

May 20, 2009

Elixir Inks \$500M Novartis Option Deal and Closes \$12M Financing

By Trista Morrison
Staff Writer

Elixir Pharmaceuticals Inc. signed a potential \$500 million deal giving Novartis AG the option either to exclusively license worldwide rights to Elixir's ghrelin antagonist program for diabetes or to acquire the biotech outright.

Paul Martha, president and CEO of Cambridge, Mass.-based Elixir, said the deal includes an up-front payment as well as milestone payments. Additional financial details were not disclosed, but Martha told BioWorld Today that some of the milestone payments will be due before the trigger for the acquisition option.

That trigger falls after Elixir successfully completes a Phase IIa trial with its lead small-molecule ghrelin antagonist. The compound is just now beginning investigational new drug application-enabling toxicology studies, Martha said, and a Phase I trial is slated to begin in the first half of next year.

Elixir has published data showing that ghrelin, a naturally occurring hormone secreted by the stomach, serves as a master regulator of metabolism, and that knockout mice lacking the ghrelin receptor have an improved metabolic profile regardless of diet. In preclinical studies, Elixir's ghrelin antagonists decreased body weight, improved blood glucose and insulin levels, lowered liver fat and improved liver function.

Dion Madsen, managing director of Elixir investor Phycis Ventures, said the company believes its small-molecule ghrelin antagonist program is the most advanced in development. He noted that the ghrelin receptor's "unique chemistry" has made it a challenging target for drug developers, but Elixir was able to develop its own program internally.

Elixir's early data were enough to pique the interest of Novartis, which had been an investor in Elixir since late 2007. Martha said Novartis originally had a first right of negotiation for several of Elixir's preclinical programs, but the new ghrelin antagonist deal ends the other options.

If Novartis decides not to acquire Elixir after seeing the Phase IIa data, the pharma still may exercise an exclusive worldwide option to develop and commercialize the ghrelin antagonist program.

The structure of the deal mirrors others done by Novartis' MPM Bio IV NVS Strategic Fund LP this year. In March, the fund made an undisclosed up-front payment to Proteon Therapeutics Inc. as part of a potential \$550 million deal that could end in an acquisition if all goes well with Phase II trials of Proteon's drug to improve arteriovenous fistula surgical procedures. (See BioWorld Today, March 6, 2009.)

Madsen said the arrangement with Novartis does "potentially cap some upside," but in exchange the company gets a very involved pharma partner, validation and milestone payments along the way. The deal "really gave us a path forward to liquidity," he added.

In addition to the potential \$500 million Novartis option deal, Elixir announced Tuesday that it closed a \$12 million equity round. The financing was co-led by existing investor MPM Capital on behalf of the MPM Bio IV NVS fund, and Physic Ventures, and included existing investors ARCH Venture Partners, Oxford Bioscience Partners and the Omega Fund.

Elixir previously raised a \$28 million Series D in 2007 and a \$46 million Series C in 2006. The company aimed for an \$86 million initial public offering in 2007 but later withdrew its filing. (See BioWorld Today, Nov. 29, 2006, and Sept. 25, 2007.)

Martha said the new equity investment will last "well into next year." Including the money from the Novartis deal, Elixir has more than a year's worth of funding.

While the new money will help advance the ghrelin antagonist program, Madsen emphasized that Elixir "isn't just a ghrelin company."

Within the ghrelin space, Elixir also has an investigational new drug application open for its ghrelin agonist program for cachexia (wasting) and diabetic gastroparesis. But beyond ghrelin, the company has a preclinical sirtuin program and two Phase III diabetes drugs, Glinsuna and Metgluna.

Glinsuna (mitiglinide) is a short-acting insulin secretagogue that's already marketed in Japan by Tokyo-based Kissei Pharmaceutical Co. Ltd. for treating diabetes. Elixir licensed North American and Latin American rights to the compound, which would compete with marketed meglitinide products like Starlix (nateglinide, Novartis AG) and Prandin (repaglinide, Novo Nordisk A/S).

During its pre-new drug application meeting, the FDA asked Elixir for a pivotal trial combining Glinsuna with the widely prescribed diabetic drug metformin in U.S. patients, specifically minorities.

The company announced positive data from that trial last fall, and Martha said Elixir is "looking at strategic relations with partners" before filing a new drug application for Glinsuna or for Metgluna, a fixed-dose combination of mitiglinide plus metformin.