Zynerba Pharmaceuticals

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Zynerba boosts cash position in 2Q, gears up for top-line data from key trials with Zygel CBD gel

Zynerba Pharmaceuticals Inc (NASDAQ:ZYNE) reported second-quarter earnings Tuesday that showed raised cash reserves as it heads into key trials and also said it expects top-line data from four neuropsychiatric disorder trials with the company's lead development candidate, Zygel.

The Devon, Pennsylvania-based company revealed that, as of June 30, it had cash and cash equivalents of $88.7 million, compared to $59.8 million on December 31. Included in that cash pile was $27 million in net proceeds from the sale of 2,082,031 shares at $13.50 per share during the second quarter.

Management said the company's $88.7 million war chest plus the anticipated proceeds from an Australian R&D cash credit will be "sufficient" to fund operations beyond the expected "New Drug Application submission and potential approval of Zygel in Fragile X syndrome and into the second half of 2021."

In July, Zynerba secured a positive decision from the Australian government regarding qualifying research cash credits spread over three years starting in 2018. In its statement, the company said this will generate $7 million to $9 million in cash tax credits over the next 18 to 24 months.

"We extended our cash runway into the second half of 2021," said Zynerba Pharmaceuticals CEO Armando Anido. "This all sets the stage for the next 12 months to be potentially transformational as we report out on our FXS pivotal trial, and our Phase 2 trials in DEE, autism spectrum disorder and 22q."

For the quarter ended June 2019, the company reported a loss of $11.1 million, or $0.50 per share. Research expenses for the quarter amounted to $8.2 million.

Top-line results from CONNECT-FX study in 2020
The company said it is on track to report top-line results from tests of Zygel, a CBD gel treatment for children and adolescents with Fragile X syndrome, the most common form of inherited learning disability and autism spectrum disorder.

Anido emphasized that pivotal data will now be available in the first half of 2020 from the CONNECT-FX study.

Zygel was earlier referred to as ZYN002 before the company selected the new brand name for the patent protected CBD skin gel.

Results from Phase 2 FAB-C clinical trial
Zynerba also shared data on Tuesday from the Phase 2 FAB-C clinical trial evaluating the potential of Zygel in children with Fragile X syndrome.

Price:	5.38
Market Cap:	$124.81 m

1 Year Share Price Graph

Share Information

Code:		ZYNE
Listing:		NASDAQ
52 week	**High**	**Low**
	16.46	**3.66**
Sector:		**Pharma & Biotech**
Website:		**zynerba.com**

Company Synopsis:
At Zynerba Pharmaceuticals, our team is dedicated to developing next-generation transdermally-delivered cannabinoid therapeutics for patients affected by rare and near-rare neuropsychiatric conditions. Often, these diseases have few, if any, treatment options and can leave patients and their families feeling helpless and alone.

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The results published in the "Journal of Neurodevelopmental Disorders" highlighted:

- Patients experienced a marked 12-week improvement over baseline scores for the majority of study efficacy endpoints, including the change from screening to week 12 in the ADAMS total score
- Observed improvements were generally greater than those demonstrated for placebo in prior controlled clinical trials in Fragile X syndrome
- Across assessments, there was improvement in both internalized symptoms like anxiety, social avoidance and externalized symptoms like irritability over the course of treatment

On a separate note, Anido underlined that the CONNECT-FX study design included very "specific entrance criteria."

"Importantly, these entrance criteria have resulted in an enrolled population with more severe behavioral symptoms than the FAB-C study population," he pointed out.

"We believe this will enhance the study's ability to demonstrate a strong signal of activity and minimize response variability."

In addition to Fragile X syndrome, Zygel is also in Phase 2 clinical development in patients with refractory epilepsy, Autism Spectrum Disorder and 22q11.2 Deletion Syndrome, a disorder caused by a small missing piece of the 22nd chromosome. This tiny missing portion of chromosome 22 can wreck every system in the body.

Topline data from BELIEVE 1 in September
Zygel is also being tested for a heterogeneous group of rare and ultra-rare epilepsies known as developmental and epileptic encephalopathies (DEE).

The company said it expects to share topline data from BELIEVE 1, an open label multidose Phase 2 clinical trial evaluating the efficacy and safety of Zygel in children and adolescents with various DEEs, in September.

The primary efficacy assessment is of a reduction in "seizure frequency at week 26" compared to baseline scores, said the company in a statement.

The US Patent and Trademark Office recently granted Zynerba a patent for treating Autism Spectrum Disorder, characterized by challenges with social skills and speech, with CBD.

The patent comes at an opportune time as enrollment speeds up in Zynerba's 14-week, open label Phase 2 BRIGHT study evaluating the safety, and potency of its Zygel CBD gel. Data is expected in the first half of 2020.

In morning trading in New York, shares in Zynerba were 1.6% higher at $9.95.

-- Adds share price --

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