UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8–K

CURRENT REPORT
Pursuant to Section 13 OR 15 (d)
of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **May 6, 2019**

ZYNERBA PHARMACEUTICALS, INC.

(Exact Name of Issuer as Specified in its Charter)

Delaware	**001-37526**	**26-0389433**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

80 W. Lancaster Avenue, Suite 300
Devon, PA 19333
(Address of Principal Executive Offices) (Zip Code)

(484) 581-7505
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ZYNE	The NASDAQ Global Market

Check the appropriate box below if the Form 8–K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a–12 under the Exchange Act (17 CFR 240.14a–12)

☐ Pre—commencement communications pursuant to Rule 14d–2(b) under the Exchange Act (17 CFR 240.14d–2(b))

☐ Pre—commencement communications pursuant to Rule 13e–4(c) under the Exchange Act (17 CFR 240.13e–4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 8.01 Other Events

On May 6, 2019, Zynerba Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration granted Fast Track Designation for the Company's lead development candidate Zygel™ (ZYN002 CBD gel) for treatment of behavioral symptoms associated with Fragile X Syndrome. A copy of this press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

The following exhibits are being filed herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Press Release, dated May 6, 2019.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 6, 2019

ZYNERBA PHARMACEUTICALS, INC.

By: /s/ Suzanne Hanlon
Name: Suzanne Hanlon
Title: Secretary, Vice President and General Counsel

Exhibit 99.1

Zynerba Pharmaceuticals Receives Fast Track Designation for Zygel™ for the Treatment of Behavioral Symptoms Associated with Fragile X Syndrome (FXS)

- Designation Facilitates and Expedites Development of Drugs for Patients with Serious Unmet Medical Needs -

- Enrollment Progressing in Pivotal CONNECT-FX Trial of Zygel in FXS, with Data Expected in the Second Half of 2019 -

DEVON, Pa., May 6, 2019 — Zynerba Pharmaceuticals, Inc. (NASDAQ:ZYNE), the leader in innovative pharmaceutically-produced transdermal cannabinoid therapies for rare and near-rare neuropsychiatric disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for the Company's lead development candidate Zygel™ (ZYN002 CBD gel) for treatment of behavioral symptoms associated with Fragile X Syndrome (FXS). FDA's Fast Track program is designed to facilitate the development of drugs intended to treat serious conditions and fill unmet medical needs, and can lead to expedited review by FDA in order to get new important drugs to the patient earlier.

"The FDA's decision to grant Fast Track Designation for Zygel underscores the significance and severity of the unmet medical need that exists for patients living with Fragile X Syndrome and their caregivers," said Armando Anido, Chairman and Chief Executive Officer of Zynerba. "We believe that Zygel has the potential to be the first treatment indicated to directly address the core behavioral symptoms of this syndrome, and we look forward to working closely with the FDA to obtain approval to market Zygel as soon as possible."

Zynerba is conducting a pivotal trial to assess the efficacy and safety of Zygel as treatment for the behavioral symptoms of FXS in pediatric and adolescent patients (three through 17 years of age). Zygel is a pharmaceutically-manufactured CBD formulated as a patent-protected permeation-enhanced clear gel, designed to provide controlled transdermal drug delivery into the bloodstream.

About Fast Track Designation

Fast Track Designation is intended to facilitate development and expedite review of drugs to treat serious or life-threatening conditions so that a product can reach the market expeditiously. A drug that is intended to treat a serious or life-threatening condition that demonstrates the potential to address an unmet medical need may qualify for Fast Track designation. Features of this designation include opportunities for frequent interactions with the review team. These include meetings with the FDA to discuss items such as study design, extent of safety data required to support approval, dose-response concerns, accelerated

approval, the structure and content of an NDA, and other critical issues. In addition, such a product could be eligible for priority review if supported by clinical data at the time of NDA.

About Fragile X Syndrome (FXS)

Fragile X syndrome is a rare genetic developmental disability that is the leading known cause of both inherited intellectual disability and autism spectrum disorder, affecting 1 in 3,600 to 4,000 males and 1 in 4,000 to 6,000 females. It is the most common inherited intellectual disability in males and a significant cause of intellectual disability in females. FXS is caused by a mutation in the Fragile X Mental Retardation gene (FMR1) located on the X chromosome and leads to dysregulation of the endocannabinoid pathway including the reduction in endogenous cannabinoids (2-AG and anandamide). The disorder negatively affects synaptic function, plasticity and neuronal connections, and results in a spectrum of intellectual disabilities and behavioral symptoms, such as social avoidance and irritability. In the US, there are about 71,000 patients suffering with FXS.

About Zygel™

Zygel (CBD gel) is the first and only pharmaceutically-manufactured CBD formulated as a patent-protected permeation-enhanced clear gel, designed to provide controlled drug delivery into the bloodstream transdermally (i.e. through the skin). Recent studies suggest that FXS and other neuropsychiatric conditions may be associated with a disruption in the endocannabinoid (EC) system. Clinical and anecdotal data suggest that CBD may modulate the EC system and improve certain core social and behavioral symptoms, including social avoidance (prefers isolation from others, prefers solitary activities, avoids new social activities), irritability (aggressive to others, tantrums/outbursts, and stubbornness), and social unresponsiveness/lethargy (lack of attention/interaction, inactive/lack of movement and can resist physical contact).

Enrollment is ongoing in the multi-national, randomized, double blind placebo controlled **C**linical study **o**f Ca**nn**abidiol (CBD) in Childr**e**n and Adoles**c**en**t**s with **F**ragile **X** (CONNECT-FX), a pivotal clinical trial of ZYN002 in FXS (https://www.connectfxtrial.com/); topline data from CONNECT-FX are expected in the second half of 2019. Additionally, Zynerba expects topline data from its Phase 2 Open La**b**el Study to Assess the Safety and **E**fficacy of ZYN002 Administered as a Transderma**l** Gel to Ch**i**ldren and Adol**e**scents with De**v**elopmental and **E**pileptic Encephalopathy (BELIEVE 1) clinical trial in the third quarter of 2019. Zynerba has also initiated a Phase 2 study of Zygel in Autism Spectrum Disorder, with data expected in the first half of 2020.

About Zynerba Pharmaceuticals, Inc.

Zynerba Pharmaceuticals is the leader in pharmaceutically-produced transdermal cannabinoid therapies for rare and near-rare neuropsychiatric disorders. We are committed to improving the lives of patients and their families living with severe, chronic health conditions including Fragile X Syndrome, Autism Spectrum Disorder, 22q11.2 Deletion Syndrome, and a heterogeneous group of rare and ultra-rare epilepsies known as developmental and epileptic encephalopathies. Learn more at www.zynerba.com and follow us on Twitter at @ZynerbaPharma.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the Company’s current expectations. For example, there can be no guarantee that the Company will obtain approval for Zygel from the U.S. Food and Drug Administration (FDA) or foreign regulatory authorities; even if Zygel is approved, the Company may not be able to obtain the label claims that it is seeking from the FDA. Management’s expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: the Company’s cash and cash equivalents may not be sufficient to support its operating plan for as long as anticipated; the Company’s ability to obtain additional funding to support its clinical development programs; the results, cost and timing of the Company’s clinical development programs, including any delays to such clinical trials relating to enrollment or site initiation; clinical results for the Company’s product candidates may not be replicated or continue to occur in additional trials and may not otherwise support further development in a specified indication or at all; actions or advice of the FDA and foreign regulatory agencies may affect the design, initiation, timing, continuation and/or progress of clinical trials or result in the need for additional clinical trials; the Company’s ability to obtain and maintain regulatory approval for its product candidates, and the labeling under any such approval; the Company’s reliance on third parties to assist in conducting pre-clinical and clinical trials for its product candidates; delays, interruptions or failures in the manufacture and supply of the Company’s product candidates the Company’s ability to commercialize its product candidates; the size and growth potential of the markets for the Company’s product candidates, and the Company’s ability to service those markets; the Company’s ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of the Company’s product candidates; and the Company’s expectations regarding its ability to obtain and adequately maintain sufficient intellectual

property protection for its product candidates. This list is not exhaustive and these and other risks are described in the Company's periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the Securities and Exchange Commission and available at www.sec.gov. Any forward-looking statements that the Company makes in this press release speak only as of the date of this press release. The Company assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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