

SILICON VALLEY / SAN JOSE

BUSINESS JOURNAL

Analysts upbeat on Affymax after it narrows drug focus

BY LISA SIBLEY

Two years after a sparkling initial public offering, Affymax Inc. is pouring all its resources and cash into upsetting Amgen Inc.'s monopoly in the dialysis market.

Analysts remain high on the company despite Affymax's growing net losses, which were \$18.9 million for the second quarter of 2008, compared with \$9.2 million for the same period a year ago. Affymax stock took a hit last week when the company and its Japanese partner Takeda Pharmaceutical Co. Ltd. suspended co-development of Hematide, aimed at treating chemotherapy-induced anemia. Hematide was in Phase I trials. The two companies decided to focus all development efforts for Hematide on the treatment of anemia related to chronic kidney disease.

That decision comes after safety and efficacy concerns surfaced over Amgen's drugs, which are in the same class — erythropoiesis-stimulating agent, or ESA — as Hematide. ESA stimulates production of red blood cells.

RBC Capital senior biotech analyst Jason Kantor anticipates that Affymax's Phase 3 trials investigating Hematide will be positive, giving the company "an outperform" recommendation. RBC Capital has a price target set at \$44. The company's stock was trading at a range of \$13 to \$32 in the past 52 weeks.

About 2,400 patients will participate in the trials over 18 months. Kantor said for the price investors pay today, it's worth the wait.

"We'll have to wait for results until the first quarter of 2010, which from an investor perspective makes it more difficult to get excited about in the near term," he said.

Advantages cited

Company officials claim Hematide's numerous advantages over Amgen will also make it worth the wait for patients.

"Affymax represents an alternative that has the additional advantage of being given once a month," said Dr. Brigitte Schiller-Moran, vice president of scientific affairs with Mountain View-based Satellite Healthcare, which was contracted to help lead the clinical trials.

Schiller-Moran said one of Amgen's drugs must be used three times a week, while the other is taken once a week. Hematide also offers a convenience factor to administer, said Affymax Chief Executive Officer Arlene Morris.

"We think this is a very exciting opportunity to break up a monopoly," Morris said.

Chronic kidney disease affects more than 26 million Americans, and these rates are steadily increasing, according to the National Kidney Foundation. In Northern California, more than 15,000

people have the disease, and in Silicon Valley there are about 2,900 patients receiving dialysis treatment for kidney failure. Anemia associated with chronic renal failure and cancer is estimated to be a \$12 billion to \$13 billion worldwide market, and about \$4 billion in the United States.

Patients such as 70-year-old San Bruno resident Debbie Parsons don't need convincing of the drug's benefits. Diagnosed with kidney failure after having breast implants, Parsons elected to participate in Affymax's clinical trials. Before enrolling in the Hematide trials, she was on Amgen's drugs but had allergic reactions to both treatments. She's had no reaction to Hematide so far.

"This is like a godsend," she said. "It isn't only my future. It's everyone on dialysis."

Other pharmaceutical companies, including F.Hoffmann-La Roche Ltd., haven't been successful in competing with Amgen's protein-based peptide because of the company's closely held patents. However, Affymax's drug is a synthetic peptide-based ESA, rather than a protein, so there are no expectations of patent infringement, Schiller-Moran said.

While Affymax hasn't publicly reported how much it is spending on the trials, Morris said the biopharmaceutical company has brought in a substantial amount of cash from its successful IPO spread in the past few years, and it was able to sell more shares than anticipated, bringing in \$90 million to \$100 million.

Affymax, a spin-out from GlaxoSmithKline, had revenue for the second quarter ending June 30 of \$19.1 million, compared with \$9.7 million for the second quarter of 2007. The increase was because of growth in collaboration revenue from its partnership with Takeda.

Affymax has a licensing agreement with Takeda for the development and commercialization of Hematide in Japan. It also has a collaboration agreement for the development and commercialization of Hematide in territories outside Japan, which includes co-development and co-commercialization of Hematide in the United States. Takeda pays for 70 percent of Affymax's out-of-pocket expenses, Morris said. Affymax's cash, investments and receivables from Takeda totaled \$180.3 million as of June 30.

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CLARIFICATION

Good Samaritan Hospital spokesperson Leslie Kelsay says the hospital is a Medi-Cal contracted health care provider for out-patient, in-patient and emergency services. In an Executive Q&A in the Aug. 29 issue, Reymundo Espinoza, chief executive officer of Gardner Family Health Network and Gardner Family Care Corp. did not include Good Samaritan Hospital when responding to a question.