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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF  
1934**

For the quarterly period ended September 30, 2019

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF  
1934**

For the transition period from to

Commission file number: 001-37526

**Zynerba Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**26-0389433**  
(I.R.S. Employer  
Identification Number)

**80 W. Lancaster Avenue, Suite 300**  
**Devon, PA**  
(Address of principal executive offices)

**19333**  
(Zip Code)

**(484) 581-7505**  
(Registrant's telephone number, including area code)

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

<u>Title of each class:</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered:</u>
Common Stock, \$0.001 par value per share	ZYNE	The Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of November 1, 2019, the registrant had 23,198,010 shares of Common Stock, \$0.001 par value per share, outstanding.

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this Quarterly Report that are not statements of historical or current facts, such as those under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements discuss our current expectations and projections relating to our financial condition, results of operations, plans, objectives, future performance and business. These statements may be preceded by, followed by or include the words “aim,” “anticipate,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “outlook,” “plan,” “potential,” “project,” “projection,” “seek,” “may,” “could,” “would,” “will,” “should,” “can,” “can have,” “likely,” the negatives thereof and other words and terms of similar meaning.

Forward-looking statements are inherently subject to risks, uncertainties and assumptions; they are not guarantees of performance. You should not place undue reliance on these statements. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that our assumptions made in connection with the forward-looking statements are reasonable, we cannot assure you that the assumptions and expectations will prove to be correct.

You should understand that the following important factors could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- our estimates regarding expenses, future revenue, capital requirements, tax credits and timing and availability of and the need for additional financing;
- the results, cost and timing of our preclinical studies and clinical trials, including any delays to such clinical trials relating to enrollment or site initiation, as well as the number of required trials for regulatory approval and the criteria for success in such trials;
- our dependence on third parties in the conduct of our preclinical studies and clinical trials;
- legal and regulatory developments in the United States and foreign countries, including any actions or advice that may affect the design, initiation, timing, continuation, progress or outcome of clinical trials or result in the need for additional clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of our product candidates, and the indication and labeling under any such approval;
- our plans and ability to develop and commercialize our product candidates;
- the successful development of our commercialization capabilities, including medical affairs and sales and marketing capabilities, whether alone or with potential future collaborators;
- the size and growth of the potential markets for our product candidates, the rate and degree of market acceptance of our product candidates and our ability to serve those markets;
- the coverage and reimbursement status for our product candidates from third-party payors;
- the success of competing therapies and products that are or become available;
- our ability to limit our exposure under product liability lawsuits;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- recently enacted and future legislation regarding the healthcare system, including changes to the Patient Protection and Affordable Care Act;
- our ability to obtain and maintain third-party manufacturing for our product candidates on commercially reasonable terms;
- delays, interruptions or failures in the manufacture and supply of our product candidates;
- the performance of third parties upon which we depend, including third-party contract research organizations, or CROs, contract manufacturing organizations, or CMOs, contractor laboratories and independent contractors;
- our ability to recruit or retain key scientific, commercial or management personnel or to retain our executive officers;
- our ability to maintain proper functionality and security of our internal computer and information systems and prevent or avoid cyberattacks, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption; and
- the other risks, uncertainties and factors discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, or our 2018 Annual Report, under the caption “Item 1A. Risk Factors”.

In light of these risks and uncertainties, expected results or other anticipated events or circumstances discussed in this Form 10-Q (including the exhibits hereto) might not occur. We undertake no obligation, and specifically decline any

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obligation, to publicly update or revise any forward-looking statements, even if experience or future developments make it clear that projected results expressed or implied in such statements will not be realized, except as may be required by law.

**PART I – FINANCIAL INFORMATION****Item 1. Consolidated Financial Statements (Unaudited)****ZYNERBA PHARMACEUTICALS, INC.  
CONSOLIDATED BALANCE SHEETS  
(UNAUDITED)**

	September 30, 2019	December 31, 2018
<b>Assets</b>		
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	<u>\$ 94,317,230</u>	<u>\$ 67,327,443</u>
<b>Liabilities and Stockholders' Equity</b>		
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:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized; 23,198,010 shares issued and outstanding at September 30, 2019 and 17,626,873 shares issued and outstanding at December 31, 2018	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	<u>\$ 94,317,230</u>	<u>\$ 67,327,443</u>

See accompanying notes to unaudited consolidated financial statements.

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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	<u>1,926,218</u>	<u>7,985,682</u>	<u>22,903,646</u>	<u>32,351,624</u>
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)	<u>(20,172)</u>	<u>178,317</u>	<u>675,054</u>	<u>230,692</u>
Net loss	<u>\$ (1,946,390)</u>	<u>\$ (7,807,365)</u>	<u>\$ (22,228,592)</u>	<u>\$ (32,120,932)</u>
Net loss per share basic and diluted	\$ (0.08)	\$ (0.47)	\$ (1.03)	\$ (2.21)
Basic and diluted weighted average shares outstanding	<u>23,186,410</u>	<u>16,587,353</u>	<u>21,598,764</u>	<u>14,531,272</u>

See accompanying notes to unaudited consolidated financial statements.

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**ZYNERBA PHARMACEUTICALS, INC.  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
(UNAUDITED)**

	Nine months ended September 30, 2019				Total stockholders' equity
	Common stock		Additional paid-in capital	Accumulated deficit	
	Shares	Amount			
<b>Balance at December 31, 2018</b>	<b>17,626,873</b>	<b>\$ 17,627</b>	<b>\$ 175,476,075</b>	<b>\$ (117,892,041)</b>	<b>\$ 57,601,661</b>
Issuance of common stock, net of issuance costs	3,439,523	3,439	18,076,359	—	18,079,798
Issuance of restricted stock	8,600	9	(9)	—	—
Stock-based compensation expense	—	—	1,496,292	—	1,496,292
Net loss	—	—	—	(9,147,017)	(9,147,017)
<b>Balance at March 31, 2019</b>	<b>21,074,996</b>	<b>21,075</b>	<b>195,048,717</b>	<b>(127,039,058)</b>	<b>68,030,734</b>
Issuance of common stock, net of issuance costs	2,082,031	2,082	27,014,371	—	27,016,453
Exercise of stock options	40,983	41	189,659	—	189,700
Stock-based compensation expense	—	—	1,481,705	—	1,481,705
Net loss	—	—	—	(11,135,185)	(11,135,185)
<b>Balance at June 30, 2019</b>	<b>23,198,010</b>	<b>23,198</b>	<b>223,734,452</b>	<b>(138,174,243)</b>	<b>85,583,407</b>
Stock-based compensation expense	—	—	1,376,225	—	1,376,225
Net loss	—	—	—	(1,946,390)	(1,946,390)
<b>Balance at September 30, 2019</b>	<b>23,198,010</b>	<b>\$ 23,198</b>	<b>\$ 225,110,677</b>	<b>\$ (140,120,633)</b>	<b>\$ 85,013,242</b>

	Nine months ended September 30, 2018				Total stockholders' equity
	Common stock		Additional paid-in capital	Accumulated deficit	
	Shares	Amount			
<b>Balance at December 31, 2017</b>	<b>13,553,873</b>	<b>\$ 13,554</b>	<b>\$ 138,916,900</b>	<b>\$ (77,980,866)</b>	<b>\$ 60,949,588</b>
Issuance of restricted stock	7,500	7	(7)	—	—
Stock-based compensation expense	—	—	1,687,024	—	1,687,024
Net loss	—	—	—	(12,306,334)	(12,306,334)
<b>Balance at March 31, 2018</b>	<b>13,561,373</b>	<b>13,561</b>	<b>140,603,917</b>	<b>(90,287,200)</b>	<b>50,330,278</b>
Stock-based compensation expense	—	—	1,755,859	—	1,755,859
Net loss	—	—	—	(12,007,233)	(12,007,233)
<b>Balance at June 30, 2018</b>	<b>13,561,373</b>	<b>13,561</b>	<b>142,359,776</b>	<b>(102,294,433)</b>	<b>40,078,904</b>
Issuance of common stock, net of issuance costs	4,062,500	4,062	29,933,443	—	29,937,505
Stock-based compensation expense	—	—	1,584,230	—	1,584,230
Net loss	—	—	—	(7,807,365)	(7,807,365)
<b>Balance at September 30, 2018</b>	<b>17,623,873</b>	<b>\$ 17,623</b>	<b>\$ 173,877,449</b>	<b>\$ (110,101,798)</b>	<b>\$ 63,793,274</b>

See accompanying notes to unaudited consolidated financial statements.

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CONSOLIDATED STATEMENTS OF CASH FLOWS  
(UNAUDITED)**

	<b>Nine months ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (22,228,592)	\$ (32,120,932)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	98,207	73,195
Stock-based compensation	4,354,222	5,027,113
Changes in operating assets and liabilities:		
Incentive and tax receivables	(10,002,361)	888,409
Prepaid expenses and other assets	1,046,133	(1,017,128)
Deferred grant revenue	—	(662,000)
Right-of-use assets	(5,723)	—
Accounts payable	(1,163,454)	121,583
Accrued expenses	548,454	1,500,251
Net cash used in operating activities	<u>(27,353,114)</u>	<u>(26,189,509)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(81,051)	(157,409)
Net cash used in investing activities	<u>(81,051)</u>	<u>(157,409)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of common stock, net of offering costs	45,096,251	30,014,017
Payment of deferred financing costs	(68,029)	—
Proceeds from the exercise of stock options	189,700	—
Net cash provided by financing activities	<u>45,217,922</u>	<u>30,014,017</u>
Net increase in cash and cash equivalents	17,783,757	3,667,099
Cash and cash equivalents at beginning of period	<u>59,763,773</u>	<u>62,510,277</u>
Cash and cash equivalents at end of period	<u>\$ 77,547,530</u>	<u>\$ 66,177,376</u>
<b>Supplemental disclosures of cash flow information:</b>		
Deferred financing costs included in accounts payable and accrued expenses	\$ 62,357	\$ 76,512
Changes in property and equipment acquired but not paid	\$ 15,594	\$ —
Reclassification of deferred rent liability to right-of-use assets upon adoption of ASC 842	\$ 12,824	\$ —
Right-of-use assets and lease liability recorded upon adoption of ASC 842	\$ 325,683	\$ —

See accompanying notes to unaudited consolidated financial statements

**ZYNERBA PHARMACEUTICALS, NC.  
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**

**(1) Nature of Business and Liquidity**

Zynerba Pharmaceuticals, Inc., together with its subsidiary, Zynerba Pharmaceuticals Pty Ltd (“Zynerba”, the “Company”, “we”), is a clinical stage specialty pharmaceutical company focused on the development of pharmaceutically-produced transdermal cannabinoid therapies for rare and near-rare neuropsychiatric disorders, 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. The Company was incorporated on January 31, 2007 under the laws of the State of Delaware as AllTranz, Inc. and changed its name to Zynerba Pharmaceuticals, Inc. in August 2014.

The Company has incurred losses and negative cash flows from operations since inception and has an accumulated deficit of \$140.1 million as of September 30, 2019. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant revenue from its product candidates currently in development. The Company's primary source of liquidity has been the issuance of equity securities.

On August 30, 2019, the Company entered into a Controlled Equity Offering Sales Agreement<sup>6M</sup> (the “2019 Sales Agreement”) with Cantor Fitzgerald & Co., Canaccord Genuity, LLC, H.C. Wainwright & Co. LLC and Ladenburg Thalmann & Co. Inc., as sales agents (the “Agents”), pursuant to which the Company may sell, from time to time, up to \$75.0 million of its common stock. As of November 1, 2019, there have been no sales of common stock under the 2019 Sales Agreement.

In June 2017, the Company entered into an Open Market Sales Agreement (the “Sales Agreement”) with Jefferies LLC, (“Jefferies”) pursuant to which the Company sold \$50.0 million of its common stock. In the first quarter of 2019, the Company sold and issued 3,439,523 shares of common stock under the Sales Agreement with Jefferies in the open market at a weighted average selling price of \$5.44 per share, resulting in gross proceeds of \$18.7 million. Net proceeds received after deducting commissions and offering expenses were \$18.1 million. In the second quarter of 2019, the Company sold and issued 2,082,031 shares of common stock under the Sales Agreement with Jefferies in the open market at a weighted average selling price of \$13.50 per share, resulting in gross proceeds of \$28.1 million. Net proceeds received after deducting commissions and offering expenses were \$27.0 million. The last sale under the Sales Agreement was made on May 16, 2019. From June 2017 through May 16, 2019, the Company has cumulative gross proceeds of \$50.0 million from shares sold in the open market under the Sales Agreement, which has terminated pursuant to its terms.

In July 2018, the Company completed a follow-on public offering, selling 4,062,500 shares of its common stock at an offering price of \$8.00 per share, resulting in gross proceeds of \$32.5 million. Net proceeds received after deducting underwriting discounts and commissions and offering expenses were \$29.9 million.

In July 2019, the Australian government’s Department of Industry, Innovation and Science (“AusIndustry”) responded to an Advance Overseas Finding (“AOF”) application submitted by Zynerba that will allow certain research and development expenses incurred with respect to the Company’s product candidate Zygel<sup>TM</sup> outside of Australia to be eligible for the Australian research and development tax incentive program. As a result of this finding, the Company is 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 ended September 30, 2019, the Company recorded \$8.3 million as an Incentive and Tax Receivable and recorded a corresponding credit to research and development expense for amounts expected to be received through the AOF for the period 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.

Management believes that current cash and cash equivalents and the proceeds anticipated from the AOF are sufficient to fund operations and capital requirements into the second half of 2021. Substantial additional financings will be needed by the Company to fund its operations, to complete clinical development of and to commercially develop its product candidates. There is no assurance that such financing will be available when needed or on acceptable terms.

The Company is subject to those risks associated with any clinical stage pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development

**ZYNERBA PHARMACEUTICALS, INC.**  
**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees and consultants.

**(2) Summary of Significant Accounting Policies**

a. Basis of Presentation

The accompanying unaudited interim consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The interim unaudited consolidated financial statements have been prepared on the same basis as the consolidated financial statements as of and for the year ended December 31, 2018 included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018 (“2018 Annual Report”), filed with the Securities and Exchange Commission (“SEC”). In the opinion of management, the accompanying consolidated financial statements of the Company include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the consolidated financial statements) considered necessary to present fairly the Company’s financial position as of September 30, 2019 its results of operations for the three and nine months ended September 30, 2019 and 2018 and cash flows for the nine months ended September 30, 2019 and 2018. Operating results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying unaudited interim consolidated financial statements should be read in conjunction with the consolidated financial statements and related notes included in the Company’s 2018 Annual Report.

b. Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from such estimates.

c. Incentive and Tax Receivables

The Company’s subsidiary, Zynerba Pharmaceuticals Pty Ltd (the “Subsidiary”), is incorporated in Australia. The Subsidiary 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. The cash refund is available to eligible companies with an annual aggregate revenue of less than \$20.0 million (Australian dollars) during the reimbursable period. The Company’s estimate of the amount of cash refund it expects to receive related to the Australian research and development tax incentive program is included in “Incentive and tax receivables” in the accompanying consolidated balance sheets. As of September 30, 2019, the Company’s estimate of the amount of cash refund it expects to receive in 2019 for 2018 eligible spending as part of this incentive program was \$3.1 million and was recorded as a current asset. The Company’s estimate of the amount of cash refund it expects to receive in 2020 for 2019 eligible spending through September 30, 2019 was \$2.1 million and was recorded as a current asset.

In July 2019, AusIndustry responded to an AOF application submitted by Zynerba that will allow certain research and development expenses incurred with respect to Zysel outside of Australia to be eligible for the Australian research and development tax incentive program. As a result of this finding, the Company is 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 ended September 30, 2019, the Company recorded \$8.3 million as an incentive and tax receivable and recorded a corresponding credit to research and development expense for amounts expected to be received through the AOF for the period January 1, 2018 through September 30, 2019. As of September 30, 2019, incentive and tax receivables included \$8.0 million related to the AOF. The reduction of \$0.3 million was due to unrealized foreign currency losses related to the remeasurement of the Subsidiary’s assets and liabilities.

In addition, the Subsidiary incurs Goods and Services Tax (“GST”) on services provided by Australian vendors. As an Australian entity, the Subsidiary is entitled to a refund of the GST paid. The Company’s estimate of the amount of cash

**ZYNERBA PHARMACEUTICALS, INC.**  
**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

refund it expects to receive related to GST incurred is included in “Incentive and tax receivables” in the accompanying consolidated balance sheets. As of September 30, 2019, incentive and tax receivables included \$0.3 million for refundable GST on expenses incurred with Australian vendors during the three months ended September 30, 2019.

Incentive and tax receivables consisted of the following as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Research and development incentive for the period 1/1/18 - 12/31/18	\$ 3,026,622	\$ 3,149,546
Research and development incentive (non-AOF) for the period 1/1/19 - 09/30/19	2,118,304	—
Research and development incentive (AOF) for the period 1/1/18 - 09/30/19	7,992,022	—
Goods and services tax	310,033	295,074
<b>Total incentive and tax receivables</b>	<b>\$ 13,446,981</b>	<b>\$ 3,444,620</b>

d. Research and Development

Research and development costs are expensed as incurred and are primarily comprised of external research and development expenses incurred under arrangements with third parties, such as contract research organizations, contract manufacturing organizations, consultants and employee-related expenses including salaries and benefits. At the end of each reporting period, the Company compares the payments made to each service provider to the estimated progress towards completion of the related project. Factors that the Company considers in preparing these estimates include the number of patients enrolled in studies, milestones achieved and other criteria related to the efforts of its vendors. These estimates will be subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, the Company will record net prepaid or accrued expenses related to these costs. Research and development expenses are recorded net of expected refunds of eligible research and development costs paid pursuant to the Australian research and development tax incentive program and GST incurred on services provided by Australian vendors. For the nine months ended September 30, 2019 and 2018, the Company incurred research and development expenses of \$12.9 million and \$22.4 million, respectively, which were net of \$10.5 million and \$2.8 million, respectively, associated with the Australian research and development tax incentive program.

e. Net Loss Per Share

Basic net loss per share is determined using the weighted average number of shares of common stock outstanding during each period. Diluted net income per share includes the effect, if any, from the potential exercise or conversion of securities, such as restricted stock and stock options, which would result in the issuance of incremental shares of common stock. Basic and dilutive computations of net loss per share are the same in periods in which a net loss exists as the dilutive effects of restricted stock and stock options would be anti-dilutive.

The following potentially dilutive securities outstanding as of September 30, 2019 and 2018 have been excluded from the computation of diluted weighted average shares outstanding, as their effects on net loss per share for the periods presented would be anti-dilutive:

	September 30,	
	2019	2018
Stock options	3,990,623	3,158,531
Unvested restricted stock	11,600	7,500
	<b>4,002,223</b>	<b>3,166,031</b>

f. Recently Adopted Accounting Pronouncements

In 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases (Topic 842), Accounting Standards Codification 842 (“ASC 842”)*, which amends a number of aspects of lease accounting and requires entities to recognize right-of-use assets and lease liabilities on the balance sheet for leases with lease terms of more than 12 months. ASC 842 became effective on January 1, 2019. In July 2018, the FASB issued

**ZYNERBA PHARMACEUTICALS, INC.**  
**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements* (“ASU 2018-11”), which offered a transition option to entities adopting ASC 842. Under ASU 2018-11, entities can elect to apply ASC 842 using a modified-retrospective adoption approach resulting in a cumulative effect adjustment, if any, to retained earnings at the beginning of the year in which the new lease standard is adopted, rather than adjustments to the earliest comparative period presented in their financial statements.

As of January 1, 2019, the Company adopted ASC 842 using the modified-retrospective method and recognized right-of-use assets and corresponding lease liability of \$325,683, which represented the present value of the remaining lease payments of \$350,507, discounted using the Company’s incremental borrowing rate of 11.17%. In addition, the Company eliminated its deferred rent liability and recorded an adjustment to decrease its right-of-use assets by \$12,824. The adoption of the standard did not have an impact on the Company’s consolidated statements of cash flows and had no impact on the Company’s consolidated statement of operations.

**(3) Fair Value Measurements**

The Company measures certain assets and liabilities at fair value in accordance with Accounting Standards Codification 820 (“ASC 820”), *Fair Value Measurements and Disclosures*. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The guidance in ASC 820 outlines a valuation framework and creates a fair value hierarchy that serves to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company maximizes the use of quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 — Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.

Level 3 — Valuations based on unobservable inputs and models that are supported by little or no market activity.

In accordance with the fair value hierarchy described above, the following table sets forth the Company's financial assets measured at fair value on a recurring basis as of September 30, 2019 and December 31, 2018:

	Carrying amount as of September 30, 2019	Fair Value Measurement as of September 30, 2019		
		Level 1	Level 2	Level 3
Cash equivalents (money market accounts)	\$ 77,413,227	\$ 77,413,227	\$ —	\$ —
	\$ 77,413,227	\$ 77,413,227	\$ —	\$ —

	Carrying amount as of December 31, 2018	Fair Value Measurement as of December 31, 2018		
		Level 1	Level 2	Level 3
Cash equivalents (money market accounts)	\$ 59,554,458	\$ 59,554,458	\$ —	\$ —
	\$ 59,554,458	\$ 59,554,458	\$ —	\$ —

[Table of Contents](#)**ZYNERBA PHARMACEUTICALS, INC.**  
**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(4) Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consisted of the following as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Prepaid development expenses	\$ 1,125,195	\$ 2,671,815
Prepaid insurance	1,175,259	393,451
Deferred financing costs	130,386	255,754
Other current assets	400,500	426,067
Total prepaid expenses and other current assets	<u>\$ 2,831,340</u>	<u>\$ 3,747,087</u>

**(5) Property and Equipment**

Property and equipment consisted of the following as of September 30, 2019 and December 31, 2018:

	Estimated useful life (in years)	September 30, 2019	December 31, 2018
Equipment	2-5	\$ 257,309	\$ 178,001
Computer equipment	3-5	30,319	30,319
Furniture and fixtures	3-5	313,137	300,407
Leasehold improvements	various	68,881	68,881
Construction in process		30,434	57,015
Total cost		700,080	634,623
Less accumulated depreciation		(360,867)	(262,660)
Property and equipment, net		<u>\$ 339,213</u>	<u>\$ 371,963</u>

Depreciation expense was \$36,027 and \$25,043 for the three months ended September 30, 2019 and 2018, respectively, and \$98,207 and \$73,195 for the nine months ended September 30, 2019 and 2018, respectively.

**(6) Accrued Expenses**

Accrued expenses consisted of the following as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Accrued compensation	\$ 1,894,724	\$ 2,188,801
Accrued research and development	3,487,224	1,928,305
Grants payable	—	747,926
Other	460,314	399,183
Total accrued expenses	<u>\$ 5,842,262</u>	<u>\$ 5,264,215</u>

**(7) Common Stock**

On August 30, 2019, the Company entered into the 2019 Sales Agreement with the Agents pursuant to which the Company may sell, from time to time, up to \$75.0 million of its common stock. As of November 1, 2019, there have been no sales of common stock under the 2019 Sales Agreement.

In June 2017, the Company entered into the Sales Agreement with Jefferies pursuant to which the Company sold \$50.0 million of its common stock. In the first quarter of 2019, the Company sold and issued 3,439,523 shares of common stock under the Sales Agreement with Jefferies in the open market at a weighted average selling price of \$5.44 per share, resulting in gross proceeds of \$18.7 million. Net proceeds received after deducting commissions and offering expenses were \$18.1 million. In the second quarter of 2019, the Company sold and issued 2,082,031 shares of common stock under the Sales Agreement with Jefferies in the open market at a weighted average selling price of \$13.50 per share,

**ZYNERBA PHARMACEUTICALS, INC.**  
**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

resulting in gross proceeds of \$28.1 million. Net proceeds received after deducting commissions and offering expenses were \$27.0 million. The last sale under the Sales Agreement was made on May 16, 2019. From June 2017 through May 16, 2019, the Company has cumulative gross proceeds of \$50.0 million from shares sold in the open market under the Sales Agreement, which has terminated pursuant to its terms.

In July 2018, the Company completed a follow-on public offering, selling 4,062,500 shares of its common stock at an offering price of \$8.00 per share, resulting in gross proceeds of \$32.5 million. Net proceeds received after deducting underwriting discounts and commissions and offering expenses were \$29.9 million.

**(8) Stock-Based Compensation**

The Company maintains the Amended and Restated 2014 Omnibus Incentive Compensation Plan, as amended (the "2014 Plan"), which allows for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, stock awards, stock units, performance units and other stock-based awards to employees, officers, non-employee directors, consultants, and advisors. In addition, the 2014 Plan provides selected executive employees with the opportunity to receive bonus awards that are considered qualified performance-based compensation. The 2014 Plan is subject to automatic annual increases in the number of shares authorized for issuance under the 2014 Plan on the first trading day of January each year equal to the lesser of 1.5 million shares or 10% of the number of shares of common stock outstanding on the last trading day of December of the preceding year. As of January 1, 2019, the number of shares of common stock that may be issued under the 2014 Plan was automatically increased by 1.5 million shares, increasing the number of shares of common stock available for issuance under the 2014 Plan to 6,304,869 shares. As of September 30, 2019, 1,765,870 shares were available for future issuance under the 2014 Plan.

Options issued under the 2014 Plan have a contractual life of 10 years and may be exercisable in cash or as otherwise determined by the board of directors. The Company has granted options to employees and non-employee directors. Stock options granted to employees vest 25% upon the first anniversary of the grant date and the balance of unvested options vests in quarterly installments over the remaining three years. Stock options granted annually to non-employee directors vest on the earlier of the one-year anniversary of the grant date, or the date of the Company's next annual stockholders' meeting that occurs after the grant date. The Company's non-employee director compensation policy enables directors to receive stock options in lieu of quarterly cash payments. Any option granted to the directors in lieu of cash compensation vests in full on the grant date. The Company records forfeitures as they occur.

During 2018, the Company granted 83,280 performance-based stock options to certain employees. These performance options have a 10-year life and an exercise price equal to the fair value of the Company's stock at the grant date. During 2019, the Company granted 5,000 performance-based restricted stock awards. Vesting of the performance-based options and restricted stock awards is dependent on meeting certain performance conditions, which relate to the Company's research and development progress, which were established by the Company's board of directors. The Company's board of directors determines if the performance conditions have been met. Stock-based compensation expense for these performance-based grants are recorded when management estimates that the vesting of these shares is probable based on the status of the Company's research and development programs and other relevant factors. For the nine months ended September 30, 2019, none of the performance-based metrics were deemed probable of achievement. Any change in these estimates will result in a cumulative adjustment in the period in which the estimate is changed, so that as of the end of a period, the cumulative compensation expense recognized for an award or grant equals the amount that would be recognized on a straight-line basis as if the current estimates had been utilized since the beginning of the service period. As of September 30, 2019, the aggregate estimated grant date fair values of options and restricted stock awards for which the satisfaction of the related-performance conditions have not been deemed probable were \$663,484 and \$24,850, respectively.

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**ZYNERBA PHARMACEUTICALS, INC.**  
**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

For the nine months ended September 30, 2019 and 2018, the Company recorded stock-based compensation expense related to its stock option grants and restricted stock awards, as follows:

	Stock Option Grants		Restricted stock awards		Total	
	2019	2018	2019	2018	2019	2018
Research and development	\$ 1,893,441	\$ 2,096,710	\$ 22,137	\$ 171,073	\$ 1,915,578	\$ 2,267,783
General and administrative	2,438,644	2,712,517	—	46,813	2,438,644	2,759,330
	<u>\$ 4,332,085</u>	<u>\$ 4,809,227</u>	<u>\$ 22,137</u>	<u>\$ 217,886</u>	<u>\$ 4,354,222</u>	<u>\$ 5,027,113</u>

The following table summarizes the stock option activity for the nine months ended September 30, 2019:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Life (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	3,152,267	\$ 12.16		
Granted	931,089	6.02		
Exercised	(40,983)	4.63		
Cancelled / Forfeited	(51,750)	10.87		
Outstanding as of September 30, 2019	<u>3,990,623</u>	<u>10.82</u>	<u>7.44</u>	<u>\$ 4,523,563</u>
Exercisable as of September 30, 2019	<u>2,351,847</u>	<u>11.91</u>	<u>6.50</u>	<u>\$ 1,822,175</u>
Vested and expected to vest as of September 30, 2019	<u>3,907,343</u>	<u>\$ 10.81</u>		

The weighted-average grant date fair values of options granted during the nine months ended September 30, 2019 and 2018 was \$4.19 and \$7.94, respectively.

The fair values of stock options granted were calculated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Nine months ended September 30,	
	2019	2018
Weighted-average risk-free interest rate	2.38%	2.51%
Expected term of options (in years)	6.16	6.13
Expected stock price volatility	80.00%	78.00%
Expected dividend yield	0%	0%

As of September 30, 2019, excluding performance-based stock options that have not been deemed probable, there was \$8.6 million of unrecognized stock-based compensation expense related to stock options, which is expected to be recognized over a weighted-average period of 2.26 years.

The following table summarizes the restricted stock award activity under the 2014 Plan for the nine months ended September 30, 2019:

	Shares	Weighted Average Grant Date Fair Value
	Unvested as of December 31, 2018	10,500
Granted	8,600	4.42
Vested	(7,500)	13.46
Unvested as of September 30, 2019	<u>11,600</u>	<u>\$ 5.31</u>

As of September 30, 2019, excluding performance-based restricted stock awards that have not been deemed probable, there was \$8,640 of unrecognized stock-based compensation expense related to unvested restricted stock awards, which is expected to be recognized over a weighted-average period of 1.32 years. The Company expects that all 6,600 of the unvested, non-performance based, restricted stock awards will vest.

**ZYNERBA PHARMACEUTICALS, INC.**  
**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(9) Operating Lease Obligations**

The Company adopted ASC 842 prospectively using the modified-retrospective method and elected the package of transition practical expedients that does not require reassessment of: (1) whether any existing or expired contracts are or contain leases, (2) lease classification and (3) initial direct costs. In addition, the Company has elected other available practical expedients to not separate lease and nonlease components, which consist principally of common area maintenance charges, and to exclude leases with an initial term of 12 months or less.

The Company leases its headquarters where it occupies 10,877 square feet of office space pursuant to a five-year lease that expires on May 31, 2020. The Company's lease contains variable lease costs that do not depend on a rate or index and consist primarily of common area maintenance, taxes, and insurance charges. As the implicit rate was not readily determinable for the Company's lease, the Company used an estimated incremental borrowing rate, or discount rate, to determine the initial present value of the lease payments. The discount rate for the lease was calculated using a synthetic credit rating model.

As of January 1, 2019, the Company recognized a lease liability of \$325,683 and right-of-use assets of \$312,859, which was recorded net of a pre-existing deferred rent liability of \$12,824. As of September 30, 2019, the Company's right-of-use asset, net of amortization, was \$152,166.

Other operating lease information as of September 30, 2019:

Weighted-average remaining lease term - operating leases	0.7 years
Weighted-average discount rate - operating leases	11.17 %

The following is a maturity analysis of the annual undiscounted cash flows of the operating lease liabilities as of September 30, 2019:

<b>Year ended:</b>	
December 31, 2019 (remaining months)	\$ 62,253
December 31, 2020	103,757
Total minimum lease payments	166,010
Less: imputed lease interest	(6,743)
Total lease liabilities	<u>\$ 159,267</u>

Lease expense for the nine months ended September 30, 2019 was comprised of the following:

Operating lease expense	\$ 178,773
Variable lease expense	44,023
Total lease expense	<u>\$ 222,796</u>

Cash payments related to operating leases for the nine months ended September 30, 2019 was \$184,496.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited interim consolidated financial statements and related notes appearing elsewhere in this Quarterly Report and the audited consolidated financial statements and notes thereto for the year ended December 31, 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our 2018 Annual Report. The following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of many factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this Quarterly Report, including those set forth under "Cautionary Note Regarding Forward-looking Statements" and "Risk Factors" in this Quarterly Report and our 2018 Annual Report.*

### **Overview**

#### **Company Overview**

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, or FXS, autism spectrum disorder, or ASD, 22q11.2 deletion syndrome, or 22q, and a heterogeneous group of rare and ultra-rare epilepsies known as developmental and epileptic encephalopathies, or DEE.

We are currently evaluating Zygel™, a patent-protected transdermal cannabidiol, or CBD, gel for the treatment of FXS, DEE, ASD and 22q. In 2017, we completed three Phase 2 clinical trials for Zygel and two of those studies have open-label extensions that are ongoing. In April 2018, we initiated an open-label Phase 2 clinical trial evaluating Zygel in children and adolescent patients with DEE. In September 2019, we completed the first six months of dosing for that study and announced positive top-line results. In July 2018, we initiated what we believe will be a pivotal clinical trial evaluating Zygel in children and adolescent patients with FXS. In March 2019, we initiated an open-label Phase 2 clinical trial evaluating Zygel in children and adolescent patients with ASD and in May 2019, we initiated an open-label Phase 2 clinical trial evaluating Zygel in children and adolescent patients with 22q.

Cannabinoids are a class of compounds derived from *Cannabis* plants. The two primary cannabinoids contained in *Cannabis* are CBD and Tetrahydrocannabinol, or THC. Clinical and preclinical data suggest that CBD has positive effects on treating behavioral symptoms of FXS, ASD, 22q and seizures in patients with epilepsy.

#### **Zygel**

Zygel is the first and only pharmaceutically-produced CBD formulated as a permeation-enhanced gel for transdermal delivery, and the formulation is patent protected through 2030. Two additional patents, directed to methods of treating FXS with synthetic or purified CBD and methods of treating ASD with synthetic CBD, respectively, will expire in 2038. CBD is the primary non-euphoric component of *Cannabis*.

In preclinical animal studies, Zygel's permeation enhancer increased delivery of CBD through the layers of the skin and into the circulatory system. These preclinical studies suggest increased bioavailability, consistent plasma levels and the avoidance of first-pass liver metabolism of CBD when delivered transdermally. In addition, an *in vitro* study published in *Cannabis and Cannabinoid Research* in April 2016 demonstrated that CBD is degraded to THC (the major psychoactive cannabinoid in *Cannabis*) in an acidic environment such as the stomach. As a result, we believe such degradation may lead to increased psychoactive effects if CBD is delivered orally and may be avoided with the transdermal delivery of Zygel, which maintains CBD in a neutral pH.

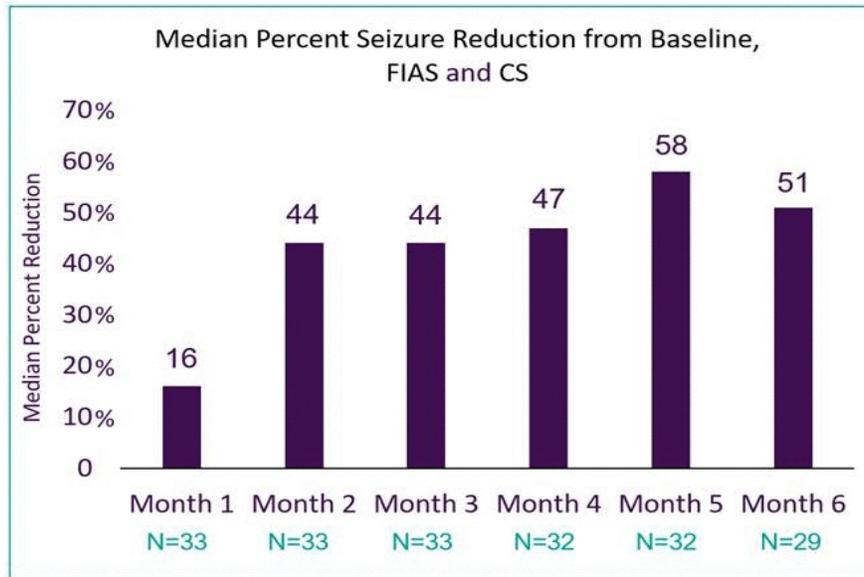
Zygel, which is being developed as a clear gel with once- or twice-daily dosing and is targeting treatment of behavioral symptoms of FXS, ASD and 22q and reduction in seizures in patients with DEE. We have been granted orphan drug designation from the U.S. Food and Drug Administration, or FDA, for the use of CBD for the treatment of FXS. In May 2019, we received Fast Track designation from the FDA for treatment of behavioral symptoms associated with FXS. The 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.

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In our Phase 1 program, Zysel was demonstrated to be safe and well tolerated, provided a favorable CBD pharmacokinetic profile, and no THC was detected in plasma or urine. As of June 2018, the Zysel safety database across all clinical studies conducted by us includes data from 570 volunteers and patients. Across these clinical studies, Zysel has been well tolerated and consistent with previously reported data.

In April 2018, we initiated the exploratory Phase 2 BELIEVE 1 (Open Label Study to Assess the Safety and Efficacy of Zysel Administered as a Transdermal Gel to Children and Adolescents with Developmental and Epileptic Encephalopathy) clinical trial, a six-month open label multi-dose clinical trial designed to evaluate the efficacy and safety of Zysel in children and adolescents (three to 17 years) with DEE as classified by the International League Against Epilepsy (ILAE) (Scheffer et al. 2017). Forty-eight patients with confirmed DEE were dosed in this clinical trial. Patients received weight-based initial doses of 250 mg or 500 mg daily and during the maintenance phase patients received up to 1000 mg daily of Zysel.

In September 2019, we reported positive top-line data from the BELIEVE 1 trial. All 48 patients enrolled in the trial were included in the safety data for the trial. Forty-six patients were included in the modified intent-to-treat population (mITT). Of the 46 patients in the mITT population, 33 (72%) had focal impaired-awareness seizures (FIAS; previously known as complex partial seizures) and/or convulsive seizures (focal to bilateral tonic-clonic seizures and generalized tonic-clonic seizures) at baseline. These patients experienced a mean baseline seizure count of 64 FIAS and/or convulsive seizures, and a median baseline seizure count of 8.2 FIAS and/or convulsive seizures. Compared to baseline seizure frequency, these patients experienced a  $\geq 44\%$  median reduction in these seizures from month two onwards using monthly seizure frequency.



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Fifty-five percent (55%) of patients with FIAS and/or convulsive seizures experienced a  $\geq 50\%$  median reduction in seizures at month six of treatment with Zysel.



Caregivers also reported improvements in alertness, awareness or energy in 58% of patients.

In the trial, Zysel was well tolerated, and the safety profile was consistent with previously released data from Zysel clinical trials. One patient discontinued the study as a result of an application site reaction, and seven discontinued as a result of withdrawal of consent or perceived lack of efficacy. Children with DEE are medically fragile, and as such adverse events, whether unrelated or related to study drug, that occur during the trial period are common and expected. Through six months of therapy, 60% of patients experienced a treatment related adverse event. Most treatment related adverse events were mild to moderate. The most common treatment related adverse events (in  $>5\%$  of patients) are application site dryness (8.3%), application site pain (8.3%), and somnolence (8.3%). Ten patients experienced a serious adverse event (SAE), eight of which were deemed to be unrelated to study drug. Two SAE's 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 patient deaths during the study.

In July 2018, we initiated the pivotal CONNECT-FX (Clinical study of Cannabidiol (CBD) in Children and Adolescents with Fragile X) clinical trial, a multi-national randomized, double-blind, placebo-controlled, 14-week study that will assess the efficacy and safety of Zysel in children and adolescents ages three through 17 years who have full mutation of the FMR1 gene. Approximately 200 male and female patients with FXS will be enrolled at approximately 20 clinical sites in the United States, Australia, and New Zealand. The study is being conducted in the United States under an Investigational New Drug (IND) application opened with the FDA. Patients will be randomized 1:1 to either trial drug or placebo. Randomization will be stratified by gender, weight, and investigator geographic region. Enrolled patients will receive weight-based doses of 250 mg or 500 mg daily. 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<sub>FXS</sub>) Social Avoidance subscale. Key secondary endpoints are the change from baseline to the end of the treatment period in the ABC-C<sub>FXS</sub> Irritability subscale score, the ABC-C<sub>FXS</sub> Socially Unresponsive/Lethargic subscale score, and improvement in Clinical Global Impression - Improvement (CGI-I) at the end of the treatment period. Based on discussions with the FDA, we will anchor the CGI-I scale to behavioral symptoms of FXS. Consistent with recent guidance from the FDA on capturing the voice of the patient in drug development, additional qualitative data on the clinical relevance of various FXS behaviors to caregivers and patients will be collected. If we obtain positive results from this trial, we plan to request a meeting with the FDA to determine the acceptability of these data as the basis for an NDA filing. We expect to report top line results from the CONNECT-FX trial in the first half of 2020.

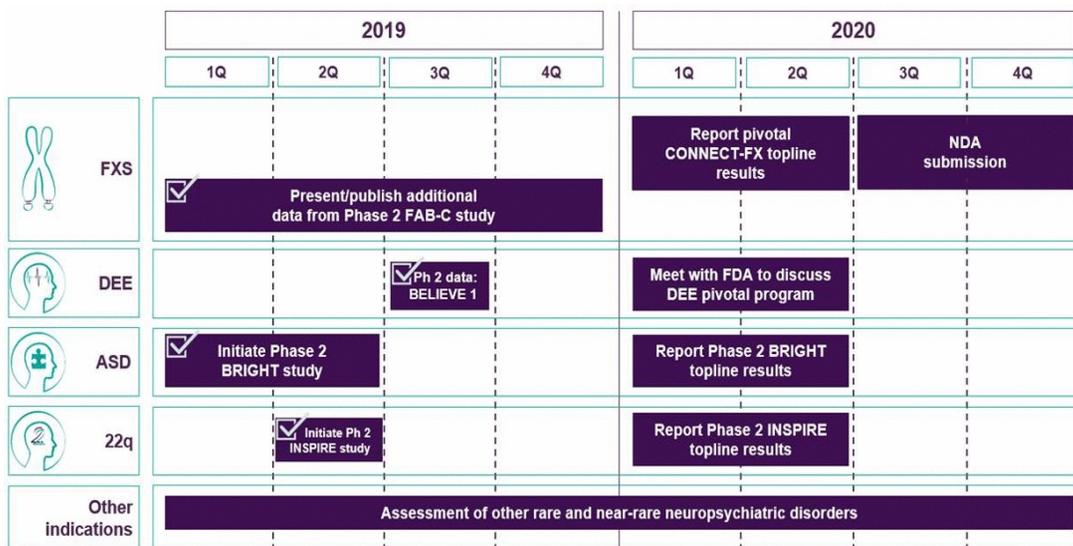
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In March 2019, we initiated the Phase 2 BRIGHT (An Open-Label Tolerability and Efficacy Study of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Autism Spectrum Disorder) trial, a 14-week open label clinical trial designed to assess the safety, tolerability and efficacy of Zygel for the treatment of behavioral symptoms of ASD. We expect to enroll approximately 36 male and female patients (age four to 17 years) and to report top line data from this study in the first half of 2020.

In May 2019, we initiated the open-label Phase 2 INSPIRE (Assessing the Impact of Zygel [Transdermal CBD Gel] on Pediatric Behavioral and Emotional Symptoms of 22q11.2 Deletion Syndrome) trial, a 14-week open label clinical trial designed to assess the safety, tolerability and efficacy of Zygel for treatment of behavioral symptoms of 22q. We expect to enroll approximately 20 male and female patients (age six to 17 years) and to report top line data from this study in the first half of 2020.

**Zygel Clinical Development Timelines**

Our key development programs and expected timelines for the development of Zygel are shown in the chart below:



We have never been profitable and have incurred net losses since inception. Our net losses were \$22.2 million and \$32.1 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, our accumulated deficit was \$140.1 million. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability.

**Financial Operations Overview**

The following discussion sets forth certain components of our consolidated statements of operations as well as factors that impact those items.

*Revenue*

Historically, our revenue consisted of state and federal research grants and fees received from research services for third-party product development. Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

[Table of Contents](#)*Research and Development Expenses*

Our research and development expenses relating to our product candidates consisted of the following:

- expenses associated with preclinical development and clinical trials;
- personnel-related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation;
- payments to third-party CROs or CMOs, contractor laboratories and independent contractors; and
- depreciation, maintenance and other facility-related expenses.

We expense all research and development costs as incurred. Clinical development expenses for our product candidates are a significant component of our current research and development expenses. Generally speaking, expenses associated with clinical trials will increase as our clinical trials progress. Product candidates in later stage clinical development generally have higher research and development expenses than those in earlier stages of development, primarily due to increased size and duration of the clinical trials. We track and record information regarding external research and development expenses for each grant, study or trial that we conduct. We use third-party CROs, CMOs, contractor laboratories and independent contractors in preclinical studies and clinical trials. We recognize the expenses associated with third parties performing these services for us in our preclinical studies and clinical trials based on the percentage of each study completed at the end of each reporting period.

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 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 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.

For the nine months ended September 30, 2019 and 2018, we incurred research and development expenses of \$12.9 million and \$22.4 million, respectively, which were net of \$10.5 million and \$2.8 million, respectively, associated with the Australian research and development tax incentive program.

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Research and development expenses - before R&D incentive	\$ 7,381,241	\$ 5,569,430	\$ 23,380,269	\$ 25,212,001
Research and development incentive (non-AOF)	(715,631)	(709,528)	(2,184,164)	(2,843,120)
Research and development expenses (before impact of AOF)	6,665,610	4,859,902	21,196,105	22,368,881
AOF - cumulative change in estimate for the period 1/1/18 through 9/30/19	(8,270,009)	—	(8,270,009)	—
Total research and development expenses	\$ (1,604,399)	\$ 4,859,902	\$ 12,926,096	\$ 22,368,881

Excluding the reduction of research and development expenses from the AOF, we expect research and development expenses to slightly increase in 2019 as compared to 2018, as we continue to advance our clinical trials. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of our

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preclinical development and clinical trials may take several years or more and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the size of patient populations participating in the clinical trials;
- the duration of patient follow-ups;
- the development stage of the product candidates; and
- the efficacy and safety profile of the product candidates.

Due to the early stages of our research and development, we are unable to determine the duration or completion costs of our development of our product candidates. As a result of the difficulties of forecasting research and development costs of our product candidates as well as the other uncertainties discussed above, we are unable to determine when and to what extent we will generate revenue from the commercialization and sale of an approved product candidate.

### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our executive, finance, legal, human resource, investor relations and commercial functions. Our general and administrative expenses also include facility and related costs not included in research and development expenses, professional fees for legal services, including patent-related expenses, consulting, tax and accounting services, insurance, market research and general corporate expenses. We expect that our general and administrative expenses will increase for the next several years as we increase our headcount with the continued development and potential commercialization of our product candidates.

### *Interest Income*

Interest income primarily consists of interest earned on balances maintained in our money market bank account.

### *Foreign Exchange (Loss) Gain*

Foreign exchange (loss) gain relates to the effect of exchange rates on transactions incurred by the Subsidiary.

### **Critical Accounting Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reported period. In accordance with GAAP, we base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying amounts of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations as well as the specific manner in which we apply those principles. Critical accounting estimates and the accounting policies critical to the process of making significant judgments and estimates in the preparation of our consolidated financial statements are discussed in our 2018 Annual Report under Part II, Item 7, "Critical Accounting Policies and Use of

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Estimates". During the nine months ended September 30, 2019, there have been no material changes to the critical accounting estimates or critical accounting policies discussed in our 2018 Annual Report.

**Results of Operations**

***Comparison of the Three Months Ended September 30, 2019 and 2018***

*Research and Development Expenses*

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, or 37%, 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.

*General and Administrative Expenses*

General and administrative expenses increased by \$0.4 million, or 13%, to \$3.5 million for the three months ended September 30, 2019 from \$3.1 million for the three months ended September 30, 2018. The increase was primarily related to an increase in pre-commercialization expense for our product candidates, an increase in directors and officers liability insurance expense and higher employee-related costs.

*Other Income (Expense)*

During the three months ended September 30, 2019 and 2018, we recognized \$0.4 million and \$0.3 million, respectively, in interest income. The increase in interest income was primarily related to a higher amount of invested cash resulting from the receipt of \$45.1 million in net proceeds from the sale of our shares of common stock under the Sales Agreement with Jefferies during the first half of 2019. During the three months ended September 30, 2019 and 2018, we recognized foreign currency losses of \$0.5 million and \$0.1 million, respectively. Foreign currency gains and losses are due primarily to the remeasurement of the Subsidiary's assets and liabilities, which are denominated in the local currency to the subsidiary's functional currency, which is the U.S. dollar.

***Comparison of the Nine Months Ended September 30, 2019 and 2018***

*Research and Development Expenses*

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 decreased by \$1.2 million, or 5%, to \$21.2 million for the nine months ended September 30, 2019 from \$22.4 million for the nine months ended September 30, 2018. The decrease was primarily related to a decrease in non-clinical trial costs related to our Zygel program and decreases in employee-related costs and stock-based compensation expense; partially offset by an increase in clinical trial costs related to our Zygel program.

*General and Administrative Expenses*

We incurred general and administrative expenses of \$10.0 million for both the nine months ended September 30, 2019 and 2018. Higher employee-related costs and an increase in directors and officers liability insurance expense were offset by decreases in stock-based compensation expense and lower costs associated with the recruiting of new employees.

*Other Income (Expense)*

During the nine months ended September 30, 2019 and 2018, we recognized \$1.2 million and \$0.6 million, respectively, in interest income. The increase in interest income was related both to a higher average interest rate earned on our investments and to a higher amount of invested cash resulting from the receipt of \$45.1 million in net proceeds from the sale of our shares of common stock under the Sales Agreement with Jefferies during the first half of 2019. During the nine months ended September 30, 2019 and 2018, we recognized foreign currency losses of \$0.6 million and \$0.4 million, respectively. Foreign currency gains and losses are due primarily to the remeasurement of the Subsidiary's

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assets and liabilities that are denominated in the local currency to the subsidiary's functional currency, which is the U.S. dollar.

### **Liquidity and Capital Resources**

Since our inception in 2007, we have devoted most of our cash resources to research and development and general and administrative activities. We have financed our operations primarily with the proceeds from the sale of equity securities (most notably our IPO in 2015, sales under our "at-the-market" offering in 2016, 2017 and 2019, and our follow-on public offerings in the first quarter of 2017 and the third quarter of 2018, of which our 2018 and 2019 transactions are described below under Equity Financings) and convertible promissory notes, state and federal grants and research services.

To date, we have not generated any revenue from the sale of products, and we do not anticipate generating any revenue from the sales of products for the foreseeable future. We have incurred losses and generated negative cash flows from operations since inception. As of September 30, 2019, our principal sources of liquidity were our cash and cash equivalents of \$77.5 million. Our working capital was \$84.5 million as of September 30, 2019.

Management believes that current cash and cash equivalents and the proceeds anticipated from the AOF are sufficient to fund operations and capital requirements beyond the expected NDA submission and potential approval of Zygel for the treatment of FXS and into the second half of 2021. Substantial additional financings will be needed to fund our operations and to complete clinical development of and to commercially develop our product candidates. There is no assurance that such financing will be available when needed or on acceptable terms.

#### *Equity Financings*

On August 30, 2019, we entered into a Controlled Equity Offering Sales Agreement<sup>SM</sup>, or the 2019 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 we may sell, from time to time, up to \$75.0 million of our common stock. As of November 1, 2019, there have been no sales of common stock under the 2019 Sales Agreement.

In June 2017, we entered into an Open Market Sales Agreement, or Sales Agreement, with Jefferies LLC, or Jefferies, pursuant to which we sold \$50.0 million of our common stock. In the first quarter of 2019, we sold and issued 3,439,523 shares of common stock under the Sales Agreement with Jefferies in the open market at a weighted average selling price of \$5.44 per share, resulting in gross proceeds of \$18.7 million. Net proceeds received after deducting commissions and offering expenses were \$18.1 million. In the second quarter of 2019, we sold and issued 2,082,031 shares of common stock under the Sales Agreement with Jefferies in the open market at a weighted average selling price of \$13.50 per share, resulting in gross proceeds of \$28.1 million. Net proceeds received after deducting commissions and offering expenses were \$27.0 million. The last sale under the Sales Agreement was made on May 16, 2019. From June 2017 through May 16, 2019, we have cumulative gross proceeds of \$50.0 million from shares sold in the open market under the Sales Agreement, which has terminated pursuant to its terms.

In July 2018, we completed a follow-on public offering, selling 4,062,500 shares of our common stock at an offering price of \$8.00 per share, resulting in gross proceeds of \$32.5 million. Net proceeds received after deducting underwriting discounts and commissions and offering expenses were \$29.9 million.

#### *Debt*

We had no debt outstanding as of September 30, 2019 or December 31, 2018.

#### *Future Capital Requirements*

During the nine months ended September 30, 2019, net cash used in operating activities was \$27.4 million, and our accumulated deficit as of September 30, 2019 was \$140.1 million. Our expectations regarding future cash requirements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make in the future. To the extent that we enter into any of those types of transactions, we may need to raise substantial additional capital.

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We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of our product candidates. If we obtain marketing approval for any of our product candidates, we will incur significant sales, marketing and manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to continue to incur significant costs to comply with corporate governance, internal controls and similar requirements associated with operating as a public reporting company.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we may develop or in-license;
- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the United States Drug Enforcement Agency, the FDA, the European Medicines Agency or other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- costs and timing of the implementation of commercial scale manufacturing activities; and
- the cost of establishing, or outsourcing, sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to independently commercialize our products.

To the extent that our capital resources are insufficient to meet our future operating and capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, collaboration and licensing arrangements or other financing alternatives. We have no committed external sources of funds. Additional equity or debt financing or collaboration and licensing arrangements may not be available on acceptable terms, if at all.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution.

### *Cash Flows*

The following table summarizes our cash flows from operating, investing and financing activities for the nine months ended September 30, 2019 and 2018.

	<b>Nine Months Ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>Statement of Cash Flows Data:</b>		
Total net cash (used in) provided by:		
Operating activities	\$ (27,353,114)	\$ (26,189,509)
Investing activities	(81,051)	(157,409)
Financing activities	45,217,922	30,014,017
Net increase in cash and cash equivalents	<u>\$ 17,783,757</u>	<u>\$ 3,667,099</u>

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### *Operating Activities*

For the nine months ended September 30, 2019, cash used in operating activities was \$27.4 million compared to \$26.2 million for the nine months ended September 30, 2018. The increase from the comparable 2018 period was primarily the result of the timing of accounts payable and accrued expenses.

Excluding the cash anticipated to be received from the July 2019 AOF application, we expect cash used in operating activities to slightly increase in 2019 as compared to 2018, as we continue to advance our clinical trials.

### *Investing Activities*

For the nine months ended September 30, 2019, cash used in investing activities represented the cost of expenditures made for manufacturing equipment. For the nine months ended September 30, 2018, cash used in investing activities represented the cost of expenditures made for manufacturing equipment and furniture and fixtures and leasehold improvements associated with our corporate headquarters.

### *Financing Activities*

Cash provided by financing activities for the nine months ended September 30, 2019 consisted primarily of \$45.1 million in net proceeds from sales of our shares of common stock under the Sales Agreement with Jefferies. Cash provided by financing activities for the nine months ended September 30, 2018 consisted primarily of \$29.9 million in net proceeds from sales of our shares of common stock under a follow-on public offering.

### **Contractual Obligations**

Other than the changes related to the adoption of the new lease accounting standard as described in Note 9 of our Notes to Unaudited Consolidated Financial Statements, there were no material changes in our contractual obligations since December 31, 2018. Our material contractual obligations consist of commitments under operating lease agreements and the related amounts of our obligations as of December 31, 2018 were disclosed in "Contractual Obligations" in Part II, Item 7 in our 2018 Annual Report.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, except for operating leases, or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

### **Recent Accounting Pronouncements**

For descriptions of recently issued accounting pronouncements, see "Note 2 – Summary of Significant Accounting Policies – Recently Adopted Accounting Pronouncements" of our Notes to Unaudited Consolidated Financial Statements included above in Part I of this report.

### **JOBS Act**

We are an "emerging growth company" as defined under the Jumpstart Our Business Startups Act of 2012, or JOBS Act. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." As an "emerging growth company," we have elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial

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statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation. These exemptions will apply until December 31, 2020 or until we no longer meet the requirements for being an "emerging growth company," whichever occurs first.

### **Item 3. *Quantitative and Qualitative Disclosures About Market Risk***

We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates, such as interest rates and foreign exchange rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes nor do we engage in any hedging activities. As of September 30, 2019, we had cash and cash equivalents of \$77.5 million, consisting primarily of cash and money market account balances. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an immediate 10% increase in interest rates would have any significant impact on the realized value of our investments. Accordingly, we do not believe we are exposed to material market risk with respect to our cash and cash equivalents.

We have engaged third parties to manufacture our product candidates in Australia and Canada and to conduct clinical trials for our product candidates in Australia and New Zealand. Manufacturing and research costs related to these operations are paid for in a combination of U.S. dollars and local currencies, limiting our foreign currency exchange rate risk. Accordingly, we do not believe our foreign currency exchange rate risk is significant due to the limited extent of our operations in foreign currencies; however, if we conduct clinical trials and seek to manufacture a more significant portion of our product candidates outside of the United States in the future, we could incur significant foreign currency exchange rate risk.

### **Item 4. Controls and Procedures.**

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms, promulgated by the Securities and Exchange Commission. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

#### **Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting during the three months ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II—OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

On October 23, 2019, a putative class action complaint was filed against the Company and certain of its current officers in the United States District Court for the Eastern District of Pennsylvania. This action was purportedly brought on behalf of a putative class of Zynerva investors who purchased the Company's publicly traded securities between March 11, 2019 and September 17, 2019. The Complaint alleges that Defendants made certain material misstatements and omissions relating to product candidate Zygel ("ZYN002") in alleged violation of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), Rule 10b-5 promulgated thereunder, and Section 20(a) of the Exchange Act. Specifically, plaintiff claims that Defendants made false statements or failed to disclose that: (i) Zygel was proving

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unsafe and not well-tolerated in the BELIEVE 1 clinical trial; (ii) that the foregoing created a foreseeable, heightened risk that Zynerba would fail to secure the necessary regulatory approvals for commercializing Zygel for the treatment of developmental and epileptic encephalopathies in children and adolescents, and (iii) as a result the Company's public statements and public filings were materially false and misleading to investors.

We believe that the claims asserted are without merit, and we intend to defend these actions vigorously. The lawsuit is in the early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us.

**Item 1A. Risk Factors.**

**We are subject to securities class action litigation, which is expensive, can divert management attention, and, if resolved unfavorably, could expose us to significant liabilities.**

On October 23, 2019, a putative class action complaint was filed against the Company and certain of its current officers in the United States District Court for the Eastern District of Pennsylvania. This action was brought on behalf of a putative class of Zynerba investors who purchased the Company's publicly traded securities between March 11, 2019 and September 17, 2019. The Complaint alleges that Defendants made certain material misstatements and omissions relating to product candidate Zygel, ZYN002, in alleged violation of Section 10(b) of the Securities Exchange Act of 1934, Rule 10b-5 promulgated thereunder, and Section 20(a) of the Exchange Act. We believe that the lawsuit is without merit and intend to vigorously defend against it. The lawsuit is in the early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us. This litigation could result in substantial costs and a diversion of management's resources and attention. In addition, any adverse determination could expose us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

You should also carefully consider the risk factors described in our December 31, 2018 Annual Report, under the caption "Item 1A. "Risk Factors." There have been no material changes to the risk factors disclosed in our 2018 Annual Report.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

**Recent Sales of Unregistered Securities**

None.

**Purchase of Equity Securities**

We did not purchase any of our registered equity securities during the period covered by this Quarterly Report on Form 10-Q.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

Not applicable.

**Item 6. Exhibits.**

The following exhibits are being filed herewith:

**EXHIBIT INDEX**

<b><u>Exhibit No.</u></b>	<b><u>Exhibit</u></b>
10.1	<a href="#">Controlled Equity Offering<sup>SM</sup> Sales Agreement, dated August 30, 2019, by and among the registrant, Cantor Fitzgerald &amp; Co., Canaccord Genuity LLC, H.C. Wainwright &amp; Co., LLC, and Ladenburg Thalmann &amp; Co. Inc. Incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (File No. 001-37526) filed on August 30, 2019.</a>
10.2	<a href="#">Amendment to the Employment Agreement, dated August 30, 2019, by and between the registrant and Armando Anido. Incorporated herein by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K (File No. 001-37526) filed on August 30, 2019.</a>
10.3	<a href="#">Amendment to the Employment Agreement, dated August 30, 2019, by and between the registrant and James E. Fickenscher. Incorporated herein by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K (File No. 001-37526) filed on August 30, 2019.</a>
10.4	<a href="#">Amendment to the Employment Agreement, dated August 30, 2019, by and between the registrant and Terri B. Seabee. Incorporated herein by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K (File No. 001-37526) filed on August 30, 2019.</a>
10.5	<a href="#">Amendment to the Employment Agreement, dated August 30, 2019, by and between the registrant and Suzanne M. Hanlon (filed herewith).</a>
10.6	<a href="#">Amendment to the Employment Agreement, dated August 30, 2019, by and between the registrant and Brian Rosenberger (filed herewith).</a>
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
32.1	<a href="#">Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).</a>
32.2	<a href="#">Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).</a>
101 INS	XBRL Instance Document (filed herewith).
101 SCH	XBRL Taxonomy Extension Schema Document (filed herewith).
101 CAL	XBRL Taxonomy Extension Calculation Linkbase Document (filed herewith).
101 DEF	XBRL Taxonomy Extension Definition Linkbase Document (filed herewith).
101 LAB	XBRL Taxonomy Extension Label Linkbase Document (filed herewith).
101 PRE	XBRL Taxonomy Extension Presentation Linkbase Document (filed herewith).



Employee as of the Termination Date that become vested pursuant to (ii) above or that are vested as of the Termination Date shall remain exercisable (to the extent applicable) until the earlier of (x) the three (3) year anniversary of the Termination Date and (y) the expiration date of the relevant stock option or other equity-based award; and (iv) provided the Change of Control results in net proceeds per share of capital stock to investors in excess of two times the Series 1 price per share, then Employee shall receive 100% of Employee's targeted annual bonus for the year in which the Termination Date occurs, without regard to whether the relevant Employee and Employer goals have been achieved.

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2. Section 4(g)(vi) of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

- (i) “Good Reason” shall be deemed to exist with respect to any termination of employment by the Employee for any of the following reasons:
  - (1) a material reduction in the Employee’s duties and responsibilities, which for purposes of this Agreement means the assignment to Employee of any duties or responsibilities which are materially inconsistent with or adverse to the Employee’s then current duties, responsibilities, positions and/or titles with the Employer;
  - (2) a material reduction of the Employee’s then-current base salary or target bonus opportunity;
  - (3) the requirement that the Employee regularly report to work at a location that is more than fifty (50) miles from the location of the Employee’s employment as of the Effective Date;
  - (4) a material breach of this Agreement by the Employer; or
  - (5) in the event of the assignment of this Agreement to a third party, the failure of the assignee or successor entity to agree to be bound to the terms of this Agreement.

provided, however, that for any of the foregoing to constitute Good Reason, the Employee must provide written notification of Employee’s intention to resign within ninety (90) days after the Employee first knows or first has reason to know of the occurrence of any such event or condition, and, the Employer must have thirty (30) business days from the date of receipt of such notice to effect a cure of the event or condition constituting Good Reason. If the Employer fails to effect a cure of the event or condition constituting Good Reason, the Employee must actually resign from employment within thirty (30) days following the expiration of the foregoing cure period. In the event of a cure of such event or condition constituting Good Reason by the Employer, such event or condition shall no longer constitute Good Reason.”

3. Section 5(a) of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

**“Non-Disclosure.** The Employee acknowledges that in the course of performing services for the Employer, the Employee will obtain knowledge of the Employer’s business plans, products, processes, software, know-how, trade secrets, formulas, methods, models, prototypes, discoveries, inventions, improvements, disclosures, names and positions of employees and/or other proprietary and/or confidential information (collectively the “Confidential Information”). The Employee agrees to keep the Confidential Information secret and confidential and not to publish, disclose or divulge to any other

party, and the Employee agrees not to use any of the Confidential Information for the Employee's own benefit or to the detriment of the Employer without the prior written consent of the Employer, whether or not such Confidential Information was discovered or developed by the Employee. The Employee also agrees not to divulge, publish or use any proprietary and/or confidential information of others that the Employer is obligated to maintain in confidence.

Nothing in this Agreement shall prohibit the Employee from (a) reporting possible violations of federal law or regulation to any governmental agency or entity or self-regulatory organization or making disclosures that are protected under the whistleblower provisions of federal law or regulation, (b) supplying truthful information to any governmental authority or in response to any lawful subpoena or other legal process, or (c) receiving an award for information provided to any governmental agency. In addition, notwithstanding anything in this Agreement, in accordance with the Defend Trade Secrets Act of 2016, (a) the Employee shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (i) is made (A) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and (B) solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal, and (b) if Employee files a lawsuit for retaliation by the Employer for reporting a suspected violation of law, the Employee may disclose a trade secret to the Employee's attorney and use the trade secret information in the court proceeding, if the Employee files any document containing the trade secret under seal and does not disclose the trade secret except pursuant to court order."

4. Except as otherwise amended hereby, all other terms and conditions of the Employment Agreement shall remain in full force and effect.

The provisions of Sections 11 through and including 17 of the Employment Agreement are incorporated herein by reference and shall apply to this amendment (this "Amendment") as if included herein, provided that all references in such sections to "this Agreement," "herein," "hereof," "hereunder" and similar phrases shall be deemed to refer to this Amendment (and not the Employment Agreement) for purposes of this Amendment.

[signature page follows]

IN WITNESS WHEREOF, this Amendment has been executed by the parties as of the date first above written.  
ZYNERBA PHARMACEUTICALS, INC.

By: /s/ Armando Anido  
Title: Chief Executive Officer

/s/ Suzanne M. Hanlon  
Suzanne M. Hanlon

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August 30, 2019

Brian Rosenberger  
1041 Haverhill Road  
Chester Springs, PA 19425

Dear Brian:

As you know, you and Zynerba Pharmaceuticals, Inc. (the “Company”) are parties to that certain employment agreement dated as of January 18, 2017 (as amended and/or restated from time to time, the “Employment Agreement”). For good and valuable consideration, you and the Company hereby agree to amend the Employment Agreement as follows:

1. The first paragraph in Section 4(e) of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“Effect of a Change of Control. Notwithstanding any provision of Section 4(d) to the contrary, if Employee’s employment is terminated or Employee resigns for Good Reason (as defined below) pursuant to Section 4(d) within the ninety (90) day period preceding a Change of Control or on or within twelve (12) months following a Change of Control, upon such termination or resignation, Employee shall be entitled to the same payments and benefits described in Section 4(d) above, subject to execution and nonrevocation of the Release and the Employee’s compliance with all terms and provisions of this Agreement that survive the termination of the Employee’s employment by the Employer, provided that in addition to the severance and other benefits set forth in Section 4(d) (iii) (A)-(C), (i) Employee shall be entitled to receive an additional six (6) months of Base Salary continuation (at the rate in effect on the Termination Date) commencing upon the conclusion of the continued Base Salary under Section 4(d)(iii)(A) and an additional six (6) months of medical and dental coverage (at the same coverage in effect on the Termination Date) commencing upon the conclusion of the continued Base Salary under Section 4(d)(iii)(B); (ii) one hundred percent (100%) of all outstanding unvested stock options and other equity-based awards held by the Employee as of the Termination Date shall become fully vested and exercisable (to the extent applicable) as

of the Termination Date; (iii) all outstanding stock options and other equity-based awards held by the Employee as of the Termination Date that become vested pursuant to (ii) above or that are vested as of the Termination Date shall remain exercisable (to the extent applicable) until the earlier of (x) the three (3) year anniversary of the Termination Date and (y) the expiration date of the relevant stock option or other equity-based award; and (iv) Employee shall be entitled to one hundred percent (100%) of Employee's targeted bonus for the year in which the Termination Date occurs, without regard to whether the relevant Employee and Employer goals have been achieved.

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2. Section 4(g)(vi) of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

- (i) “Good Reason” shall be deemed to exist with respect to any termination of employment by the Employee for any of the following reasons:
  - (1) a material reduction in the Employee’s duties and responsibilities, which for purposes of this Agreement means the assignment to Employee of any duties or responsibilities which are materially inconsistent with or adverse to the Employee’s then current duties, responsibilities, positions and/or titles with the Employer;
  - (2) a material reduction of the Employee’s then-current base salary or target bonus opportunity;
  - (3) the requirement that the Employee regularly report to work at a location that is more than fifty (50) miles from the location of the Employee’s employment as of the Effective Date;
  - (4) a material breach of this Agreement by the Employer; or
  - (5) in the event of the assignment of this Agreement to a third party, the failure of the assignee or successor entity to agree to be bound to the terms of this Agreement.

provided, however, that for any of the foregoing to constitute Good Reason, the Employee must provide written notification of Employee’s intention to resign within ninety (90) days after the Employee first knows or first has reason to know of the occurrence of any such event or condition, and, the Employer must have thirty (30) business days from the date of receipt of such notice to effect a cure of the event or condition constituting Good Reason. If the Employer fails to effect a cure of the event or condition constituting Good Reason, the Employee must actually resign from employment within thirty (30) days following the expiration of the foregoing cure period. In the event of a cure of such event or condition constituting Good Reason by the Employer, such event or condition shall no longer constitute Good Reason.”

3. Section 5(a) of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

**“Non-Disclosure.** The Employee acknowledges that in the course of performing services for the Employer, the Employee will obtain knowledge of the Employer’s business plans, products, processes, software, know-how, trade secrets, formulas, methods, models, prototypes, discoveries, inventions, improvements, disclosures, names and positions of employees and/or other proprietary and/or confidential information (collectively the “Confidential Information”). The Employee agrees to keep the Confidential Information secret and confidential and not to publish, disclose or divulge to any other

party, and the Employee agrees not to use any of the Confidential Information for the Employee's own benefit or to the detriment of the Employer without the prior written consent of the Employer, whether or not such Confidential Information was discovered or developed by the Employee. The Employee also agrees not to divulge, publish or use any proprietary and/or confidential information of others that the Employer is obligated to maintain in confidence.

Nothing in this Agreement shall prohibit the Employee from (a) reporting possible violations of federal law or regulation to any governmental agency or entity or self-regulatory organization or making disclosures that are protected under the whistleblower provisions of federal law or regulation, (b) supplying truthful information to any governmental authority or in response to any lawful subpoena or other legal process, or (c) receiving an award for information provided to any governmental agency. In addition, notwithstanding anything in this Agreement, in accordance with the Defend Trade Secrets Act of 2016, (a) the Employee shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (i) is made (A) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and (B) solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal, and (b) if Employee files a lawsuit for retaliation by the Employer for reporting a suspected violation of law, the Employee may disclose a trade secret to the Employee's attorney and use the trade secret information in the court proceeding, if the Employee files any document containing the trade secret under seal and does not disclose the trade secret except pursuant to court order."

4. Except as otherwise amended hereby, all other terms and conditions of the Employment Agreement shall remain in full force and effect.

The provisions of Sections 11 through and including 17 of the Employment Agreement are incorporated herein by reference and shall apply to this amendment (this "Amendment") as if included herein, provided that all references in such sections to "this Agreement," "herein," "hereof," "hereunder" and similar phrases shall be deemed to refer to this Amendment (and not the Employment Agreement) for purposes of this Amendment.

[signature page follows]

IN WITNESS WHEREOF, this Amendment has been executed by the parties as of the date first above written.

ZYNERBA PHARMACEUTICALS, INC.

By: /s/ Armando Anido  
Title: Chief Executive Officer

/s/ Brian Rosenberger  
Brian Rosenberger

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Confidential

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**Exhibit 31.1**

**CERTIFICATION**

I, Armando Anido, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Zynerva Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Armando Anido  
Name: Armando Anido  
Title: Chairman and Chief Executive Officer

**CERTIFICATION**

I, James E. Fickenscher, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Zynerva Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ James E. Fickenscher

Name: James E. Fickenscher

Title: Chief Financial Officer

Dated: November 6, 2019

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of Zynerva Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Armando Anido, Chairman and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Armando Anido

Armando Anido  
Chairman and Chief Executive Officer

Dated: November 6, 2019

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**Exhibit 32.2**

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of Zynerva Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James E. Fickenscher, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James E. Fickenscher

James E. Fickenscher  
Chief Financial Officer

Dated: November 6, 2019

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