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BioMarin Reports Positive Phase III Aryplase Results

By Kim Coghill
Washington Editor

BioMarin Pharmaceutical Inc. on Thursday released favorable data from a Phase III trial of Aryplase, an enzyme-replacement therapy for mucopolysaccharidosis-VI patients.

Also, the company said it would seek regulatory approval throughout the world early in the fourth quarter by filing a single common technical document.

BioMarin's stock (NASDAQ:BMRN) Thursday fell 8 cents to close at \$6.45.

Fredric Price, chairman and CEO of Novato, Calif.-based BioMarin, told *BioWorld Today* the firm expects regulatory agencies to take action on the orphan drug application within a year of filing, that is, unless it is granted priority-review status, in which case the evaluation period would be shortened to six months in the U.S.

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Maxygen Sells Plant Sciences Unit To DuPont For \$64M Cash

By Karen Pihl-Carey
Staff Writer

Staying on track with a corporate plan to focus on therapeutics, Maxygen Inc. sold its plant sciences business for \$64 million in cash to partner DuPont.

Wilmington, Del.-based DuPont bought Maxygen's subsidiary Verdia Inc. outright, gaining worldwide, royalty-free exclusive rights to use MolecularBreeding directed evolution platform technology for agricultural applications.

"This has been a fantastic return on the investment for Maxygen shareholders," said Russell Howard, CEO of the Redwood City, Calif.-based company. "Maxygen has spent minimal funds on this activity over the last seven years."

All 50 of Verdia's employees will receive offers for employment with DuPont, which will retain Verdia's name,

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FDA, CV Therapeutics Nail Down Ranexa Trial Protocol

By Randall Osborne
National Editor

Firming up an advisory panel's opinion in December, the FDA has agreed to a special protocol assessment (SPA) program for the next clinical trial of Ranexa, CV Therapeutics Inc.'s treatment for chronic angina.

The company's stock (NASDAQ:CVTX) rose \$2.32 on the news, or 17.6 percent, closing Thursday at \$15.53, after trading as high as \$16.88.

"This really mitigates the regulatory uncertainty," said John Bluth, senior director of corporate communications at CV Therapeutics.

The FDA's SPA program "has been around for a few years now," he noted. "Some of them are for your first pivotal Phase III studies" – whereas CV Therapeutics already has completed two and gained an approvable letter from

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Panacos, Vitex Merging In \$27M Stock Exchange, Plus Milestones

By Aaron Lorenzo
Senior Staff Writer

Bringing together two infectious disease pipelines, Panacos Pharmaceuticals Inc. entered a definitive merger agreement with V.I. Technologies Inc., also called Vitex.

Publicly traded Vitex, which is developing anti-infective technologies to improve blood safety, is testing its Inactine technology in a Phase III program for the inactivation of pathogens in red blood cells. Privately held Panacos' portfolio features small-molecule antiviral drugs such as PA-457, a first-in-class HIV-maturation inhibitor in Phase I testing.

Watertown, Mass.-based Vitex will issue 25 million common shares in exchange for all of Panacos' outstanding shares upon closing the transaction, expected next quarter. That values the merger at about \$27 million,

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Merger

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based on Wednesday's \$1.08 closing price of Vitex stock. Given that price, the merger's worth to Panacos stockholders could grow to \$48.6 million if various near-term clinical milestones for PA-457 are met, triggering Vitex to issue up to an additional 20 million shares.

Vitex's stock (NASDAQ:VITX) traded up 7 cents Thursday to close at \$1.15.

The merged company will be headed by Samuel Ackerman, a familiar figure to both firms' management teams – Ackerman is Vitex's chairman and the chairman and acting CEO of Panacos. He will continue as chairman and CEO of the combined business, which will be called V.I. Technologies.

"There is excellent synergy in their pipelines," Ackerman told *BioWorld Today*. "The Panacos programs involve innovative antiviral drugs for HIV therapy and other serious viral illnesses, based on new viral targets. The Panacos scientists discovered viral maturation as a target for HIV drug discovery, and they also have a platform in which they are discovering new oral viral fusion-inhibitor products. Both of these give to Vitex a major entry into high-value, anti-infective therapeutics, which extends its technologies substantially beyond the blood-safety program."

For Gaithersburg, Md.-based Panacos, Ackerman said merging with a company that has a late-stage program also is advantageous. For the new entity, there is a synergy in the combination of Panacos' drug discovery research, pharmacology and early stage clinical trial experience with Vitex's late-stage clinical trial history and its infrastructure.

A recently concluded, dose-escalating Phase I trial of PA-457 showed that the product was well tolerated and exhibited favorable oral bioavailability and pharmacokinetics in healthy volunteers. A multiple-dose Phase I study is under way, and the combined company will look to begin a proof-of-concept Phase IIa trial in HIV-infected subjects later this year. Completion of both represents milestones for which Vitex would issue additional shares to Panacos stockholders – they would receive 5 million shares at the end of the ongoing Phase I trial and 15 million shares at the end of the proposed Phase IIa study.

PA-457, which has shown activity against HIV strains resistant to current therapies, was discovered through a collaboration with the University of North Carolina at Chapel Hill. That agreement dates to Panacos' origins within Boston Biomedica Inc., a diagnostics company based in West Bridgewater, Mass.

Vitex's Inactine technology is designed to inactivate a range of viruses, bacteria and parasites, and has demonstrated an ability to remove prion proteins. It works by attaching to the RNA or DNA of the pathogen, forming an irreversible bond to the pathogenic nucleic acid, thus preventing replication and effectively killing the pathogens.

The Phase III program involves 22 sites around the U.S., and the system primarily is expected to see use in acute patients.

"The development programs of both companies are going to continue in parallel," Ackerman said, adding that the merger would not result in a reduction in headcount. "We're going to keep everybody very busy with the programs we have and hope to grow."

Operations will be maintained at each company's respective sites. Graham Allaway, Panacos' chief operating officer and co-founder, will continue to have responsibility for the Panacos programs in the combined company. Its oral HIV fusion-inhibitor technology, which is being developed under the direction of Carl Wild, the company's other co-founder, is scheduled to enter pre-clinical development next year. Earlier-stage research is focused on a second-generation maturation inhibitor product and a fusion inhibitor for respiratory syncytial virus.

Panacos, which employs 19 people, has raised more than \$26 million in two rounds of private equity funding since its 2000 inception, including an \$18.3 million financing last month. Its investors include Ampersand Ventures, A.M. Pappas & Co., Mitsui & Co. Venture Partners Inc., Novo A/S, Lakeview Capital Management, William Harris Investors, New England Partners and the Maryland Department of Business and Economic Development. (See *BioWorld Today*, May 19, 2004.)

Ackerman, who came to Panacos as a board member late last year, said the latest venture capital financing was independent of the merger. He became a board member at Vitex in 2000, following its merger with Pentose Pharmaceuticals Inc., a Cambridge, Mass.-based company at which he served as president and CEO.

Vitex had \$14 million in cash at the end of its most recent quarter, which closed March 27, as well as about 47.7 million shares outstanding. The 39-employee company posted a \$3.7 million net loss in the preceding three months, during which it also raised \$10.9 million through a private placement.

The combined company will have about \$27.9 million in cash. ■

OTHER NEWS TO NOTE

• **Trimeris Inc.**, of Durham, N.C., and **Array BioPharma Inc.**, of Boulder, Colo., renewed their agreement to discover small-molecule entry inhibitors directed against HIV. Trimeris will screen small-molecule compounds created by Array against HIV entry inhibitor targets. Array will be entitled to receive research funding and milestone payments, as well as potential royalties. The original agreement was signed in August 2001.