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): **November 14, 2022**

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)

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 November 14, 2022, Zynerba Pharmaceuticals, Inc. issued a press release announcing its financial results and operational highlights for the third quarter ended September 30, 2022. A copy of the 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, 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, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

The following exhibits are being filed herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Press Release, dated November 14, 2022*
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.

Date: November 14, 2022

ZYNERBA PHARMACEUTICALS, INC.

By: /s/ Albert P. Parker
Name: Albert P. Parker
Title: Chief Legal Officer

Zynerba Pharmaceuticals Reports Third Quarter 2022 Financial Results and Operational Highlights

Enrollment continues in RECONNECT, a confirmatory pivotal Phase 3 trial of Zygel™ in patients with Fragile X syndrome (FXS); topline results expected second-half 2023

$55.9 million in cash and cash equivalents at September 30, 2022; Cash runway into first quarter 2024

DEVON, Pa., November 14, 2022 – Zynerba Pharmaceuticals, Inc. (Nasdaq: ZYNE), the leader in innovative pharmaceutically-produced transdermal cannabinoid therapies for orphan neuropsychiatric disorders, today reported financial results for the third quarter ended September 30, 2022, and provided an overview of recent operational highlights and a pipeline update.

"Enrollment in our confirmatory pivotal Phase 3 RECONNECT trial continues, and we expect topline results in the second half of 2023," said Armando Anido, Chairman and Chief Executive Officer of Zynerba. "With a cash runway into the first quarter of 2024, we remain well-positioned on achieving our goal of bringing Zygel to market as the first FDA approved treatment option for the significant unmet medical need that affects FXS patients and their families."

Operational Highlights and Pipeline Update

Zygel in Fragile X Syndrome (FXS)

- The Company continues to expect topline results from RECONNECT, a confirmatory pivotal Phase 3 trial of Zygel in patients with FXS, in the second half of 2023. The Company believes that the results from RECONNECT, if positive, will be sufficient to support the submission of a New Drug Application (NDA) for Zygel in patients with FXS.

- In October 2022 the Company announced that the U.S. Patent and Trademark Office (USPTO) issued a patent titled "Treatment of Fragile X Syndrome With Cannabidiol," which includes claims directed to methods of treating Fragile X syndrome with cannabidiol. This new patent, which expires in 2038, is part of an expanding international intellectual property portfolio covering the Company's transdermal cannabidiol product candidate, Zygel. (Press Release)

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

- Based on the positive Phase 2 INSPIRE trial data announced in June 2022 (Press Release), the Company requested and has been granted an initial meeting with the U.S. Food and Drug Administration (FDA) before the end of 2022 to obtain feedback on the Phase 2 data and regulatory pathway for Zygel in patients with 22q. The Company currently plans to initiate a Phase 3 program in children and adolescents with 22q following topline results from RECONNECT.

- In November 2022, the Company announced that the USPTO issued a patent titled "Treatment of 22q11.2 Deletion Syndrome With Cannabidiol," which includes claims directed to methods of treating one or more behavioral symptoms of 22q with cannabidiol, and expires in 2040. (Press Release)

- The Company presented data at *The Society for the Study of Behavioural Phenotypes (SSBP) 24th International Research Symposium* in September 2022 and the *2022 National Organization for Rare Disorders (NORD) Rare Diseases and Orphan Products Breakthrough Summit* in October 2022 from the first 14-week treatment period of the Phase 2 INSPIRE trial. These data suggest a positive risk-benefit profile for Zygel in improving anxiety-related and behavioral symptoms in children and adolescents with 22q. Statistically significant improvements from baseline were seen in the Pediatric Anxiety Rating Scale (PARS-R), the total score and all five subscales of the Anxiety, Depression and Mood Scale (ADAMS) and all five subscales of the Aberrant Behavior Checklist – Community (ABC-C). In addition, the majority of patients showed clinically meaningful improvements as demonstrated by the Clinical Global Impression – Improvement (CGI-I). Zygel was shown to be well tolerated, and the safety profile was consistent with previously released data from other Zygel clinical trials. (Posters).

Third Quarter 2022 Financial Results

Research and development expenses were $5.0 million for the third quarter of 2022, including stock-based compensation of $0.5 million. General and administrative expenses were $3.5 million in the third quarter of 2022, including stock-based compensation expense of $0.6 million. Net loss for the third quarter of 2022 was $8.7 million, with basic and diluted loss per share of $(0.20).

Financial Outlook

As of September 30, 2022, cash and cash equivalents were $55.9 million, compared to $67.8 million as of December 31, 2021.

On May 11, 2021, the Company entered into a Controlled Equity Offering[SM] Sales Agreement (2021 Sales Agreement), with Cantor Fitzgerald & Co., Canaccord Genuity, LLC, H.C. Wainwright & Co. LLC and Ladenburg Thalmann & Co. Inc., as sales agents, pursuant to which the Company may sell, from time to time, up to $75.0 million of its common stock. In the third quarter of 2022, the Company sold and issued 2,579,346 shares of its common stock under the 2021 Sales Agreement in the open market resulting in gross proceeds of $3.2 million and net proceeds of $3.0 million, after deducting commissions and offering expenses.

On July 21, 2022, the Company entered into a Purchase Agreement and registration rights agreement for up to $20 million with Lincoln Park Capital Fund, LLC (LPC), a Chicago-based institutional investor. In the third quarter of 2022, the Company sold and issued 200,000 shares of its common stock under the 2022 Purchase Agreement with LPC in the open market resulting in gross proceeds of $0.2 million and net proceeds of $0.1 million, after deducting offering expenses.

Management believes that the Company's cash and cash equivalents are sufficient to fund operations and capital requirements into the first quarter of 2024. Top-line results from the Company's confirmatory pivotal Phase 3 RECONNECT trial of Zygel in patients with FXS are expected in the second half of 2023.

About Zygel

Zygel is the first and only pharmaceutically-manufactured cannabidiol 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 cannabidiol may modulate the endocannabinoid system and improve certain behavioral symptoms associated with neuropsychiatric conditions. Zygel is an investigational drug product in development for the potential treatment of behavioral symptoms associated with Fragile X syndrome (FXS), 22q11.2 deletion syndrome (22q) and autism spectrum disorder (ASD). The Company has received orphan drug designation for cannabidiol, the active ingredient in Zygel, from the FDA and the European Commission in the treatment of FXS and from the FDA for the treatment of 22q. Additionally, Zygel has been designated a Fast Track development program for treatment of behavioral symptoms of FXS.

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, 22q11.2 deletion syndrome and autism spectrum disorder. 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 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; and the extent to which inflation or global instability, including political instability, may disrupt our business operations or our financial condition. 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 September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 5,039,228	$ 6,341,171	$ 15,632,150	$ 16,402,129
General and administrative	3,453,648	3,869,481	10,933,411	11,531,824
Total operating expenses	8,492,876	10,210,652	26,565,561	27,933,953
Loss from operations	(8,492,876)	(10,210,652)	(26,565,561)	(27,933,953)
Other income (expense):				
Interest income	251,855	5,038	439,590	16,614
Foreign exchange loss	(435,128)	(376,637)	(893,803)	(576,619)
Total other income (expense)	(183,273)	(371,599)	(454,213)	(560,005)
Net loss	$ (8,676,149)	$ (10,582,251)	$ (27,019,774)	$ (28,493,958)
Net loss per share - basic and diluted	$ (0.20)	$ (0.26)	$ (0.65)	$ (0.73)
Basic and diluted weighted average shares outstanding	43,746,878	40,092,128	41,831,998	38,933,209
Non-cash stock-based compensation included above:				
Research and development	$ 482,306	$ 818,390	$ 1,500,447	$ 2,443,667
General and administrative	558,794	751,603	1,809,678	2,325,512
Total	$ 1,041,100	$ 1,569,993	$ 3,310,125	$ 4,769,179

ZYNERBA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	(unaudited) September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 55,934,491	$ 67,808,000
Incentive and tax receivables	1,378,738	9,580,468
Prepaid expenses and other current assets	3,487,626	2,831,392
Total current assets	60,800,855	80,219,860
Property and equipment, net	419,863	385,833
Incentive and tax receivables	751,815	—
Right-of-use assets	394,205	565,814
Total assets	$ 62,366,738	$ 81,171,507
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,619,697	$ 1,798,813
Accrued expenses	7,598,187	7,896,598
Lease liabilities	213,428	209,068
Total current liabilities	9,431,312	9,904,479
Lease liabilities, long-term	178,672	353,694
Total liabilities	9,609,984	10,258,173
Stockholders' equity:		
Common stock	47,063	41,218
Additional paid-in capital	319,210,944	310,353,595
Accumulated deficit	(266,501,253)	(239,481,479)
Total stockholders' equity	52,756,754	70,913,334
Total liabilities and stockholders' equity	$ 62,366,738	$ 81,171,507

Zynerba Contacts

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