
**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 29, 2019**

ZYNERBA PHARMACEUTICALS, INC.

(Exact Name of Issuer as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-37526
(Commission
File Number)

26-0389433
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value per share	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 29, 2019, Zynerva Pharmaceuticals, Inc. (the "Company") issued a press release announcing that it has initiated the Phase 2 INSPIRE (Assessing the Impact of Zysel [Transdermal CBD Gel] on Pediatric Behavioral and Emotional Symptoms of 22q11.2 Deletion Syndrome) trial. 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 29, 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 29, 2019

ZYNERBA PHARMACEUTICALS, INC.

By: /s/ Suzanne Hanlon

Name: Suzanne Hanlon

Title: Secretary, Vice President and General Counsel



Zynerba Pharmaceuticals Announces Initiation of Phase 2 Trial of Zygel™ in 22q11.2 Deletion Syndrome

- Topline Data from the INSPIRE Trial Expected in the First Half 2020 -

DEVON, Pa., May 29, 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 it has initiated the Phase 2 INSPIRE (Assessing the Impact of Zygel [Transdermal CBD Gel] on Pediatric Behavioral and Emotional Symptoms of 22q11.2 Deletion Syndrome) trial. The INSPIRE trial will assess the safety, tolerability and efficacy of Zygel (ZYN002 CBD gel) for the treatment of behavioral symptoms of 22q11.2 Deletion Syndrome (22q). The Company expects to present topline data from this study in the first half of 2020.

“Children born with 22q often require surgeries to rectify acute physical concerns, like anomalies of the heart and palate; once corrected, there are a myriad of behavioral symptoms that need to be addressed,” said Armando Anido, Chairman and Chief Executive Officer of Zynerba. “Parents of children with 22q report significantly higher rates of withdrawn behavior, affective disorders, pervasive developmental problems and anxiety in their children compared to non-affected children. There is also an increased risk of developing psychoses such as schizophrenia later in life, compared to the general population. We are very excited to initiate the INSPIRE trial to assess the potential impact of Zygel in these children and adolescents, and look forward to presenting topline data in the first half of 2020.”

The 14-week INSPIRE trial is an open-label multi-dose Phase 2 clinical trial designed to evaluate the efficacy and safety of Zygel in approximately 20 children and adolescents (ages six through 17) with genetically-confirmed 22q. Enrolled patients will receive weight-based doses of 250 mg daily or 500 mg daily of Zygel. The efficacy assessments include the Aberrant Behavior Checklist-Community (ABC-C), the Anxiety, Depression and Mood Scale (ADAMS), the Columbia Suicide Severity Rating scale (C-SSRS), the Qualitative Caregiver Reported Behavioral Problem Survey, and Clinical Global Impression — Severity and Improvement.

About 22q11.2 Deletion Syndrome (22q)

As the second most common chromosomal disorder after Down syndrome, 22q is caused by a small missing piece of the 22nd chromosome. The deletion occurs near the middle of the chromosome at a location designated q11.2. It is considered a mid-line condition, with physical symptoms including characteristic palate abnormalities, heart defects, immune dysfunction, and esophageal / GI issues, as well as debilitating neuropsychiatric and behavioral challenges. Anxiety is among the most common neuropsychiatric symptoms of 22q and researchers have found that for children with 22q, anxiety is linked

to poorer adaptive behaviors such as self-care and communication skills that affect daily life. Children with 22q also experience withdrawn behavior, ADHD, cognitive impairment, and autism spectrum disorder that affect communication and social interaction. Later in life, they are at an increased risk of developing mental illnesses such as schizophrenia. It is estimated that 22q occurs in between one in 3,000 and one in 6,000 live births, suggesting that there are approximately 81,000 people living with 22q in the U.S.

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 Fragile X Syndrome (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), social unresponsiveness/lethargy (lack of attention/interaction, inactive/lack of movement and can resist physical contact), and anxiety.

Zygel has been designated a Fast Track development program by the U.S. Food and Drug Administration for treatment of behavioral symptoms of FXS. Enrollment is ongoing in CONNECT-FX, a multi-national, randomized, double blind placebo controlled pivotal clinical trial of Zygel in FXS (<https://www.connectfxtrial.com/>); topline data are expected in the second half of 2019. Additionally, Zynerba expects topline data from its Phase 2 open label BELIEVE 1 trial of Zygel in developmental and epileptic encephalopathies (DEE) in the third quarter of 2019. Zynerba has also initiated the Phase 2 BRIGHT trial in Autism Spectrum Disorder and the Phase 2 INSPIRE trial in 22q11.2 Deletion Syndrome, with data expected from both studies 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](https://twitter.com/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.

Zynerba Contact

William Roberts, Vice President, Investor Relations and Corporate Communications

Zynerba Pharmaceuticals

484.581.7489

robertsw@zynerba.com
