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Psylin Neurosciences, Amylin's Psych-Drug Offspring, Nearing First Clinical Trial

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There are still great voids in understanding the effects of even approved psychiatric drugs. But there's no doubt that the business of selling antidepressants and the like can be extremely lucrative. Psylin Neurosciences—a joint venture of San Diego-based Amylin Pharmaceuticals and New York drug research firm PsychoGenics—is very much a product of both of those realities. And now Psylin has identified its first potential product, a peptide drug for depression. The company says its drug candidate could help boost peoples' moods while providing the added benefit of helping them drop weight, which, of course, could be very lucrative.

Psylin plans to complete toxicity and other tests on the drug, dubbed "PSN0041," with the intent of asking the FDA for permission to start an initial clinical trial in early 2010, says William Rote, the chief operating officer of Psylin, who is also a vice president of business development and New Ventures at Amylin. Amylin and PsychoGenics, which is based in Tarrytown, NY, have together committed \$20 million to fund Psylin through the first clinical trial, Rote tells me.

Identifying its first drug candidate is a major step for two-year-old Psylin. Amylin (NASDAQ:AMLN), which markets peptide-based drugs exenatide (Byetta) and pramlintide (Symlin) for Type 2 diabetes, has long suspected that among its vast library of peptide hormones are some with the potential to treat psychiatric disorders. Several years before the formation of Psylin, Rotes says, Amylin contracted PsychoGenics to use its proprietary psychiatric drug screening technology to determine whether its peptides were in fact capable of treating psychological disorders. When the testing showed such potential, Amylin decided that a joint venture with PsychoGenics would be the best way for the company to move into the psychiatric drug market, Rote says.

"With each company bringing very different pieces to the puzzle," Rote says, "the whole becomes greater than the sum of the parts."

There's no shortage of depression treatments already on the market—which is valued at about \$12 billion annually in the U.S.—but there's also no shortage of side effects. Popular antidepressants such as



fluoxetine hydrochloride, marketed as Prozac and other trade names, can cause sexual dysfunction. Others are linked to weight gain, and some just plain don't work on some patients. Such drawbacks make Rote feel optimistic about the prospects for Psylin's antidepressant, which he and other executives call "41" for short.

In lab tests, the drug has provided hints that it treats depression as well as anxiety. Other clues give the team at Psylin hope that there are other perks of the drug, including weight loss, cognitive improvement, and a lack of sexual side effects. Of course, it's extremely early in the game to be promising anything about this drug. Exactly how the drug works at the molecular level is unknown, Rote says, and history has proven that drugs that work in lab mice and rats often don't provide the same benefits to humans.

Another hurdle is there are only hints (and no way of knowing for sure) whether a mouse or rat is de-

pressed, Rote says. Yet PsychoGenics appears to be one of the best in the business at testing the effects of psychiatric drugs in lab rodents. Rote explains that the company has recorded behavioral trends among mice and rats treated with all psychiatric drugs known to be effective. The effects of experimental drugs are compared with the effects of proven drugs, and a computer system programmed to recognize behavioral trends provides feedback on whether an experimental drug could work. How can one tell whether a mouse is depressed? One popular way, known as the forced swimming test, involves dropping a mouse into a container of water and

watching how long it struggles to stay afloat. Depressed mice tend to give up quicker than their cheery counterparts. Again, this isn't perfect science.

Amylin, of course, brings knowledge of peptides to the Psylin venture. The firm's peptide hormones are synthesized chains of amino acids. Rote says data from the PsychoGenics animal tests help Amylin scientists tweak the form of the peptides to optimize their effects.

Psylin has no offices or employees of its own, but rather exists virtually in the labs and offices of its corporate parents. This organizational

scheme is cheaper than launching a company with separate offices and executives, Rote says. Also, the chief executive responsibilities are shared by Mark Gergen, senior VP of corporate development at Amylin, and PsychoGenic's CEO, Emer Leahy, are co-CEOs of Psylin.

"Psylin's been the first company that we have formed through this [joint venture] process and to date has been very successful," Rote says. "It's been a productive collaboration and we've moved very quickly." ■

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