

Numoda Capital Buys VitreoRetinal Assets, Seeks To Revive Vision Drug



Brian Gormley
March 10, 2011

Numoda Capital Innovations is reviving an effort to develop a drug for the blinding disease diabetic retinopathy that stalled in the hands of venture-backed VitreoRetinal Technologies Inc.

The firm has acquired the assets of VitreoRetinal Technologies and will advance the company's diabetic-retinopathy drug, Vitreosolve, through a special-purpose entity it formed early this year, Innovations In Sight LLC.

VitreoRetinal, which raised a \$9 million Series A round in 2007 from De Novo Ventures and individuals, turned its assets over to creditors last year after clinical studies of Vitreosolve hit a snag. Numoda Capital bought Vitreosolve and other assets for an undisclosed amount in September, said Terrance S. McGovern, Numoda Capital's managing director. De Novo Managing Director Frederick Dotzler was not available for comment.

Numoda Capital contends that VitreoRetinal mistakes caused its clinical studies to run aground. Through Innovations In Sight, a virtual entity, it will either raise capital to run further clinical trials or find a corporate partner to fund them. Its ultimate goal is to sell the product or license it out.

Innovations In Sight is funded by Numoda Capital, the venture arm of Numoda Corp., an information- and process-management company that helps drug companies manage clinical trials.

Innovations In Sight plans to begin testing Vitreosolve in two, 225-patient Phase III trials next quarter. Numoda Corp. will be the general contractor for the trials and will work to ensure they are carried out correctly, while technology from a Numoda Corp. affiliate, Numoda Technologies Inc., will enable Innovations In Sight to track trial data as they are produced.

Poor study design and execution are what derailed Vitreosolve, according to Numoda, which hopes the product will emerge as the first drug to treat diabetic retinopathy. In this disease, fragile blood vessels can grow into the back of the eye and leak blood and fluid, causing vision loss.

In Phase II clinical trials of Vitreosolve, which is injected into the eye, the drug showed that it can cause the vitreous, the eye's transparent inner filling, to separate from the retina, the light-sensitive tissue lining the back of the eye. This separation, known as posterior vitreous detachment, appears to stall the disease by depriving blood vessels of nutrients.

VitreoRetinal targeted patients with severe nonproliferative diabetic retinopathy, the third of the condition's four stages. The disease, whose fourth and most-severe form is called proliferative diabetic retinopathy, is the most common diabetic-eye disease and is a leading cause of blindness, according to the National Eye Institute.

VitreoRetinal ran into problems when it began Phase III studies, in which it intended to enroll a total of 450 patients. In a January 2010 interim analysis of 75 study participants, it found that control-arm patients--who got a miniscule dose of Vitreosolve--were faring almost as well as those injected with the full dose.

Nine of the 25 control-arm subjects, or 36%, had a posterior vitreous detachment, while 26 of the 50, or 52%, of those getting the full dose were found to have gotten that benefit, according to McGovern.

VitreoRetinal and prospective investors wanted to see a 20% or greater difference between the studies' "active" and control arms. Unable to raise more money, the company turned its assets over to creditors, who auctioned them off, McGovern said.

The trial results may have been different if VitreoRetinal had injected a true placebo--a dummy drug--instead of a low dose of Vitreosolve, according to Numoda. When VitreoRetinal initiated the Phase III trial a couple years ago, it was not as common to inject drugs into the vitreous as it is today, according to McGovern. As a result, the company feared that it wouldn't be able to recruit patients to a study in which some people would get a placebo, he said.

With the emergence of injected drugs such as Lucentis--a treatment for the wet form of age-related macular degeneration--intravitreal injections are now more accepted, he said. In its Phase III studies, Innovations In Sight intends to inject saline instead of Vitreosolve into the control-group patients. The company also plans to monitor study sites closely to ensure that the injection procedure is done correctly, he said.

Diabetic retinopathy is a slow-moving disease, and most drug companies are not keen on running long clinical trials to show that a particular drug stops its march. Because clinicians generally agree that posterior vitreous detachment will stymie it, however, the Food and Drug Administration has indicated that Vitreosolve can be approved if it causes vitreous detachment in Phase III trials, according to McGovern.

Innovations In Sight, based in Numoda Corp.'s Philadelphia offices, also has acquired another VitreoRetinal asset, Neurosolve, a glaucoma drug that has yet to enter clinical trials. It will advance this drug as well, according to McGovern, who said the firm will also consider using Innovations In Sight as a platform to acquire other ophthalmology medicines.

<http://www.numodacapital.com>

The firm has acquired the assets of VitreoRetinal Technologies and will advance the company's diabetic-retinopathy drug, Vitreosolve, through a special-purpose entity it formed early this year, Innovations In Sight LLC. VitreoRetinal raised a \$9 million Series A round in 2007 from De Novo Ventures and individuals.