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 12, 2021**

ZYNERBA PHARMACEUTICALS, INC.

(Exact Name of Issuer as Specified in Charter)

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

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

(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:

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))

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, $0.001 par value per share	ZYNE	The NASDAQ Global Market

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 2.02 Results of Operations and Financial Condition

On May 12, 2021, Zynerba Pharmaceuticals, Inc. issued a press release announcing its financial results and operational highlights for the first quarter ended March 31, 2021. A copy of this press release is furnished as Exhibit 99.1 hereto.

The information furnished pursuant to this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Document
99.1	Press Release, dated May 12, 2021*
104	The cover page from this current report on Form 8-K, formatted in Inline XBRL

* Furnished herewith

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.

ZYNERBA PHARMACEUTICALS, INC.

Date: May 12, 2021

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

Exhibit 99.1

Zynerba Pharmaceuticals Reports First Quarter 2021 Financial Results and Operational Highlights

– RECONNECT, a confirmatory pivotal trial of Zygel™ in patients with FXS, expected to be initiated in the third quarter of 2021 –

– Cash runway well into first half 2024; $93.1 million at March 31, 2021 –

DEVON, Pa., May 12, 2021 – Zynerba Pharmaceuticals, Inc. (Nasdaq: ZYNE), the leader in innovative pharmaceutically-produced transdermal cannabinoid therapies for rare and near-rare neuropsychiatric disorders, today reported financial results for the first quarter ended March 31, 2021, and provided an overview of recent operational highlights and a pipeline update.

"We are committed to delivering on our important milestones in 2021 as we develop Zygel in multiple neuropsychiatric indications, including initiating a confirmatory pivotal Phase 3 trial, RECONNECT, in the third quarter of 2021, after productive dialogue and alignment with the FDA," said Armando Anido, Chairman and Chief Executive Officer of Zynerba. "With a cash runway that takes us well into the first half of 2024, we believe that we are ideally positioned to continue our efforts to develop the first FDA approved treatment for patients with Fragile X syndrome."

First Quarter 2021 and Recent Highlights and Zygel Pipeline Update

Zygel in Fragile X Syndrome (FXS)

- Zynerba expects to initiate RECONNECT (A **R**andomiz**e**d, Double-Blind, Pla**c**ebo-C**on**trolled, Multiple-Ce**n**t**e**r, Effi**c**acy and Safe**t**y Study of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome), a pivotal, multi-national confirmatory Phase 3 trial of Zygel in children and adolescents with FXS, in the third quarter of 2021. The trial is designed to confirm the positive results observed in a population of responders in the Company's previously conducted CONNECT-FX trial. (Press release)

- The RECONNECT trial will be an 18-week trial which will enroll approximately 200 children and adolescents of which approximately 160 patients will have complete (100%) methylation of their *FMR1* gene and approximately 40 patients will have partial methylation of their *FMR1* gene. The primary endpoint for the trial will be the change in the Aberrant Behavior Checklist-Community FXS Specific (ABC-C_{FXS}) Social Avoidance subscale in patients who have complete methylation of their *FMR1* gene. All patients, including the cohort of partially methylated patients, will be included in a key secondary endpoint analysis. The Company believes that the results, if positive, from RECONNECT will be sufficient to support the submission of a New Drug Application for Zygel in patients with FXS.

- Presented data at the Society of Biological Psychiatry (SOBP) 2021 Virtual Meeting demonstrating that the ABC-C_{FXS} subscales capture behaviors that are impactful and meaningful in clinical trials of children with FXS. Furthermore, the data showed that Zygel provided meaningful improvements in behavioral symptoms of FXS in patients with ≥90% methylation of the *FMR1* gene. (Press release)

- Presented data at the SOBP 2021 Virtual Meeting suggesting that effective silencing of the *FMR1* gene may have led to differences in treatment response in patients with ≥90% methylation of the *FMR1* gene in the CONNECT-FX trial. In the ≥90% methylation group of CONNECT-FX, Zygel was superior to placebo in multiple analyses, including reaching statistical significance on the primary endpoint in a pre-planned ad hoc analysis. (Press release)

Zygel in 22q11.2 Deletion Syndrome (22q)

- As the COVID-19-related restrictions in Australia are easing, the Company has resumed screening of patients for the 14-week open label Phase 2 INSPIRE trial in children and adolescents with genetically confirmed 22q. Once enrollment is complete, a timeframe for disclosing topline results of the trial will be provided.

Zygel in Autism Spectrum Disorder (ASD)

- In the first half of 2021, Zynerba intends to discuss with the FDA data supporting the potential efficacy of Zygel in ASD, including the results of the Phase 2 BRIGHT trial in children and adolescents with moderate to severe ASD, to determine the regulatory path forward.

Zygel in Developmental and Epileptic Encephalopathies (DEE)

- Zynerba is conducting an observational trial that will help finalize target syndrome selection in one or more DEE syndromes in 2021. Due to the heterogeneity of patients who fall under the DEE umbrella, Zynerba will pursue individual syndromes rather than considering DEE as a single disorder or condition (Press release).

First Quarter 2021 Financial Results

Research and development expenses were $4.6 million for the first quarter of 2021, including stock-based compensation of $0.6 million. General and administrative expenses were $3.3 million in the first quarter of 2021, including stock-based compensation expense of $0.6 million. The net loss for the first quarter of 2021 was $8.0 million with basic and diluted loss per share of $(0.20).

Financial Outlook

In August 2019, the Company entered into a Controlled Equity Offering^{SM} Sales Agreement (the "2019 Sales Agreement") with Cantor Fitzgerald & Co., Canaccord Genuity, LLC, H.C. Wainwright & Co. LLC and Ladenburg Thalmann & Co. Inc., as sales agents. In the first quarter of 2021, the Company sold and issued 10,244,326 shares of common stock under the 2019 Sales Agreement in the open market at a weighted average selling price of $4.22 per share, resulting in gross proceeds of $43.2 million. Net proceeds after deducting commissions and offering expenses were $42.2 million.

As of March 31, 2021, cash and cash equivalents were $93.1 million, compared to $59.2 million as of December 31, 2020. Management believes that the Company's cash and cash equivalents as of March 31, 2021 are sufficient to fund operations and capital requirements well into the first half of 2024.

About Zynerba Pharmaceuticals, Inc.

Zynerba Pharmaceuticals is the leader in innovative 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. 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 expectations, projections and estimates regarding expenses, future revenue, capital requirements, incentive and other tax credit eligibility, collectability and timing, and availability of and the need for additional financing; 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 U.S. Food and Drug Administration 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; the Company’s expectations regarding its ability to obtain and adequately maintain sufficient intellectual property protection for its product candidates; the timing and outcome of current and future legal proceedings; and the extent to which health epidemics and other outbreaks of communicable diseases, including COVID-19, could disrupt our operations or adversely affect our business and financial conditions. 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 PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	(unaudited) Three months ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 4,609,010	$ 6,882,793
General and administrative	3,275,797	3,916,569
Total operating expenses	7,884,807	10,799,362
Loss from operations	(7,884,807)	(10,799,362)
Other income (expense):		
Interest income	5,633	201,684
Foreign exchange gain (loss)	(82,454)	(1,740,151)
Total other expense	(76,821)	(1,538,467)
Net loss	$ (7,961,628)	$ (12,337,829)
Net loss per share - basic and diluted	$ (0.20)	$ (0.53)
Basic and diluted weighted average shares outstanding	40,065,715	23,399,438
Non-cash stock-based compensation included above:		
Research and development	$ 619,391	$ 510,476
General and administrative	645,446	812,876
Total	$ 1,264,837	$ 1,323,352

ZYNERBA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	(unaudited) March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 93,130,194	$ 59,157,187
Incentive and tax receivables	9,009,814	9,042,586
Prepaid expenses and other current assets	5,060,547	5,166,401
Total current assets	107,200,555	73,366,174
Property and equipment, net	535,003	585,403
Incentive and tax receivables	338,810	—
Right-of-use assets	733,933	105,199
Total assets	$ 108,808,301	$ 74,056,776
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,678,193	$ 2,522,716
Accrued expenses	10,680,655	11,280,843
Lease liabilities	209,325	109,689
Total current liabilities	12,568,173	13,913,248
Lease liabilities, long-term	525,141	—
Total liabilities	13,093,314	13,913,248
Stockholders' equity:		
Common stock	41,252	29,975
Additional paid-in capital	305,807,818	262,286,008
Accumulated deficit	(210,134,083)	(202,172,455)
Total stockholders' equity	95,714,987	60,143,528
Total liabilities and stockholders' equity	$ 108,808,301	$ 74,056,776

Zynerba Contacts

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