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Treatment Superior to Vancocin

Positive Data in *C. Difficile* Send Optimer Shares Soaring

By Jennifer Boggs
Assistant Managing Editor

Much awaited data from Optimer Pharmaceuticals Inc.'s pivotal study of macrocyclic antibiotic OPT-80 in the troublesome *Clostridium difficile*-based infection space did not disappoint investors, as top-line results showed that the drug not only met the primary endpoint of noninferiority compared to Vancocin but actually demonstrated superior activity to the marketed drug.

The news sent shares of San Diego-based Optimer (NASDAQ:OPTR) skyrocketing 99.6 percent, or \$4.58, to close Tuesday at \$9.18.

Optimer CEO Michael Chang called the trial results "pretty amazing," adding that the cure rate seen with OPT-80 was "very, very high."

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Shares Fall 86%

Anesiva Restructures Following Setbacks with Adlea and Zingo

By Trista Morrison
Staff Writer

Shares of Anesiva Inc. plunged 86 percent on Tuesday after the company revealed a slew of bad news, including a Phase III failure for pain drug Adlea, plans to stop selling pain drug Zingo and financial difficulties necessitating the termination of more than 80 percent of the company's work force.

Yet president and CEO Michael Kranda maintained that Anesiva will emerge from the turmoil as a "lean new company" with a "new culture."

During a conference call with investors, Kranda outlined his vision for Anesiva, which he said involves taking the South San Francisco-based company "down to the bare bones" to focus on Adlea, despite the Phase III miss.

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Sangamo Shares Take a 65% Hit as Diabetic Nerve Drug Misses

By Catherine Hollingsworth
Staff Writer

Sangamo BioSciences Inc. said that its experimental drug SB-509 for diabetic nerve damage was no different than placebo in a Phase II study, causing shares in the company to fall 65.5 percent Tuesday.

The Richmond, Calif.-based company said that the negative results were unexpected given the encouraging results from a previous study. While SB-509 did not perform as the company had hoped, Sangamo maintained that the product candidate is safe.

The diabetic nerve damage trial, known as study 601, was one of three Phase II studies in the company's zinc-finger protein program. The study of 110 patients was designed to evaluate the clinical safety and clinical effects of repeat administration of SB-509 in diabetics with mild to

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Biotech 2008

Strategically Presenting Data Avoids Overexpectations

By Donna Young
Washington Editor

PHILADELPHIA – One of the most challenging issues biotechnology companies face is managing the expectations of investors, analysts, physicians and patients. The slightest miscommunication or misinterpretation of study data can send a company's stock prices spiraling or patients' hopes soaring, only later to be disappointed.

Managing expectations, said Laura Liotta, president of the public relations firm Sam Brown Inc., is a "discipline" that involves knowing how to effectively communicate, which she said is more of an art than a science.

Publicly traded small-cap and mid-size biotechs carry the heaviest burden of managing expectations because those firms generally have only one or two products in

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development, which means there could be long gaps in their communications and few opportunities to converse with those on Wall Street, Liotta said Tuesday during a panel discussion at the Biotech 2008 conference, hosted this year by Pennsylvania Bio and BioNJ.

"And the Street is hungry for information," she said. As a result, Liotta added, "it's easy to fall into that temptation of continuing to give them information." But, she warned, by "overpromising" in an attempt to keep investors interested and patients encouraged, a company can quickly lose credibility that, once lost, is extremely difficult to regain.

To ensure there is a balance between the need to keep stakeholders enthusiastic and optimistic with protecting a firm's credibility, biotechs must create disclosure policies and then "stick with them," Liotta advised.

In setting those disclosure policies, she said, companies should keep their lists short on the types of information they plan to disclose and then "stick with the message."

"I'm not saying don't be accessible," Liotta said, noting that it is especially important to be available to investors.

But, she warned, firms should not fall into the trap of falling back on setting new expectations to please investors and other stakeholders.

"You can be accessible by providing context into what you are doing without going too far," Liotta contended.

Biotechs must first and foremost understand the art of giving themselves "room" in their communications. President-elect Barack Obama's speech on the night he was elected is the perfect example of that practice, Liotta noted.

Obama warned the country that the "road ahead will be long, and we may not get there in one year or even one term. There will be setbacks and false starts. And we know that government can't solve every problem, but I will always be honest with you about the challenges we will face."

Biotechs need to be honest about the challenges they face and educate and communicate with their stakeholders about "some of the curves that could come up" in their way.

Communicating strategies for dealing with those curves, Liotta said, is "where you gain your credibility."

Firms should be clear about what is and is not in their control, she said. For instance, even though a biotech may have a Prescription Drug User Fee Action date set by the FDA, regulators lately have been inclined to miss or delay those dates, and firms should educate their stakeholders about that trend with the agency.

Companies also should communicate what is in their control, Liotta said. For example, she said, biotechs should refrain from sending out press releases when they have filed a new drug or biologics license application with the FDA and instead, issue those communications when the agency has accepted the application for review.

That way, Liotta said, the firm is not under pressure

from stakeholders about when it will hear from the FDA on the filing. Rather, she said, the clock starts with the acceptance of the filing rather than the submission.

John Elicker, vice president of investor relations for Bristol-Myers Squibb Co., said it has been his firm's long-standing policy to issue a press release about the acceptance of an application rather than the date of submission. However, he said, as a public company, it is difficult not to answer the question when someone asks whether BMS has submitted an application, and therefore, representatives of his company often confirm the submission when asked.

Strategies in Medical Meeting Reports

Elicker noted that the importance of medical meetings has grown dramatically over the past couple of years to regulators, payers, patients and Wall Street, and more and more, the value of drugmakers, particularly small and medium-size biotechs, is being judged by data presented at those meetings.

Drugmakers can no longer simply present study data from a scientific standpoint, but must strategically plan how best to communicate their information and consider all constituents in that process, he advised.

Historically, Elicker said, Princeton, N.J.-based BMS had taken a standard approach to medical meetings by having its product clinical teams control how the data was presented, with the company issuing press releases when it thought that was necessary.

However, at last December's annual meeting of the American Society of Clinical Oncology, BMS and its partner, New York-based ImClone Systems Inc., learned a valuable lesson after presenting data about Erbitux (cetuximab) in colorectal cancer.

"We went again through our normal process, and the product teams put the presentation together with the investigators and presented the data," he explained.

However, Elicker said, the data showed that patients with the KRAS gene mutation, or about 30 to 40 percent of colorectal cancer patients, were unlikely to benefit from Erbitux.

What got lost in some communication was that the data also showed patients with the nonmutated, or wild-type, KRAS gene – about 65 percent – benefited most from the drug.

"The take-away from the media and investors was, 'Oh, my gosh, ImClone and Erbitux [are] in big trouble because Erbitux doesn't work in 30 to 40 percent of the patients,'" Elicker said.

BMS, he said, "missed a huge opportunity by not taking a more strategic and integrated approach" in communicating the data as "delivering on the promise of targeted and personalized medicine, and by testing for KRAS and the KRAS mutation, payers, physicians and the government have an opportunity to identify patients that will double

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their survival rate over standard therapy, and by the way, we also have identified patients that we can exclude from treatment with Erbitux, a fairly expensive treatment.”

While the company missed its opportunity last year, it now is “something that we are changing and moving forward in terms of how we approach medical meetings from a more strategic standpoint of trying to take all constituents into consideration, rather than just having the clinical teams present scientific data.”

Consistent Communication

Brian Gill, vice president of global corporate communications for Celgene Corp., said his firm has adopted the mantra that “all roads of communications impact share-

holder value.” From early on, the Summit, N.J.-based biotech put in place a strategy of ensuring that communications were “fully integrated across all functions globally,” he said.

“We work very hard to make sure that our positioning in our messages are consistent worldwide in various venues,” Gill said.

The other strategic positioning the company has adopted is that its actions are guided by a long-term thought process, which he said has “served us well over the last several years.”

The company has a commitment to be in the market as often as possible communicating and helping its stakeholders to understand its story, and “making sure that their assumptions are straight.” Gill said he keeps in constant communication with Celgene’s key executives no matter where they are traveling. ■

CLINIC ROUNDUP

- **CytRx Corp.**, of Los Angeles, said its orally available dual Bcr-Abl and Lyn-kinase inhibitor INNO-406 demonstrated clinical responses in patients with chronic myeloid leukemia. All patients demonstrated intolerance or resistance to imatinib (Gleevec), and the majority of patients demonstrated intolerance or resistance to a second, and in some cases a third, Bcr-Abl inhibiting tyrosine kinase inhibitor. A positive, dramatic decrease in the number of leukemia cells in the bone marrow was seen in 35 percent of the patients who were randomly chosen to begin their treatment with the optimal INNO-406 dose of 240 mg twice per day. Only 13 percent of patients, across all dose groups, discontinued dosing due to unacceptable toxicity.

- **ImClone Systems Inc.**, of New York, said its disease-directed Phase II trial of IMC-1121B in combination with paclitaxel and carboplatin as first-line therapy in advanced non-small-cell lung cancer has opened for patient enrollment. IMC-1121B is ImClone’s proprietary fully human, IgG1 antivasular growth factor receptor-2 monoclonal antibody. The study is designed to evaluate the progression-free survival rate at six months of IMC-1121B in combination with paclitaxel and carboplatin, each administered as an intravenous infusion every three weeks, in that disease setting.

- **LifeCycle Pharma A/S**, of Horsholm, Denmark, reported positive data on LCP-AtorFen obtained in a 12-week Phase II study in approximately 220 patients with dyslipidemia. A 52-week safety and efficacy extension is still ongoing. Data were presented at the American Heart Association’s 2008 Scientific Sessions in New Orleans

- **Oxygen Biotherapeutics Inc.**, of Costa Mesa, Calif., said a study published in the October 2008 edition of *Neurosurgery* demonstrated that Oxycyte, its perfluor-

rocarbon therapeutic oxygen carrier, can improve cognitive recovery and has a protective effect on hippocampal neurons in an experimental traumatic brain injury model in rats. New studies will focus on finding the lowest dose of Oxycyte that reduces the platelet reduction (thrombocytopenia) and still provides clinical benefit in traumatic brain injury. Due to the slight redesign of the protocol and regulatory and administrative processes, patient enrollment is anticipated to begin in the first quarter of 2009.

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