xconomy

LIFE SCIENCES, PHARMACEUTICALS, DEALS

Acorda Acquires Medtronic Drug, Fills Out Mid-Stage Neurology Pipeline

Arlene Weintraub 7/1/11

Today Hawthorne, NY-based Acorda Therapeutics (NASDAQ: ACOR) announced that it licensed an experimental compound to treat spinal cord injury from medical-device giant Medtronic (NYSE: MDT). Acorda paid $3 million up front for worldwide rights to the compound, and pledged up to $32 million in regulatory and development milestone payments to Medtronic, which is based in Minneapolis. Medtronic will also receive a "single digit" percentage royalty if the product is commercialized, Acorda says.

The Medtronic deal is part of Acorda's grand plan to build up its Phase 2 pipeline of drugs to address unmet medical needs in neurology. The fast-growing company already has two marketed products—dalfampridine (Ampyra) to treat multiple sclerosis, and tizanidine hydrochloride (Zanaflex) to relieve muscle spasms—plus one drug in Phase 1 clinical testing and two more on the way. "But we have nothing in the middle," said CEO Ron Cohen in a phone interview this spring, when he hinted the company was on the hunt for molecules to acquire. "To diversify our risk and leverage our core expertise—neurological therapeutics—we feel we need to have middle-stage projects."

The Medtronic compound, which Acorda will call AC105, is a modified form of the mineral magnesium. It has long been known that a loss of magnesium after spinal cord injuries creates a cascade of problems that lead to the loss of motor function that commonly results. "If you can restore magnesium to proper levels, you can protect the tissue" in the brain and spinal cord, says Acorda's chief scientific officer, Andrew Blight.

Problem is, it's difficult to give magnesium to patients in high enough levels without causing dangerous side effects, such as heart and brain issues. So Medtronic created a formulation of the mineral that includes polyethylene glycol. That improves the process of getting magnesium from the blood to the injured nervous system, but without the need for the large magnesium doses that raise the risk for serious side effects. In rodent models of spinal cord injury, the drug promoted recovery of some movement to paralyzed limbs and performed better than simple magnesium salt formulations that have been tried in the past.

There are about 12,000 incidents of spinal cord injuries in the U.S. every year. But Blight believes that AC105 may prove useful in other neurological applications, too, such as traumatic brain injury. "Anything that's useful in spinal cord injury is likely to be useful in other conditions, as well," he says. Medtronic has already done a Phase 1 safety study in healthy volunteers, so Acorda is picking up the project in time to plan the Phase 2 program in spinal cord injury.

Acorda is also moving forward on compounds in its early-stage pipeline—including one that may take the company beyond its neurology comfort zone. Glial Growth Factor 2 (GGF2) is a "neuregulin"—a molecule that stimulates tissue repair in the nervous system. Acorda licensed GGF2 from a company called CeNeS Pharmaceuticals (now owned by Paion) in 2002. Since then, Acorda has been examining the compound in animal models of multiple sclerosis, Parkinson's disease, and stroke.

In the course of those studies, Acorda's scientists recognized that GGF2 was showing promise in cardiology. "Neuregulins are potent stimulators of cardiomyocytes—the muscle cells in the heart," says Anthony Caggiano, V.P. of research and development for Acorda. "What's exciting for us is that it's very clear that these are naturally occurring growth factors that have broad and potent effects on the heart." Acorda has begun a Phase 1 study of GGF2 in patients with heart failure.

Even though the cardiology project takes Acorda beyond its core neurology expertise, Cohen believes it's important to pursue, because the company needs to be nimble and opportunistic, he says. "We're going where the science takes us," Cohen says. "If we show proof-of-concept, we'll have a decision to make: create a cardiology department or partner with someone else."

Further back in the development pipeline is rHIgM22, an antibody that Acorda licensed from the Mayo Clinic a decade ago. Acorda has shown that the compound stimulates remyelination in animal models of MS—meaning it restores the protective sheath around axons, which in turn restores electrical signals between neurons. Acorda hopes to file for approval from the FDA to begin human trials of rHIgM22 "as soon as we can," Caggiano says.

And AC105 isn't the only spinal-cord-injury play in Acorda's pipeline. Another early-stage compound that the company is studying is chondroitinase, an enzyme that may also help patients with such injuries. The company's animal studies have shown that the enzyme promotes the recovery of visual and motor functions in injuries to the brain or spinal cord. Caggiano says Acorda will need to do more preclinical work on the compound before the company can determine its potential for human use.

It remains to be seen how investors will react to the addition of Medtronic's compound to Acorda's pipeline. But a string of good news has already prompted investors to horde the company's stock. In mid-April, rumors emerged that Acorda's patent exclusivity on dalfampridine might be extended from 2018 to 2026—creating such a frenzy on Wall Street that trading in the company's shares was halted temporarily. The company confirmed the rumors on April 19.

The extra years of patent protection could make a huge difference in the development plan for dalfampridine, Cohen says. "Having a runway out to 2026 substantially changes the risk/benefit equation," he says. "We're more likely now to invest in new trials to see what the drug will do."

Acorda's stock got more of a boost on May 20, when the European Medicine Agency (EMA) recommended conditional marketing approval of the overseas version of dalfampridine, which will be marketed by Biogen Idec. All told, Acorda's stock has jumped more than 50 percent since April 14, trading at about $32.40 before the Medtronic announcement.

Some analysts believe investors are still undervaluing Acorda. Lazard Capital Markets analyst Joel Sendek wrote in a May report that the patent extension alone makes Acorda an "attractive acquisition target, given its steady cash flow, profitability, and fielded sales force which can be easily incorporated into a larger commercial organization, with greater economies of scale." He estimates Acorda will pull in sales of $283.7 million this year—up 50% from last year—and it will turn a profit this quarter. His price target for the company's stock is $37.

Cohen declines to comment on acquisition speculation, preferring instead to focus on the task at hand. "Our mission is to develop therapies that restore function and improve the lives of people with neurological disease," he says. "Now that [dalfampridine] is out and providing a revenue stream, we can leverage our expertise and develop the next great drug to help people with these terrible diseases."

Arlene Weintraub is the editor of Xconomy New York. She can be reached at aweintraub@xconomy.com and followed on Twitter @awjourn.