

NewCo News: AMD 'Ohr' Cachexia? It's Both; Distress Sale Stokes New Firm.

25 November 2009

[BIOWORLD Today](#)

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A recent addition to the U.S. public biotech sector, Ohr Pharmaceutical Inc. emerged onto the scene with two lead compounds: cancer cachexia candidate OHR/AVR118 and wet age-related macular degeneration drug Evizon.

If either of those seems familiar, there's good reason. Yonkers, N.Y.-based Advanced Viral Research Corp. had been working on AVR118 until January, when a lack of funding forced it to suspend operations, and Evizon had been developed by Plymouth Meeting, Pa.-based Genaera Corp., which opted to liquidate earlier this year after running out of cash.

"We lucked out in terms of what we were able to buy in two distress sales," said Orin Hirschman, director at the Dover, Del.-based company, which completed its 12-month transition earlier this month from a public holding firm - BBM Holdings Inc. - into a full-fledged biotech.

BBM's existing investors had put up the money to make those initial purchases, with the aim of finding drug candidates that either had been abandoned due to lack of funding or shelved because of poor trial design or misunderstood mechanisms of action, he said.

Last year, BBM made an unsuccessful bid for nimotuzumab developer YM BioSciences Inc., which had been trading far below its cash position. The Mississauga, Ontario-based firm, however, rejected the offer and, instead, later agreed to merge with Australian company Cytopia Ltd. (See BioWorld Today, Nov. 14, 2008

(http://www.bioworld.com/servlet/com.accumedia.web.Dispatcher?next=bioworldToday_article&forceid=49277).)

After that, Ohr kept a low profile, "hunkering down and wanting to make sure we made the right acquisitions," Hirschman said. And, with OHR/AVR118 and Evizon, "we got [products] that have had north of \$100 million invested in them and lots of human data."

The company also was able to bring on board as consultants the top scientists who had worked on each program, including Shalom Z. Hirschman, Ohr's chief scientific officer, who previously headed up Advanced Viral Research and was more than a little familiar with OHR/AVR118. "It was the kind of due diligence everyone dreams of," Hirschman told BioWorld Today.

OHR/AVR118 is designed to inhibit and modulate cellular pro-inflammatory chemokine and cytokine synthesis, including tumor necrosis factor-alpha. Basically, it provides "better immune

homeostasis," Hirschman said, combating the cachexia seen in cancer patients so they are able to better withstand chemotherapy and radiation.

Data from a 32-patient, open-label, Phase II trial showed an increase in weight, strength and fat percentages in all four dose groups, ranging from 0.4 ml/day to 4 ml/day, over 28 days. The drug is in an ongoing Phase II study at McGill University in Stage III and Stage IV cancer patients, with data anticipated in late 2010, though Hirschman said interim data might be available at a scientific meeting before then.

While further cachexia studies would be small and inexpensive enough for Ohr to take on, "we'd love to have a big pharma partner, who could take it much farther," he said. That includes earlier-stage cancer patients, potentially becoming the standard of care in cancer cachexia, as well as in HIV-associated cachexia, where OHR/AVR118 also has shown promise in early studies.

And early stage work has hinted that the drug might prove effective in autoimmune diseases such as rheumatoid arthritis.

With Evizon (squalamine), Ohr didn't have the same kind of expertise as it did with OHR/AVR118, but "there were huge amounts of human data" showing the compound's safety and efficacy in wet AMD, Hirschman said. In Phase I and Phase II testing, the drug showed "excellent visual acuity, comparable to Lucentis," while avoiding any signs of the hypertension risks sometimes associated with the market-leading AMD drug.

Like Lucentis (ranibizumab, Genentech Inc.), Evizon targets VEGF, but it's designed to work by inhibiting the pathway of angiogenesis, rather than binding onto the site like the antibody drug. Ohr plans to "slightly reformulate" the drug and conduct a small safety study before moving into Phase IIb testing, hopefully within the next 18 months, Hirschman said.

Despite its early potential, Genaera had halted work on Evizon two years before the company went belly up, citing slower-than-expected patient accrual in a Phase III trial, likely due to the success of Lucentis, which also had crushed AMD competitors Macugen (pegaptanib sodium, Pfizer Inc.) and Visudyne (photodynamic therapy, QLT Inc.) (See BioWorld Today, Jan. 5, 2007 (http://www.bioworld.com/servlet/com.accumedia.web.Dispatcher?next=bioworldtoday_article&forceid=42138)).

But Ohr is "less worried" about finding patients for its trial, Hirschman said, since Evizon offers a different route of administration - intravenous rather than intravitreal injections into the eye - and can treat both eyes at once. Many patients with AMD are affected in both eyes, he noted.

Beyond its lead drugs, Ohr also has some earlier programs. For now, though, all efforts are on moving OHR/AVR118 and Evizon forward.

The company, which operates as a virtual organization, has "about 10 key individuals" on hand, some of those part-time, Hirschman said.

Shares of Ohr (OTC BB:OHRP) gained 19 cents, or 46.3 percent, to close Tuesday at 60 cents.

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