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Amira Completes \$25M Round To Support Emerging Pipeline

By **Trista Morrison Staff Writer**

In less than two years, Amira Pharmaceuticals Inc. established operations, discovered three anti-inflammatory molecules, advanced a lead compound into IND-enabling studies and signed a significant deal with Hoffmann-La Roche Inc. that led to another discovery and ongoing clinical trials.

And San Diego-based Amira did it all on a \$15 million Series A round: \$6 million in a mid-2005 Series A-1 deal and \$9 million in a mid-2006 Series A-2.

Now the closing of a \$25 million Series B round gives the company "enough runway to reach a significant value inflection point," said Bradley Bolzon, managing director with Versant Ventures. Specifically, Bolzon expects Amira to reach clinical proof of concept with multiple drug candidates.

All three founding investors – Versant, Avalon Ventures and Prospect Venture Partners – participated in the Series B round. Bolzon said they "showed [the deal] to four other select firms, and all four wanted in," but the investment team chose Novo A/S as the lead.

Unlike many start-ups today, Amira is not virtual. In fact, the company boasts 30 employees, including the in-house discovery group responsible for lead drug AMI03.

Bolzon said Amira has proved "very capital efficient in that \$15 million has built a development-stage portfolio." He added that the company presented a "unique opportunity" because it was built around a "world-class scientific team."

Amira founders Peppi Prasit, chief scientific officer; John Hutchinson, vice president of chemistry; and Jilly Evans, vice president of biology, all hail from Whitehouse Station, NJ.-based Merck and Co. Inc., where they worked on programs such as the asthma drug Singulair (montelukast sodium). But when Merck decided to close its San Diego location in 2005, the three gathered about 20 colleagues and founded Amira. They've since picked up several ex-Pfizer Inc. scientists, hired a chief business officer and are looking for a CEO.

Proceeds from the financing primarily will be used to advance the lead drug, AMI03, initially in the treatment of asthma and later against allergic rhinitis, chronic obstructive pulmonary disease and cardiovascular inflammation. AMI03 is designed to inhibit the synthesis of leukotrienes but works upstream from Singulair, which hits only one of the four

leukotriene receptors. Prasit said that potentially would allow AMI03 to target a broader patient population than Singulair, which generated \$3.6 billion in revenues in 2006.

Prasit said he expects AMI03 to compete more directly with Zyflo (zileuton tablets, Critical Therapeutics Inc.), which brought in about \$6.6 million in 2006. Yet while Zyflo requires a high dose and "has some liver-function issues," according to Prasit, AMI03 will be administered in a lower, once-daily dose and has not shown any liver toxicities.

Amira plans to file an investigational medicinal product dossier for AMI03 in Europe in early May, with a Phase I biomarker trial expected to begin in the summer and a Phase I trial in asthmatic patients following in the third or fourth quarter. In 2008, Amira expects to pursue an investigational new drug application filing with the FDA so Phase II trials can be conducted in the U.S.

A backup compound for AMI03 also is advancing through preclinical studies, and Prasit said he expects to file an IMPD for that drug in September and begin a biomarker study in October. Although Amira has discovered an additional backup compound, Prasit said it is more of an "insurance policy" and may not advance into humans if the other compounds look good.

In early 2006, Amira further expanded its pipeline by licensing an option to two Phase I programs from Roche. While one of the clinical programs is temporarily on hold, Amira has reformulated the other and is conducting a Phase Ib trial in psoriasis. (See *BioWorld Today*, Jan. 12, 2006.)

The Roche deal also involves a drug discovery partnership for three additional targets. Amira earlier this year identified a lead candidate for the first target. That announcement triggered a milestone payment from Roche, and Bolzon said he expects Amira will achieve additional milestones in the next 12 months.

Yet the company has no plans to put its drug discovery capabilities to work for other partners, instead choosing to follow a product rather than platform model. On the commercialization side, however, partners already are sniffing around AMI03 and its related compounds. Prasit said he's not sure how long Amira can "hold off the partners," but that he'd like to get the drug into humans prior to making any decisions. ■

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