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Combination Therapies the Way Forward

Newcomers Looking for Slice Of Expanding AMD Market

By Peter Winter
Editor

In this second part of our focus on ocular diseases, we look at the latest developments taking place in the treatment of central vision disorders such as age-related macular degeneration (AMD). This disease, along with cataracts, diabetic retinopathy, and glaucoma, represents a considerable economic burden to the health systems of developed and developing countries . . . and the situation is predicted to get worse.

The importance of the opportunity in this therapeutic area was recently reflected by a $175 million investment that Ophthotech Corp., of Princeton, N.J., attracted in May to support a global Phase III program for its lead product Fovista, an antiplatelet-derived growth factor (anti-PDGF) agent, in combination with anti-VEGF therapy for age-related macular degeneration (AMD). Their Phase III trial will enroll about 1,900 patients across 200 clinical centers worldwide.

The company is one of the leading contenders in the wet AMD space and it is hoping to take a large bite out of the $5 billion market now shared by leading VEGF inhibitors, such as Lucentis (ranibizumab, Roche AG), off-label Avastin (bevacizumab, Roche AG) and Eylea (aflibercept, Regeneron Pharmaceuticals Inc.).

Further Down the Line

Ophthotech is further along the product development pipeline than other potential competing companies. Clinical results with Fovista so far have been very promising showing that in combination with Lucentis it superior to Lucentis alone.

The Phase IIb study assessed efficacy and safety of Fovista 0.3 mg in combination with Lucentis 0.5 mg, Fovista 1.5 mg with Lucentis 0.5 mg, or sham with Lucentis 0.5 mg. Patients in the 1.5 mg Fovista/0.5 mg Lucentis group gained a mean of 10.6 letters of vision on the ETDRS standardized chart after 24 weeks of treatment, compared to 6.5 letters for patients receiving Lucentis monotherapy.

While Ophthotech has not signed with a partner, it has not ruled out the possibility. "We would carefully consider any proposals and the board is also looking at various

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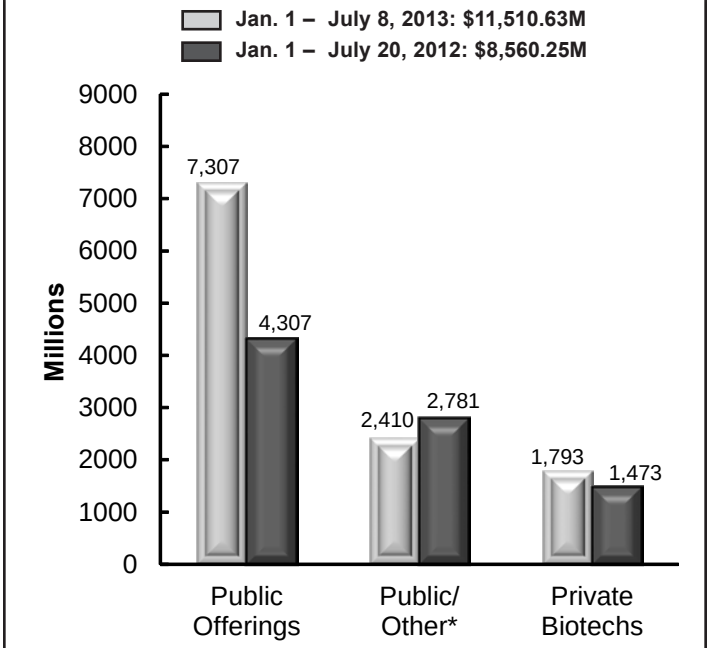
Money Raised By Biotech In 2013 vs. 2012



* Includes financings of public biotech firms with the exceptions of public offerings and certain investments from corporate partners.

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'Not a Typical Shell Merger'

IPOs Hot, but Ocera Chooses Reverse Merger to Go Public

By Brian Orelli
Contributing Writer

The IPO window has turned into a sliding glass door with biotechs seizing the opportunity to tap the public markets. According to *BioWorld Snapshots*, 19 biotechs have hit the U.S. markets since the beginning of the year. And there are quite a few others building their books hoping to price in the coming weeks.

Ocera Therapeutics Inc., however, chose the path less traveled at the moment, closing its reverse merger with Tranzyme Inc., of Research Triangle Park, N.C., last week to access a public listing.

While a bit unorthodox in this market, merging with Tranzyme made sense given the synergies between San Diego-based Ocera and Tranzyme; both were developing drugs to treat liver disease.

"This is not a typical shell merger," Linda Grais, Ocera's president and CEO, told *BioWorld Insight*.

Ocera was planning on remaining a private company, perhaps accessing the public markets in a year, but the opportunity to merge with Tranzyme was a special situation where the benefits from the fit couldn't be passed up.

Prior to the merger, Ocera was operating as a virtual biotech, but Grais eventually planned on hiring employees to run its clinical trials. The merger allowed Ocera to inherit a clinical development team experienced with liver drugs to push its ammonia scavenger OCR-002 through the clinic.

"We felt the Tranzyme team was top tier. It would have taken six to 12 months to build a team like that," Grais said.

The process started in January when Tranzyme decided to explore strategic alternatives after its gastroparesis candidate, TZP-102, missed its endpoint in a Phase IIb trial and a second Phase IIb trial was discontinued after an interim futility analysis showed a large placebo effect and no additional effect from the drug. (See *BioWorld Today*, Nov. 16, 2012, and Dec. 18, 2012.)

In April, the companies entered into a definitive agreement to merge, which closed last week after shareholders approved the transaction and Tranzyme effected a 12-to-1 reverse split. The new company, which took Ocera's name, began trading on the Nasdaq Global Market under the symbol "OCRX" last week.

In conjunction with the merger, Ocera's investors, including Domain Associates, Thomas McNerney & Partners, Sofinnova Ventures, InterWest Partners, Greenspring Associates, Agechem, CDIB and Wasatch Advisors, invested approximately $20 million through a private placement financing at $6.0264 per share. The company was trading above $11 per share last week.

Combined with the cash remaining in the companies' coffers, Ocera has approximately $25 million, which Grais said should get it substantially though a planned Phase IIb study of OCR-002 that will be completed in late 2014 or early 2015.

OCR-002 is designed to reduce ammonia levels in patients with compromised liver function. The Phase IIb study, which is expected to begin enrolment in late 2013, will test OCR-002 as an intravenous treatment for acute hepatic encephalopathy in hospitalized patients with liver cirrhosis.

> "This is not a typical shell merger."
>
> –Linda Grais, president and CEO, Ocera Therapeutics Inc.

Kristalose (lactulose, Cumberland Pharmaceuticals Inc.), the current standard of care for acute hepatic encephalopathy – a worsening of brain function because the liver isn't able to remove toxic substances such as ammonia – works by causing massive diarrhea, which clears the gut of toxins, but isn't particularly pleasant for the patient or their caregiver and typically leads to patients staying in the hospital for a week or longer.

Ocera hopes to prove that OCR-002 not only improves acute hepatic encephalopathy by lowering levels of ammonia in the blood, but also decreases the length of stay in the hospital.

Longer term, Ocera plans to develop an oral version of OCR-002 that could be used to treat chronically increased levels of ammonia in patients with damaged livers. ■