

# Zynerba Pharmaceuticals

10:50 06 Aug 2019

## 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:** 4.92

**Market Cap:** \$114.13 m

### 1 Year Share Price Graph



February 2019 August 2019 February 2020

### Share Information

**Code:** ZYNE

**Listing:** NASDAQ

<b>52 week</b>	<b>High</b>	<b>Low</b>
	16.46	4.39

**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.*

action@proactiveinvestors.com

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 --

Contact Uttara Choudhury at [uttara@proactiveinvestors.com](mailto:uttara@proactiveinvestors.com)

Follow her on Twitter: [@UttaraProactive](https://twitter.com/UttaraProactive)

Proactive Investors facilitate the largest global investor network across 4 continents in 4 languages. With a team of analysts, journalists & professional investors Proactive produce independent coverage on 1000's of companies across every sector for private investors, private client brokers, fund managers and international investor communities.

Contact us +44 (0)207 989 0813 [action@proactiveinvestors.com](mailto:action@proactiveinvestors.com)

**No investment advice**

The Company is a publisher. You understand and agree that no content published on the Site constitutes a recommendation that any particular security, portfolio of securities, transaction, or investment strategy is suitable or advisable for any specific person. You understand that the Content on the Site is

provided for information purposes only, and none of the information contained on the Site constitutes an offer, solicitation or recommendation to buy or sell a security. You understand that the Company receives either monetary or securities compensation for our services. We stand to benefit from any volume which any Content on the Site may generate.

You further understand that none of the information providers or their affiliates will advise you personally concerning the nature, potential, advisability, value, suitability or profitability of any particular security, portfolio of securities, transaction, investment, investment strategy, or other matter.

You understand that the Site may contain opinions from time to time with regard to securities mentioned in other products, including Company-related products, and that those opinions may be different from those obtained by using another product related to the Company. You understand and agree that contributors may write about securities in which they or their firms have a position, and that they may trade such securities for their own account. In cases where the position is held at the time of publication and such position is known to the Company, appropriate disclosure is made. However, you understand and agree that at the time of any transaction that you make, one or more contributors may have a position in the securities written about. You understand that price and other data is supplied by sources believed to be reliable, that the calculations herein are made using such data, and that neither such data nor such calculations are guaranteed by these sources, the Company, the information providers or any other person or entity, and may not be complete or accurate.

From time to time, reference may be made in our marketing materials to prior articles and opinions we have published. These references may be selective, may reference only a portion of an article or recommendation, and are likely not to be current. As markets change continuously, previously published information and data may not be current and should not be relied upon.

The Site does not, and is not intended to, provide investment, tax, accounting, legal or insurance advice, and is not and should not be construed as providing any of the foregoing. You should consult an attorney or other relevant professional regarding your specific legal, tax, investment or other needs as tailored to your specific situation.

In exchange for publishing services rendered by the Company on behalf of Zynherba Pharmaceuticals named herein, including the promotion by the Company of Zynherba Pharmaceuticals in any Content on the Site, the Company receives from said issuer annual aggregate cash compensation in the amount up to Twenty Five Thousand dollars (\$25,000).