Zynerba Pharmaceuticals, (NASDAQ:ZYNE)

Updated November 15, 2019

SUMMARY

SanaCurrents is providing a **pivotal** sentiment rating to the results of a phase II study of ZYN002, a cannabidiol (CBD) gel compound from Zynerba Pharmaceuticals (ZYNE) to treat 3- to 17-year-old patients with Fragile X syndrome. The primary assessments in the phase II study, named CONNECT-FX, should be completed in July 2019 and final evaluations of the data by October 2019.

(*Zynerba subsequently guided the CONNECT-FX trial results would be released in the first half of 2020. If the results are positive, the company plans to file an NDA in 2020*.)

ZYN002 became the primary focus of Zynerba in the last 12 months after another Zyne drug, ZYN001, faltered in an epilepsy trial in 2017. Zynerba essentially ceded the epilepsy market to GW Pharmaceuticals (OTC: GWPRF) after GW's CBD-based drug Epidiolex gained FDA approval in June 2018.

The approval of GW's Epidiolex benefits Zynerba, creating a clear path for CBD- based drugs that can demonstrate clinical efficacy in important diseases. After Epidiolex, the US Drug Enforcement Agency (DEA) in September issued a guideline stating CBD drugs with THC content below 0.1% are now considered Schedule 5 drugs, as long as they are FDA approved. Until September, all cannabis-based formulations were regarded as Schedule 1 drugs, a federal law category reserved for drugs with a high potential for abuse and no medical value, thereby invalidating CBD drugs for commercial use. The DEA guideline creates a new avenue to patients for drugs such as Epidiolex and ZYN002.

Like GW's Epidiolex, ZYN002 addresses a significant unmet need. There are no approved therapies to treat Fragile X syndrome. Moreover, the patient population is genetically identified. In 2016, Zynerba received orphan drug designation for ZYNOO2, which is now branded as Zygel.

THE EDGE

Parents of children with Fragile X have been using CBD products, obtained at medical marijuana dispensaries, as treatments for the past several years, according to a Fragile X researcher. While the dosage is not precise, the results are impressive – fewer uncontrolled outbreaks, less withdrawal and calmer behavior. As a result, parents have been networking on their own to determine the best CBD options, said the researcher. ZYNOO2 can deliver a controlled, prescription treatment alternative, if the CONNECT-FX results are positive.

Zynerba likewise holds an advantage in advancing ZYNOOO2 through its transdermal delivery (skin patch) and the first synthetic CBD formulation as a permeation-enhanced gel. Transdermal delivery allows ZYN002 to bypass the GI tract and the consequent ability of stomach acids to degrade CBD into trace levels of THC, the compound in cannabis plants that produces a psychoactive effect. This in turn leads to more efficient uptake of the liver and reduces potential GI side effects. Also, by producing CBD as synthetic oil, Zynerba should avoid the manufacturing challenges and costs of greenhouse production.

PROBABILITY SENTIMENT

- ☐ SUPERIOR (highest)
- ☑ Pivotal
- ☐ Advantageous

Key Catalyst(s)

- Phase II study of ZYN002 to treat Fragile X

Key Catalyst Date(s)

- **1H 20** (Originally Q3 2019)

Insider & Institutional Holdings

13.78% - % of Shares Held by All Insider

14.72% - % of Shares Held by Institutions

17.07% - % of Float Held by Institutions

76 - Number of Institutions Holding Shares

Key Executives

Mr. Armando Anido M.B.A., MBA, Chairman & CEO

Ms. Terri B. Sebree **Pres**

Mr. James E. Fickenscher, CFO, VP of Corp. Devel. & Treasurer

Mr. William C. Roberts, VP of Investor Relations & Corp. Communications

Ms. Suzanne M. Hanlon, Sec., VP & Gen. Counsel

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Website

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THE EDGE cont'd

One potential flag for ZYN002 is the outcomes are measured by user-recorded data, which can be unreliable if patients are not consistent with their data entries. This problem frequently arises in studies of central nervous system (CNS) drugs. However, given the parent involvement in advancing a treatment for Fragile X, it should not be a concern.

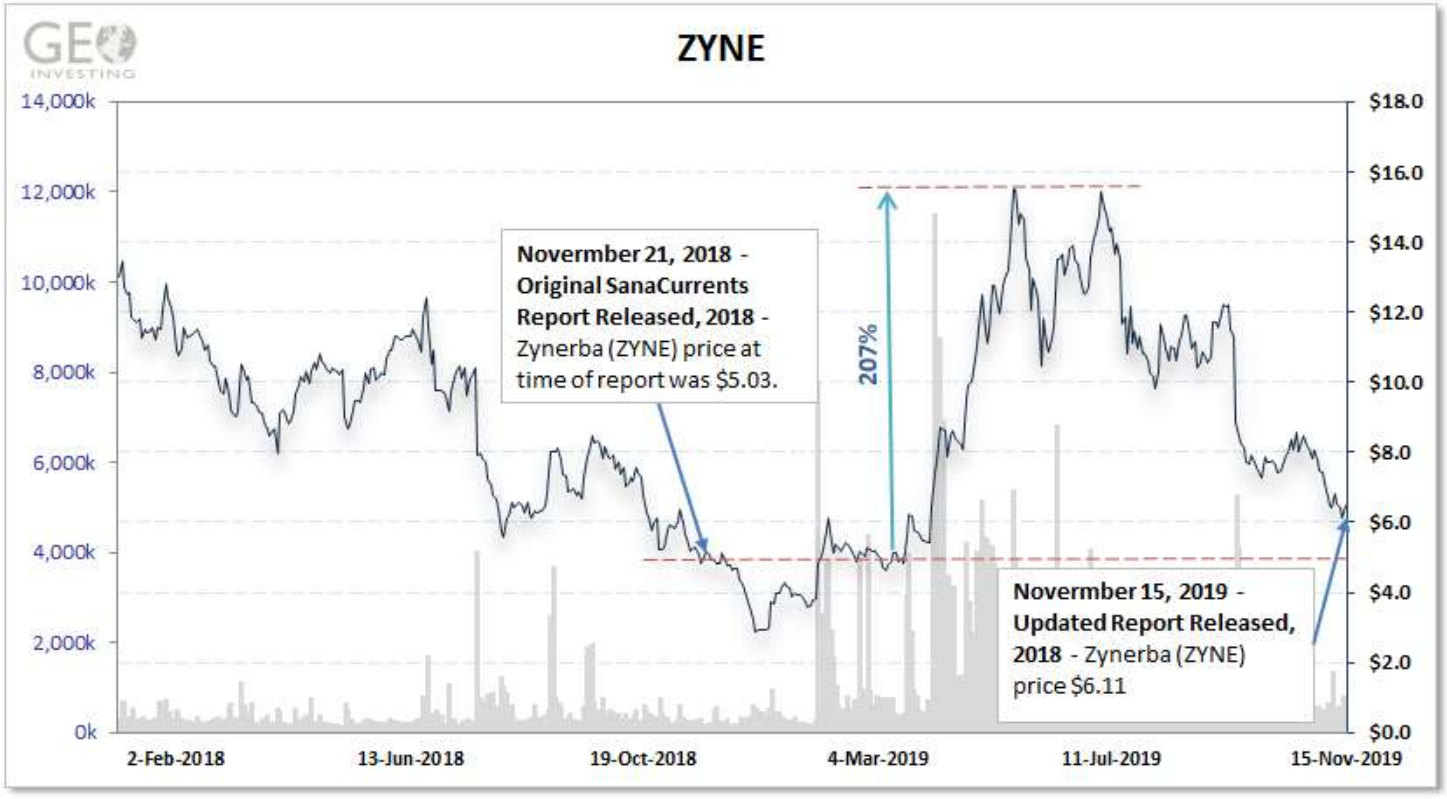
After Zynerba reported positive 12-week results of its 20-patient, ZYNOO2 open label study in Fragile X patients in September 2017, the company's shares rose 42% the next day. That study enrolled patients between 6 and 17 years of age, with a 3:1 ratio in favor of males. The mean age was 10.6.

Zynerba has since reported ZYN002 sustained improvement of core behavioral symptoms of FXS with statistical significance versus baseline through 38 weeks of treatment. In one example, significant improvements vs. baseline in social avoidance as measured by the ABC-CFXS were demonstrated at 12 weeks (58%; p=0.0040) and 38 weeks (75%; p=0.0013) of treatment with ZYN002.

For the CONNECT-FX trial, Zynerba has expanded the 204-patient trial to be conducted at 20 locations in New Zealand, Australia and the US. The company also has hired a manager in Australia for the Australia and New Zealand locations, and recruited local autism specialists to lead the studies at individual locations.

While Zynerba also is testing ZYN002 in two other indications, the company recently closed a $30 million financing aimed at completing the CONNECT-FX trial on time.

Zynerba's stock is approaching its 52-week low. Depending on the length of the recent market turbulence, an entry into ZYNE over the next two months could prove to be beneficial by the second half of 2019, when the CONNECT-FX results are announced.



Zynerba Pharmaceuticals, Inc. (ZYNE) — data provided by Sentieo

Zynerba Pharmaceuticals, Inc. operates as a clinical stage specialty pharmaceutical company. The company focuses on developing and commercializing pharmaceutically-produced transdermal cannabinoid treatments for rare or near-rare neuropsychiatric disorders. Its product candidates include ZYN002, which completed Phase II clinical trial for pediatric and adolescent patients with fragile X syndrome, pediatric and adolescent patients with developmental and epileptic encephalopathies, and adult patients with refractory epileptic focal seizures; and ZYN001 that is in Phase I clinical trial to treat Tourette syndrome. The company was formerly known as AllTranz, Inc. and changed its name to Zynerba Pharmaceuticals, Inc. in August 2014. Zynerba Pharmaceuticals, Inc. was founded in 2007 and is headquartered in Devon, Pennsylvania.

GICS Sector	Pharmaceuticals
GICS Industry	Health Care
Next FQ/FH End Date	12/31/2019
Next FY End Date	12/31/2019
Next Earnings Date	03/09/2020
Latest Earnings Date	11/06/2019

In millions USD, except per share data	
Market Cap	141.74
EV	64.19
Shares Outstandin	17.63
Annual Dividend	0.00
Dividend Yield	0.00
Dividend Payout	0.0%

FIN. SUMMARY			
Period end	12/31/2018	12/31/2019	12/31/2020
Revenue	0.086	0.000	0.000
Gross Profit	0.086	0.000	0.000
Gross Margin	100.0%		
Operating Profit	(40.40)	(44.29)	(51.81)
Operating Margin	-46973.3%		
Net Income	-39.91	-38.41	-48.70
EPS	-2.61	-2.03	-1.89

VALUATION RATIOS	12/31/2019
EV/Sales	
EV/EBITDA	-1.38 x
P/E	-3.02 x
P/B	1.81 x
FCF Yield	-28.15 x

STOCK PRICE PERFORMANCE*	*As of 11/15/2019
Last price	6.11
52 Week High	16.47
52 Week Low	2.75
YTD Change	109.1%
1 Year Change	56.2%
5 Year Change	
10 Year Change	

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