Seelos Therapeutics

20:00 25 Apr 2019

Seelos Therapeutics has catalysts for its ketamine depression drug, multiple shots on goal with a strong pipeline

• The New York clinical stage biopharmaceutical company focuses on central nervous system, neurological and psychiatric disorders • At the helm of the company is scientifically trained Raj Mehra, who founded Seelos in 2016 • Wall Street is bullish about the company's SLS-002 intranasal ketamine depression drug aimed at patients with post-traumatic stress disorder (PTSD) and major depressive disorder (MDD) at risk of committing suicide • Seelos plans to begin its pharmacokinetics and pharmacodynamics study linked to SLS-002 in the second half of 2019 • The company has other late-stage pipeline products like SLS-005 which target rare orphan diseases

Company overview

Seelos Therapeutics Inc (NASDAQ:SEEL) is a New York clinical stage biopharmaceutical company focused on central nervous system, neurological and psychiatric disorders.

In January, Seelos transitioned into a Nasdaq-listed company by completing a reverse merger with Apricus Biosciences.

At the helm of the company is scientifically trained Raj Mehra who founded Seelos in 2016. Mehra has five degrees, including a Ph.D and MBA from Columbia University.

"What gets me excited is reading 20 to 30 scientific articles - that's where you see how much we don't know and the gaps we can fill," Mehra told Proactive Investors.

Mehra developed a sixth sense for biotech over three decades of investing, by building a robust portfolio of companies and turning risk into profit. He worked nine years at Auriga USA as a managing director focused on equity investments in global health care companies. He has also managed a large hedge fund.

Blockbuster ketamine depression drug

Once dismissed as a "party drug" for its hallucinogenic effects, ketamine is emerging as a novel alternative treatment for depression. The approval last month of Johnson & Johnson's (NYSE:JNJ) ketamine-derived depression treatment shines a light on Seelos which is advancing its own medication for depression.

Wall Street is bullish that Seelos Therapeutics' SLS-002 intranasal ketamine depression drug under development is safe and will reach millions of patients with post-traumatic stress disorder (PTSD) and major depressive disorder (MDD) at imminent risk of committing suicide.

J&J's nasal spray SPRAVATO and Seelos' SLS-002 nasal spray both have formulations of ketamine, with subtle differences. J&J's nasal spray contains the esketamine compound, which is one half of the ketamine compound. However, Seelos Therapeutics' nasal form of racemic ketamine is made of two mirror-image molecules and is likely to

Price:	US$2.12
Market Cap:	US$45.11M

1 Year Share Price Graph

Share Information

Code:		SEEL
Listing:		NASDAQ
52 week	**High**	**Low**
	$13.95	**$1.33**
Sector:		**Pharma & Biotech**
Website:		**seelostherapeutics.com**

Company Synopsis:

Seelos Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and advancement of novel therapeutics to address unmet medical needs for the benefit of patients with central nervous system (CNS) disorders and other rare disorders. The Company's robust portfolio includes several late-stage clinical assets targeting psychiatric and movement disorders, including orphan diseases.

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be given at a lower dose because it is far more potent.

"J&J's SPRAVATO is the single isomer (the S isomer) of ketamine, whereas our SLS-002 product is the racemic version, which means it contains both the R and S isomer in equal proportions," said Mehra.

A Zanos publication shows in the animal depression model, that racemic/R ketamine has more potency and minimal side effects versus S-ketamine. The R isomer also lacks the negative psychoactive effects associated with ketamine.

"SPRAVATO is treating treatment-resistant depression, while we are treating suicidality with underlying PTSD or major depressive disorder," said Mehra. "The key benefit for SLS-002 is that we hope to get these patients out of the ER/psychiatric hospital sooner using our drug."

Inflection points
Seelos plans to kick off its pharmacokinetics and pharmacodynamics study in the second half of 2019.

"After we complete the study and review the data, Seelos plans to request a post-Phase II meeting with the FDA to discuss trial design requirements for a pivotal study," said Mehra.

SLS-002 is a lower dose of ketamine compared to its use in the anesthetic setting. The risk of misuse has been addressed, according to the company as SLS-002 will only be administered in a physician's clinic, or ER and will come as a single-use device making it safe and convenient.

Orphan drug
The company has strong late-stage pipeline drugs, like SLS-005, which target rare orphan diseases. SLS-005, or trehalose, is a protein stabilizer, that will begin a pivotal trial in Sanfilippo Syndrome in the second quarter, fully funded by the Team Sanfilippo Foundation.

Sanfilippo is a rare genetic condition in which the body doesn't have certain enzymes to break down long chains of sugar molecules and it can cause fatal brain damage. It's referred to as a childhood disease because sadly most patients never reach adulthood.

The Team Sanfilippo Foundation is finalizing the protocol for an up to 20 patient open-label Phase 2B study. Seelos will provide the drug for the 52-week study as well as an extension study and own the data that comes out of the trial. The first patient with Sanfilippo is expected to be dosed with trehalose in the Phase 2b trial in the second quarter of 2019.

SLS-005 has safe and effective data in other disorders such as OPMD, which is a type of muscular dystrophy, and Spinocerebellar ataxia type 3 (SCA3), a condition characterized by progressive problems with movement, which the company may pursue after Sanfilippo.

Parkinson's disease therapy
Seelos has exclusively in-licensed the rights to a potential disease-modifying Parkinson's disease therapy created by researchers at the University of California, Los Angeles (UCLA). As a result, it has the rights to a family of peptide inhibitors from UCLA that target the aggregation of alpha-synuclein (α-synuclein).

The function of α-synuclein proteins in the healthy brain is unknown, but Parkinson's researchers are interested in it because it is a major constituent of Lewy bodies, protein clumps that are the pathological hallmark of the neurological disorder.

Seelos has named the new program SLS-007, with an initial focus on Parkinson's disease.

Seelos will evaluate the potential for in-vivo delivery of SLS-007 in a Parkinson's disease transgenic mice model in the second quarter.

"Alpha-synuclein is a normal protein that all of us have," said Mehra. "But it turns out that in Parkinson's patients the

accumulation of alpha-synuclein is always present and that has been identified as a key target."

Addressable market
The market for the SLS-002 depression drug is substantial, more than 900,000 people were admitted to the ER for suicidality last year.

On the other hand, SLS-005 could be a lifeline for about 1,000 children in the US who suffer a rare pediatric orphan disease.

The drug is also aimed at disorders such as OPMD, which is a type of muscular dystrophy, which has 20,000 patients worldwide. Again, SLS-007 has a more sizable addressable market as there are six million patients worldwide with Parkinson's disease.

A bullish investment case
Seelos completed a capital raise in conjunction with the Apricus Biosciences reverse merger in Janary, so it is sitting pretty with $18 million in cash and investments.

"For a small company, Seelos has multiple assets in development with massive potential. Success in any one program justifies the investment at this time," says Mehra. "Having three strong candidates is almost like having three companies under one roof. It gives us multiple shots on goal."

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