

Essentialis Taps Insiders For Series B, Shops Triglyceride Drug

By [Brian Gormley](#)

10/11/2010

Essentialis Inc., which has seen good results from mid-stage trials of a drug aimed at patients with very high triglyceride levels, has raised new Series B funding as it shops the compound to potential corporate partners, according to one of its executives.

Insiders Forward Ventures, Palo Alto Investors, Technology Partners and Vivo Ventures provided an undisclosed amount of capital over the summer, said Chief Commercial Officer Aaron D. Berg. He declined to discuss Essentialis' financing history, but VentureWire previously reported that the company closed a \$14 million Series A round in 2007.

Essentialis's drug is designed to lower triglycerides to prevent pancreatitis, or damage to the pancreas. High blood-triglyceride levels also can increase the risk of coronary artery-disease in some people. Essentialis targets patients with triglyceride levels of 500 milligrams per deciliter or higher. Below 150 milligrams per deciliter is normal.

In Phase II studies, the drug lowered triglyceride levels in a manner comparable to Lovaza, a drug now used to prevent pancreatitis in this patient population, according to Berg.

An added benefit is that Essentialis's drug didn't increase low density lipoprotein, or bad cholesterol, he said. Lovaza can increase LDL levels in some patients, according to GlaxoSmithKline PLC, which markets the drug.

Essentialis doesn't expect that it will need to prove that its therapy reduces the number of pancreatitis cases to gain U.S. approval. Demonstrating an ability to lower triglyceride levels should be sufficient, according to Berg.

If Phase III trials were to get underway now, the drug could earn U.S. approval in 2013, he said. The drug's promise led Essentialis's venture backers to provide the funds needed to pitch corporations that could finance these studies.

Corporate interest in triglyceride medicines has grown as their potential has become clear. In 2006, for example, Abbott Laboratories bought Kos Pharmaceuticals Inc. to obtain Niaspan, which lowers triglyceride and LDL levels while elevating high-density lipoprotein, or good cholesterol.

Niaspan 2009 sales were \$855 million, Abbott said in January. Meanwhile, triglyceride-lowering medicines TriCor (fenofibrate) and Trilipix (fenofibric acid) combined for \$1.3 billion in 2009 sales, the company said.

Essentialis said its drug offers similarly big potential to a company that explores all of its therapeutic possibilities. The product, called DCCR, is a novel, crystalline salt of diazoxide, a potassium-channel agonist, or activator. Diazoxide, first synthesized about 40 years ago, is the basis of Proglycem, a treatment for hypoglycemia, or low blood glucose.

San Diego-based Essentialis has developed an oral, once-daily formulation. Because of diazoxide's history of safe use, it has been able to pursue a 505(b)(2) regulatory route, an expedited pathway that enables a company to build on the safety data gathered from previous studies.

"There's no surprises left with DCCR because there's such a history," Berg said.

The drug's side effects include modest fluid retention and a mild, initial increase in blood glucose, Berg said. Over time, DCCR reduces insulin resistance, so in theory it could lead to a net reduction in blood glucose levels, he said.

DCCR has other effects that could expand its market potential. Patients with high triglycerides may have other medical problems, such as obesity and hypertension. DCCR helps reduce waist circumference and has a modest but significant ability to lower diastolic and systolic blood pressure, Berg said.

Since patent protection on DCCR extends to 2028, there's time for a company to run additional studies to expand the drug's label and to make a return on the investment, he said.

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