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 6, 2019**

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 6, 2019, Zynerba Pharmaceuticals, Inc. issued a press release announcing its financial results and operational highlights for the third quarter ended September 30, 2019. 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, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

The following exhibit is being filed herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Press Release, dated November 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: November 6, 2019

ZYNERBA PHARMACEUTICALS, INC.

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

Exhibit 99.1

Zynerba Pharmaceuticals Reports Third Quarter 2019 Financial Results and Operational Highlights

- Positive Topline Results from BELIEVE 1 Phase 2 Trial of Zygel™ in Children and Adolescents with Developmental and Epileptic Encephalopathies Suggest Compelling Seizure Reductions and Excellent Tolerability -

- Topline Results from Pivotal Trial in Fragile X Syndrome On Track for 1H2020 -

- Phase 2 Topline Results in Autism Spectrum Disorder and 22q11.2 Deletion Syndrome On Track for 1H2020 -

DEVON, Pa., November 6, 2019 — 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 third quarter ended September 30, 2019 and provided an overview of recent operational highlights.

“The third quarter of 2019 was a remarkable period of progress and execution for Zynerba,” said Armando Anido, Chairman and Chief Executive Officer of Zynerba. “We announced compelling topline safety and efficacy results from our six month BELIEVE Phase 2 trial of Zygel™ in childhood epilepsies. In this study, patients experienced median reductions in their most common and debilitating seizures of 44% or more starting at month two and continuing through month six. In this medically fragile patient population, and consistent with our prior trials, Zygel was very well tolerated. Caregivers also reported important improvements in seizure intensity and duration in their children, and in socio-behavioral and cognitive impairments that are common in this population. Finally, we continued to progress towards full enrollment in our pivotal CONNECT-FX trial in children and adolescents with Fragile X syndrome, and expect to announce topline results in the first half of next year.

Third Quarter 2019 Highlights

Zygel in Developmental and Epileptic Encephalopathies (DEE)

Presented Positive Topline Efficacy and Tolerability Results from BELIEVE 1 Open Label Phase 2 DEE Study

The topline results of this six month Phase 2 evaluation of Zygel in 48 children and adolescents with various DEEs showed meaningful reductions in seizures and excellent tolerability. Patients experienced 44% to 58% monthly median reductions in focal impaired-awareness seizures (FIAS; previously known as complex partial seizures) and/or convulsive seizures (CS; focal to bilateral tonic-clonic seizures and generalized tonic-clonic seizures), the most common and debilitating seizure types, starting at month two and continuing through month six. In addition, 42% to 63% of patients experienced a ≥50% monthly reduction in these seizures. Children with DEE are medically fragile, and as such, adverse events (all events, whether unrelated or related to study drug, that occur during the trial period) are

common and expected. Only ten patients experienced a serious adverse event (SAE). Of those ten, eight were deemed to be unrelated to drug and only two were deemed possibly related to study drug, including one case of lower respiratory tract infection and one case of status epilepticus, both of which are common events in this patient population. There were no drug-related hepatic, gastrointestinal, or lethargy-related SAEs observed during this study.

Presented Qualitative Data Evaluating the Impact of Zygel on Quality of Life of Children with DEE

As part of the BELIEVE 1 study, caregivers were asked to provide a qualitative assessment regarding their child's overall experiences during treatment with Zygel. Caregiver feedback to a series of open-ended questions was collected and coded by two independent reviewers. These qualitative assessments indicated improvements in alertness, awareness, or energy (58% of caregivers); seizures (51% of caregivers); cognition/concentration (47% of caregivers); socially-avoidant behaviors (44% of caregivers); and school attendance (28% of caregivers).

Preparations Underway for First Half 2020 Meeting with U.S. Food and Drug Administration (FDA) to Discuss Pathway for Zygel in DEE

Zynerba intends to meet with the FDA in the first half of 2020 to discuss the clinical path forward in DEE. Based on the Phase 2 trial design and results, the Company anticipates that it will discuss the pursuit of an indication that includes all syndromes and encephalopathies in the DEE category that present with FIAS and/or CS, the most common and debilitating seizure types representing 75% to 80% of all seizures.

Zygel in Fragile X Syndrome (FXS)

Fragile X Syndrome Pivotal Data Expected in the First Half of 2020

Enrollment is progressing in CONNECT-FX, a pivotal, multi-national, randomized, double blind, placebo-controlled trial evaluating the efficacy and safety of Zygel in treating common behavioral symptoms of FXS in three through 17-year old patients with FXS. The Company expects to report top line results in the first half of 2020. The primary endpoint is the change from baseline to the end of the treatment period in the Aberrant Behavior Checklist-Community FXS Specific (ABC-C_{FXS}) Social Avoidance subscale. Key secondary endpoints are the change from baseline to the end of the treatment period in the ABC-C_{FXS} Irritability subscale score, the ABC-C_{FXS} Socially Unresponsive/Lethargic subscale score, and improvement in Clinical Global Impression - Improvement (CGI-I) at the end of the treatment period. If the results are positive, the Company expects to submit its New Drug Application (NDA) for Zygel in FXS to the U.S. Food and Drug Administration (FDA) in the second half of 2020, with potential approval by mid-year 2021.

Poster Further Validating the Use of the ABC-C_{FXS} Presented at the 22nd Society for the Study of Behavioural Phenotypes (SSBP) Symposium

The poster described data collected via web-based journals and in-depth interviews of caregivers of children with FXS. The data indicate that nine of ten caregivers (90%) reported that their children had behaviors representative of social avoidance, socially unresponsiveness/lethargic, and irritability and that the described behaviors had strong concordance with individual domains of the ABC-C_{FXS}. We believe that these data help elucidate the most common core behaviors of FXS, and further validate the appropriateness of the ABC-C_{FXS} as an effective tool for use in clinical studies as a means to measure improvements in these core and common FXS behaviors.

Zygel 12-week Open Label Phase 2 FXS Data Published in the Journal of Neurodevelopmental Disorders

The results of the Phase 2 FAB-C clinical trial have been published in the peer-reviewed *Journal of Neurodevelopmental Disorders* in a paper entitled, 'A Phase 1/2, Open Label Assessment of the Safety, Tolerability, and Efficacy of Transdermal Cannabidiol (ZYN002) for the Treatment of Pediatric Fragile X Syndrome' (Heussler, Helen; Cohen, Jonathan; Silove, Natalie, *et al.*).

Zygel in Autism Spectrum Disorder (ASD)

Phase 2 Open Label Trial of Zygel in ASD Ongoing; Data Expected in the First Half of 2020

The Company is conducting the Phase 2 BRIGHT trial to assess the safety, tolerability and efficacy of Zygel for the treatment of child and adolescent patients with ASD. The 14-week trial is designed to evaluate the efficacy and safety of Zygel in approximately 36 children and adolescents (ages four through 17) with ASD as confirmed by DSM-5 diagnostic criteria for ASD. The efficacy assessments include the Aberrant Behavior Checklist, Parent Rated Anxiety Scale — Autism Spectrum Disorder, Autism Impact Measure, and Clinical Global Impression — Severity and Improvement. Zynerba expects to report topline results from this study in the first half of 2020.

Poster Describing the Shared Sociobehavioral Symptoms in ASD, FXS, and 22q11.2 Deletion Syndrome Presented at the 22nd SSBP Symposium

The poster described the results of a retrospective literature review on patients with ASD, FXS, and 22q11.2 deletion syndrome (22q) conducted to determine symptomatic overlap between these disorders. The data indicate that patients with ASD, FXS, and 22q share a constellation of sociobehavioral symptoms and that the pharmacology of CBD is broad, continues to be defined, and may prove to be beneficial in addressing important behavioral symptoms of these conditions.

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

Phase 2 Open Label Trial of Zygel in 22q Ongoing; Data Expected in the First Half of 2020

The Company is conducting the 14-week Phase 2 INSPIRE trial to evaluate the safety, tolerability and efficacy of Zygel in approximately 20 children and adolescents (ages six through 17) with genetically-confirmed 22q. The efficacy assessments include the Aberrant Behavior Checklist-Community (ABC-C), the Anxiety, Depression and Mood Scale (ADAMS), the Qualitative Caregiver Reported Behavioral Problem Survey, and Clinical Global Impression — Severity and Improvement. Zynerba expects to report topline results from this study in the first half of 2020.

Third quarter 2019 Financial Results

Our Australian subsidiary, Zynerba Pharmaceuticals Pty Ltd, or the Subsidiary, is incorporated in Australia and is eligible to participate in an Australian research and development tax incentive program. As part of this program, the Subsidiary is eligible to receive a cash refund from the Australian Taxation Office for a percentage of the research and development costs expended by the Subsidiary in Australia. In July 2019, the Australian government's Department of Industry, Innovation and Science, or AusIndustry, responded to an Advance Overseas Finding, or AOF, application submitted by Zynerba that will allow certain research and development expenses incurred with respect to our product candidate Zygel outside of Australia to be eligible for the Australian research and development tax incentive program. As a result of this finding, we are eligible to receive a cash refund from the Australian Taxation Office for the qualifying research and development costs expended outside of Australia in 2018, 2019 and 2020. During the three months ending September 30, 2019, we recorded an $8.3 million credit to research and development expenses for amounts expected to be received through the AOF for the period from January 1, 2018 through September 30, 2019. Although the AOF approval extends into 2020, management believes that substantially all qualifying amounts have been recorded as of September 30, 2019.

The following table summarizes research and development expenses for the three months ended September 30, 2019 and 2018.

	Three months ended September 30,	
	2019	2018
Research and development expenses (before impact of AOF)	$ 6,665,610	$ 4,859,902
AOF - cumulative change in estimate for the period 1/1/18 through 9/30/19	(8,270,009)	—
Total research and development expenses	$ (1,604,399)	$ 4,859,902

Excluding the $8.3 million reduction in research and development expenses for amounts expected to be received through the AOF for the period from January 1, 2018 through September 30, 2019, research and development expenses increased by $1.8 million to $6.7 million for the three months ended September 30, 2019 from $4.9 million for the three months ended September 30, 2018. The increase was primarily related to an increase in clinical trial and

manufacturing costs related to our Zygel program. Stock based compensation included in the R&D costs were $0.6 million.

General and administrative expenses for the third quarter of 2019 were $3.5 million, including stock-based compensation expense of $0.8 million.

The net loss for the third quarter of 2019 was $1.9 million with basic and diluted net loss per share of $(0.08).

Financial Outlook

The Company's cash and cash equivalent position as of September 30, 2019 was $77.5 million. Management believes that the cash and cash equivalent position is sufficient to fund operations and capital requirements beyond the expected NDA submission and potential approval of Zygel in FXS and into the second half of 2021.

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. 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 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; 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 PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ (1,604,399)	$ 4,859,902	$ 12,926,096	$ 22,368,881
General and administrative	3,530,617	3,125,780	9,977,550	9,982,743
Total operating expenses	1,926,218	7,985,682	22,903,646	32,351,624
Loss from operations	(1,926,218)	(7,985,682)	(22,903,646)	(32,351,624)
Other income (expense):				
Interest income	436,846	278,214	1,226,998	639,702
Foreign exchange loss	(457,018)	(99,897)	(551,944)	(409,010)
Total other income (expense)	(20,172)	178,317	675,054	230,692
Net loss	$ (1,946,390)	$ (7,807,365)	$ (22,228,592)	$ (32,120,932)
Net loss per share - basic and diluted	$ (0.08)	$ (0.47)	$ (1.03)	$ (2.21)
Basic and diluted weighted average shares outstanding	23,186,410	16,587,353	21,598,764	14,531,272
Non-cash stock-based compensation included above:				
Research and development	$ 573,446	$ 743,153	$ 1,915,578	$ 2,267,783
General and administrative	802,779	841,077	2,438,644	2,759,330
Total	$ 1,376,225	$ 1,584,230	$ 4,354,222	$ 5,027,113

ZYNERBA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	(unaudited) September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 77,547,530	$ 59,763,773
Incentive and tax receivables	13,446,981	3,444,620
Prepaid expenses and other current assets	2,831,340	3,747,087
Total current assets	93,825,851	66,955,480
Property and equipment, net	339,213	371,963
Right-of-use assets	152,166	—
Total assets	$ 94,317,230	$ 67,327,443
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,302,459	$ 4,461,567
Accrued expenses	5,842,262	5,264,215
Lease liabilities	159,267	—
Total current liabilities	9,303,988	9,725,782
Total liabilities	9,303,988	9,725,782
Stockholders' equity:		
Common stock	23,198	17,627
Additional paid-in capital	225,110,677	175,476,075
Accumulated deficit	(140,120,633)	(117,892,041)
Total stockholders' equity	85,013,242	57,601,661
Total liabilities and stockholders' equity	$ 94,317,230	$ 67,327,443

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