

es Depression Drug That Works In One Day Passes Key Test

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Luke Timmerman

CONTRIBUTOR

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Good drugs for depression have been around for years, but they tend to take weeks to kick in, and don't work for everyone. Millions of people still need more help.

Now a little biotech company, [Naurex](#), is gathering data that suggests it may have a drug that works faster and better than anything on the market.

Naurex, a private company founded by a [Northwestern University](#) professor in Evanston, Ill., is reporting today that an experimental drug with a new biochemical way of working helped push patients out of a major depressive state within 24 hours of getting a single intravenous shot. The company-sponsored study, which enrolled 140 patients at a dozen U.S. medical centers, showed the new drug had no severe side effects and was significantly more effective than a placebo. The difference was both statistically significant—meaning it was unlikely the result of random chance—and clinically meaningful, said Susan McElroy, one of the study's investigators. The next step is to see if the company can repeat the success in another clinical trial with a once-daily oral pill form of the drug, which could achieve broad use in the real world. If the drug can be consistently shown to work within a single day, it would be a godsend for many patients who currently have to wait weeks to see if they will get any relief.

“If these results can be replicated, they are almost revolutionary. They will change the treatment of depression,” said [Dr. McElroy](#), a study investigator and professor of psychiatry and behavioral neuroscience at the [University of Cincinnati](#) College of Medicine.

While millions of people manage depression with generic drugs known as selective serotonin reuptake inhibitors (SSRIs), those molecules tend to take two to six weeks to start working and fail to help millions of patients. Each year, about 6.7 percent of U.S. adults are estimated to experience a major depressive episode—defined as depression that interferes with the ability to work, sleep, study, eat, and enjoy life, [according to the National Institute of Mental Health](#). An estimated 4 million people in the U.S. every year are thought to have depression that persists after treatment with two different SSRI drugs.

Part of what’s intriguing about the Naurex compound is that it doesn’t go down the same tried-and-true biochemical pathway as existing SSRI drugs like sertraline (Zoloft) and paroxetine (Paxil), or a related class of serotonin and norepinephrine reuptake inhibitors (SNRIs) like venlafaxine (Effexor) and duloxetine (Cymbalta). Instead, the Naurex drug is designed to interact with what’s known as the brain’s [NMDA receptor](#), which plays a role in the formation of synaptic connections and memories.

Scientists have known for years that a common anesthetic called [ketamine](#) blocks the NMDA receptor, and that it curiously can resolve depression symptoms. That observation has spurred about a half-dozen drugmakers, [including Johnson & Johnson](#), to see if they can develop new antidepressants that work on the NMDA receptor, but without causing the delusions and hallucinations sometimes seen when people take ketamine in high doses. Because of that troubling effect, ketamine has been abused as a party drug with the street name of “[Special K](#).”

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Naurex has developed a variety of drugs that work on the NMDA receptor, with an eye toward tweaking it to get the antidepressant effect without the hallucinations. The drug it is reporting on today, dubbed NRX-1074, is designed, in part, to stimulate the target, rather than shut it down.

The data gathered so far are encouraging, but preliminary. Patients with major depressive disorder were enrolled in the study, based on the standard [Hamilton rating score](#) in which medical professionals conduct a detailed interview about depression symptoms. About 72 percent of patients in the study had what was considered to be a clinically meaningful response to the new drug within 24 hours, compared with 39 percent who did that well on a placebo. The difference was statistically significant at the highest of three doses studied, and patients appeared to do best at the highest dose. The magnitude of benefit at that dose seen was about twice as high, after just 24 hours, as what is typically seen with standard antidepressants after four to six weeks, Dr. McElroy, the study investigator, said. Patients weren't cured. But in practical terms, they went from severe depression to a mild state, she said. Patients with the most severe depression, those who told clinicians they've had suicidal thoughts, were excluded from the trial for safety reasons. Detailed results are expected to be presented at a medical meeting, and submitted for publication in a peer-reviewed journal.

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As with any small clinical trial, there are a number of caveats to consider. The benefits of the single shot didn't last long, disappearing at the two-week follow-up visit. The Naurex drug was given in an intravenous form, which can only be administered in a medical facility. The drug is also a peptide molecule. While Naurex has re-engineered it into a more convenient oral pill form, it is a difficult feat of chemistry to make a peptide into a pill. Ensuing studies will need to show that the oral pill works in larger numbers of patients, in repeat doses, at multiple clinical sites, and that it likely offers a benefit beyond existing anti-depressants. The FDA likely will ask the company for long-term follow-up data to assess the safety of a drug that would likely be taken by many people on an ongoing basis.

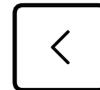
Naurex is planning to start the next clinical trial of NRX-1074 in April or May, said Norbert Riedel, the company's CEO. By July, it plans to start another trial of a different drug, rapastinel, that is further along in development, but which is only available in the IV form, and in combination with existing antidepressants. Naurex is also developing other molecules that interact with the same target, and it hopes they will be useful for more than just depression. The list of potential uses includes dementia and neuropathic

pain, Riedel said.

Although [Naurex raised \\$80 million of venture capital](#) last month, it would need more money to run an ambitious slate of clinical trials for multiple neurological disorders. The company is considering going public to take advantage of optimistic investor sentiment toward biotech stocks. “This is not just a depression company. It’s a CNS (central nervous system) company we are building,” Riedel said.

Luke Timmerman is the founder and editor of [Timmerman Report](#), a subscription publication for biotech professionals.

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