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## Viamet, Novartis Fund Targeting Metalloenzymes in \$200M Deal

**By Catherine Hollingsworth**  
**Staff Writer**

Viamet Pharmaceuticals Inc. signed a deal worth more than \$200 million with the Novartis Option Fund to discover and develop metalloenzyme inhibitors of interest to the Swiss drugmaker.

Morrisville, N.C.-based Viamet said the Novartis agreement provides an opportunity to expand its Metallophile technology beyond the current development programs aimed at metalloenzymes involved in infectious disease and oncology.

Viamet did not disclose any further details about the Novartis deal. In fact, Viamet has been tight-lipped about even its unpartnered preclinical programs. The company has said that its programs are based on well-validated metalloenzymes.

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## FDA Raises Endpoint Concerns in Study of Salix Liver Drug

**By Donna Young**  
**Washington Editor**

WASHINGTON – Although the analysis of the primary endpoint of Salix Pharmaceuticals Inc.'s single study of Xifaxan (rifaximin) as a maintenance therapy for the remission of hepatic encephalopathy appeared statistically significant, FDA reviewers raised concerns about the interpretability of the observed outcome in the trial.

The assessment of the primary endpoint, which was time to first breakthrough overt hepatic encephalopathy episode, was subjective and hinged on observer evaluation of subtle differences in neurologic function, the reviewers said in briefing documents released ahead of Tuesday's meeting of the FDA Gastrointestinal Drugs Advisory Committee.

The FDA also noted that there were higher rates of  
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*Sucking all the Marrow out of GBM*

## Blocking Backup Pathway Could Prevent Glioblastoma Comeback

**By Anette Breindl**  
**Science Editor**

When people talk about the progress that has been made in the war on cancer, it is not glioblastoma multiforme they are referring to.

Scientific papers on the disease refer to three-year survival as "long-term," and the five-year survival rate for this particular type of brain cancer is less than 10 percent. But two papers published on Monday suggested new targets for fighting the disease.

The low survival rate of patients with glioblastoma multiforme is due to a high recurrence rate: Though radiation will, in many cases, lead to a brief remission, ultimately the cancer recurs. And often it does so in the same spot as the original tumor.

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*Financings Roundup*

## New Money Scarce, so ITS Founders Chip in \$13.4M

**By Nuala Moran**  
**BioWorld Today Correspondent**

LONDON – Immune Targeting Systems raised £8.65 million (US\$13.4 million) from existing investors, enabling the company to stage Phase I and Phase IIa trials of its universal flu vaccine.

The decision by founding investors Novartis Venture Fund, Truffle Capital and HealthCap to put in the money as an extension to the Series A followed a fruitless nine-month search for funding from other sources.

Even given this blue chip backing, CEO Carlton Brown failed to find a single new investor in a hunt lasting from April 2009 until the end of the year. "The feedback we got is no one is investing in new companies – and especially not new vaccines companies, and even more especially not new

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## Viamet

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Despite its efforts to stay under the radar, Viamet's core technology has been "attracting attention" from interested companies, Neil Moore, vice president of business development, told *BioWorld Today*.

Viamet also has grabbed the attention of corporate investors, the Novartis Option Fund, part of the Novartis Corporate Venture Funds, and Lilly Ventures, which led an \$18 million Series B financing round at Viamet last year. (See *BioWorld Today*, July 8, 2009).

With the Series B funds, Viamet hopes to take its independent programs through proof of concept before looking for partners.

Many of the companies Viamet has been spoken with so far have their own metalloenzyme programs, CEO Robert Schotzinger told *BioWorld Today*.

The company's Metallophile technology is used to optimize the metal-binding component of existing inhibitors, including currently marketed drugs. Viamet's metal-binding approach potentially could be used "to resurrect failed compounds from failed programs" or to "make good programs even better," said Schotzinger, former CEO of BioStratum Inc.

He added that Novartis is "looking to us to solve the metal-binding problem."

About a third of known enzymes have metals such as zinc or iron associated with their structure or activity, making metalloenzymes a well-known class of drug targets. Lotensin (benazepril HCl, Novartis AG) and other angiotensin converting enzyme (ACE) inhibitors target metalloenzymes, as does Viagra (sildenafil citrate, Pfizer Inc.).

However, certain classes of drugs that target metalloenzymes tend not be selective enough and can inhibit unintended, related targets. Histone deacetylase inhibitors have had problems with selectivity and matrix metalloproteinase (MMP) inhibitors, a hot angiogenesis-based drug target in the 1990s and early 2000s, also has run into problems in the clinic.

British Biotech plc, of Wokingham, UK, suffered through several failed clinical trials with MMP inhibitor Marimastat in various types of cancer. Celltech Group plc and several big pharmas also stumbled with MMP inhibitors.

Viamet raised \$4 million in a Series A financing to support preclinical development work, and prior to that it operated on about \$500,000 in seed funding provided by Inter-south Partners, which incubated the company in its Durham, N.C. facilities.

The Series A funds allowed Viamet to find its own space and expand its team. (See *BioWorld Today*, June 11, 2007.) ■

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## CLINIC ROUNDUP

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- **Alnylam Pharmaceuticals Inc.**, of Cambridge, Mass., started a Phase IIb trial in adult lung transplant patients with ALN-RSV01, an RNAi therapeutic for respiratory syncytial virus infection. The study, expected to enroll 76 patients randomized to receive either ALN-RSV01 plus standard of care or placebo plus standard of care, will test the reduction in incidence of new or progressive bronchiolitis obliterans syndrome, a life-threatening complication. Secondary endpoints include assessments for safety and additional measurements of efficacy, including antiviral activity, recovery of lung function and improvement of RSV symptoms.

- **BioSante Pharmaceuticals Inc.**, of Lincolnshire, Ill., reported additional positive safety data from its ongoing Phase III trial of LibiGel and said the data monitoring committee unanimously recommended continuation of the study under the FDA-agreed protocol, with no modifications. The cardiovascular and breast cancer safety study is designed to enroll between 2,400 and 3,100 women who are exposed to LibiGel or placebo for 12 months. Pending further positive data, BioSante is targeting mid-2011 for submitting a new drug application.

- **EnzymeRx LLC**, of Paramus, N.J., completed enrollment in a Phase I trial of pegsitacase (formerly Uricase-PEG

20), a pegylated uricase in development for refractory gout and the management of hyperuricemia associated with tumor lysis syndrome. The drug was found to be well tolerated, with no infusion reactions. The company recently launched a Phase Ib trial to study multiple doses of the drug. Results from that trial are expected later this year.

- **Merrimack Pharmaceuticals Inc.**, of Cambridge, Mass., said the first patient received an initial dose in a Phase I/II study combining MM-121 with Tarceva (erlotinib, Genentech Inc. and OSI Pharmaceuticals Inc.) in patients with non-small-cell lung cancer. The study is designed to evaluate safety and pharmacokinetics, establish a safe combination regimen and test its efficacy. MM-121 is a monoclonal antibody aimed at blocking signaling of the ErbB3 receptor. Merrimack and partner **Sanofi-Aventis Group**, of Paris, expect to initiate further Phase II trials in 2010.

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## OTHER NEWS TO NOTE

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- **Amgen Inc.**, of Thousand Oaks, Calif., said the FDA evaluated the company's complete response submission for Prolia (denosumab) in the treatment of postmenopausal osteoporosis and classified it as a Class 2 resubmission, with an action date of July 25, 2010. (See *BioWorld Today*, Feb. 10, 2010.)