty units Pfizer will form after its portfolio expands with the addition of Wyeth’s products include vitamins, vaccines, and even veterinary medicine. Kindler also said no research division would employ more than 150 scientists, in an effort to facilitate speedier decision-making.

Kindler said this model should make Pfizer’s wellbeing less dependent on the success or failure of a single product, like Lipitor. “Once you reach a certain size,” Kindler said, “if you are dependent on 1 or 2 huge blockbusters to move the needle, you are raising the bar on R&D productivity beyond an amount anyone can deliver.” He expressed admiration for the business model used by Johnson & Johnson, the company to which Pfizer sold its consumer product division only a few years ago. He assured investors the process of integrating Wyeth would go much quicker than the Warner-Lambert Co. and Pharmacia Corporation acquisitions.

Pfizer also announced that it was halting development of esereboxine, a drug in phase III trials for fibromyalgia; and PD 332,334, designed to treat anxiety disorder. Data showed the drugs were no more effective than current treatments. In January 2009, Pfizer scrapped trials investigating an indication for axitinib in pancreatic cancer; the drug is still undergoing investigation in a host of other carcinomas.

As part of its new strategy, Pfizer said it will shift its research and development focus to unmet medical needs. The company said it has experimental drugs in the pipeline that show potential as treatments for Alzheimer’s disease and thrombosis.

Wall Street Reacts

Discussing the Pfizer-Wyeth merger in a letter to investors, obtained by Business Week, Credit Suisse analyst Catherine Arnold wrote, “Such an acquisition makes strategic and financial sense. This deal will instantly make (Pfizer) a top-tier biologics player.” In the same letter, Ms. Arnold noted that the reported deal does not come as a surprise, adding that Wyeth would boost Pfizer’s revenue and cash flow in the short term and its profits in the short and long term. “[It] may also mark the beginning of a year of sector consolidation,” she wrote.

Not everyone is as enthused about the pending merger. Pfizer shares dropped 24% after the deal was announced, which Kindler attributed to its decision to cut shareholder dividends. In mid-February 2009, Pfizer shares traded at a low of $13.28, a price not seen since 1996.
Cell Therapeutics Struggling to Stay Alive in 2009

Despite several costly past missteps and a difficult economy, it appeared 2009 would be a pivotal year for Cell Therapeutics, Inc (CTI), Seattle, Washington, but the company was recently dealt another blow when it had to sell its remaining 50% stake in its cancer drug Zevalin (ibritumomab tiuxetan) to Spectrum Pharmaceuticals. CTI had anticipated receiving a label expansion for Zevalin this year, broadening the product’s indications to include first-line treatment as consolidation therapy after remission induction in previously untreated patients with follicular non-Hodgkin lymphoma (NHL).

“With the progress we made in removing many of the barriers that prevent its more widespread use, we are confident Spectrum will be able to ultimately make Zevalin a commercially attractive product,” said James Bianco, MD, CEO, CTI.

Although the sale of Zevalin brought in $18 million, it is unclear how long this cash infusion will help CTI remain afloat. According to filings with the Securities and Exchange Commission, the company has a debt load of approximately $124 million and is spending $13.5 million per quarter, despite various cost-cutting measures. Past attempts to raise cash from institutional investors have been unsuccessful, but there may be a ray of hope.

Pixantrone, which is in the late stages of CTI’s research and development pipeline, appears to be a promising product candidate based on the EXTEND data, a phase III trial originally reported in November 2008. Recently released information on the study, which was posted on the CTI Website, shows that pixantrone continues to demonstrate a robust clinical benefit when used as single-agent therapy in multiple relapsed aggressive NHL. “The rapid time-to-response data, coupled with the relatively low incidence of traditional anthracycline toxicities and a safety profile that compares favorably to standard chemotherapy, positions pixantrone to live up to the promise of providing patients with relapsed aggressive NHL a meaningful clinical benefit,” said Jack Singer, MD, Chief Science Officer, CTI. Based on these positive findings, the company is focusing its resources on the approval of this drug for relapsed aggressive NHL, and it remains hopeful approval will be granted before the end of this year. A U.S. launch could result in upfront and approval payments, as well as milestone payments, to CTI, should Novartis elect to exercise its option to enter into an exclusive worldwide license to develop and commercialize pixantrone.

In addition, CTI is also seeking European approval for Omacetaxine as a first-line treatment for patients with non-small cell lung cancer. If Novartis, which has a contract giving it first option to market the drug, elects to commercialize Omacetaxine in Europe, CTI could earn additional cash reimbursement payments and royalties on the sale of this drug. Other potential products in the CTI pipeline include the novel agent brostallicin (PNU-166196), a potential treatment for a range of cancers, including sarcomas and ovarian cancer, and a novel bisplatinum analogue for use in treating a range of solid tumors.

-Christina Loguidice

ChemGenex Drug Gets Orphan Status in MDS

ChemGenex Pharmaceuticals Limited recently announced that the FDA had granted Omacetaxine (homoharringtonine) an orphan drug designation for the treatment of myelodysplastic syndromes (MDS). Although ChemGenex has primarily focused on Omacetaxine as a treatment in chronic myeloid leukemia (CML), Greg Collier, MD, managing director and CEO of ChemGenex, praised the drug’s new designation. “Orphan designation for Omacetaxine reflects our corporate strategy of expanding the use of the drug to other hematological conditions where new treatment options are needed to improve patient outcomes,” he said. Orphan drug status means that ChemGenex has exclusive rights to market Omacetaxine as a treatment for MDS for 7 years.

Dr. Collier said ChemGenex is committed to pursuing an indication for Omacetaxine as a treatment for patients with CML who have the T315I mutation, which has remained the company’s primary objective for the drug. “The enrollment target for our registration-directed clinical trial for Omacetaxine was achieved on schedule in December 2008,” he said, “and we remain on track to complete the rolling new drug application submission to the FDA in mid-2009.” Data from a recent phase III trial found that Omacetaxine induced complete hematologic response in 80% of patients with CML and the T315I mutation whose disease was in the chronic phase. In addition 20% had major cytogenetic responses. Investigators reported that the drug was well tolerated.

Omacetaxine is administered subcutaneously; it is a first-in-class cetaxine that has demonstrated clinical activity as monotherapy for various hematological malignancies. The drug has a novel mechanism of action and induces apoptosis by inhibiting synthesis primarily of the protein Mcl-1. Omacetaxine acts independently of tyrosine kinase inhibitors and may provide a treatment option for patients refractory to tyrosine kinase inhibitors.

Immunomedics’ Pancreatic Cancer Drug on the Fast Track

The NCI says pancreatic cancer is the fourth leading cause of cancer death in the United States. Patients with pancreatic cancer have a poor prognosis, and the lack of treatment options does not help. If all goes well for Immunomedics, however, oncologists may soon have a new weapon in their limited arsenal of pancreatic cancer therapies: the company has received Fast Track designation from the FDA for yttrium-90-labeled hPAM4.

Cynthia L. Sullivan, president and CEO, Immunomedics, said, “We are pleased to receive the Fast Track designation from the FDA, which is an acknowledgment of the need for viable treatment options for patients with pancreatic cancer...We look forward to closely working with the FDA for the development and regulatory review of this important new antibody, a potential first-in-class radioimmunotherapeutic agent for pancreatic cancer.”

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—Cynthia L. Sullivan

The agent under consideration, hPAM4, is a humanized monoclonal antibody that targets an epitope in the MUC1 antigen that is expressed in most pancreatic cancers. In preclinical studies, hPAM4 in conjunction with the radioisotope yttrium-90 produced favorable tumor responses, which may be further improved when combined with gemcitabine (Gemzar). A phase I single-dose escalation study of yttrium-90-labeled hPAM4 in pancreatic cancer patients also produced encouraging results. The therapy is currently being used in a phase Ib fractionated-dose escalation study, along with gemcitabine, in patients with newly diagnosed stage III/IV pancreatic cancer.

Gemcitabine is generally viewed as the current treatment standard for pancreatic cancer, alone or in combination with other chemotherapy agents. If Immunomedics can demonstrate that hPAM4 complements gemcitabine-based therapy, the company could capture significant market share soon after hPAM4 launches.

According to an FDA spokesperson, the Fast Track designation is designed to expedite the development and review of new drugs designed to treat serious or life-threatening conditions. Selected compounds must also demonstrate the potential to address unmet medical needs. The designation allows for close and frequent interaction with the FDA and consideration for priority review. Fast Track designation does not guarantee approval for the drug, however.