
**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, 2020

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
Smaller reporting company
Emerging growth company

Non-accelerated filer

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 5, 2020, the registrant had 29,439,175 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 expectations, projections and estimates regarding expenses, future revenue, capital requirements, incentive and other tax credit eligibility, collectability and timing, and availability of and the need for additional financing;
- the 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 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, shareholder class action lawsuits or other litigation;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- legislative changes and recently proposed changes regarding the healthcare system, including changes and proposed 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;
- the timing and outcome of current and future legal proceedings;
- 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;
- the timing and outcome of the Australian Taxation Office’s, or ATO, review regarding our eligibility to receive a tax credits related to the Advance Overseas Finding, or AOF;

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- the extent to which health epidemics and other outbreaks of communicable diseases, including the ongoing COVID-19 pandemic, could disrupt our operations or materially and adversely affect our business and financial conditions; and
- the other risks, uncertainties and factors discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, or our 2019 Annual Report and our Quarterly Report on Form 10-Q for the quarters ended June 30, 2020 and March 31, 2020, or our 2020 Quarterly Reports, 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 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, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 64,311,205	\$ 70,063,242
Incentive and tax receivables	6,533,079	14,613,969
Prepaid expenses and other current assets	3,913,112	2,378,812
Total current assets	74,757,396	87,056,023
Property and equipment, net	596,512	362,724
Incentive and tax receivables	1,684,616	—
Right-of-use assets	166,889	345,849
Total assets	<u>\$ 77,205,413</u>	<u>\$ 87,764,596</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,404,129	\$ 4,740,981
Accrued expenses	6,987,653	7,073,506
Lease liabilities	174,073	243,677
Total current liabilities	10,565,855	12,058,164
Lease liabilities, long-term	—	109,689
Total liabilities	10,565,855	12,167,853
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; 29,449,175 shares issued and outstanding at September 30, 2020 and 23,211,391 shares issued and outstanding at December 31, 2019	29,449	23,211
Additional paid-in capital	259,164,854	226,409,156
Accumulated deficit	(192,554,745)	(150,835,624)
Total stockholders' equity	66,639,558	75,596,743
Total liabilities and stockholders' equity	<u>\$ 77,205,413</u>	<u>\$ 87,764,596</u>

See accompanying notes to unaudited consolidated financial statements.

ZYNERBA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Operating expenses:				
Research and development	\$ 5,805,948	\$ (1,604,399)	\$ 30,038,582	\$ 12,926,096
General and administrative	3,425,831	3,530,617	11,834,434	9,977,550
Total operating expenses	<u>9,231,779</u>	<u>1,926,218</u>	<u>41,873,016</u>	<u>22,903,646</u>
Loss from operations	<u>(9,231,779)</u>	<u>(1,926,218)</u>	<u>(41,873,016)</u>	<u>(22,903,646)</u>
Other income (expense):				
Interest income	10,781	436,846	239,066	1,226,998
Foreign exchange gain (loss)	172,467	(457,018)	(85,171)	(551,944)
Total other income	<u>183,248</u>	<u>(20,172)</u>	<u>153,895</u>	<u>675,054</u>
Net loss	<u>\$ (9,048,531)</u>	<u>\$ (1,946,390)</u>	<u>\$ (41,719,121)</u>	<u>\$ (22,228,592)</u>
Net loss per share basic and diluted	<u>\$ (0.31)</u>	<u>\$ (0.08)</u>	<u>\$ (1.59)</u>	<u>\$ (1.03)</u>
Basic and diluted weighted average shares outstanding	<u>29,243,375</u>	<u>23,186,410</u>	<u>26,258,626</u>	<u>21,598,764</u>

See accompanying notes to unaudited consolidated financial statements.

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

	Nine months ended September 30, 2020				
	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2019	23,211,391	\$ 23,211	\$ 226,409,156	\$ (150,835,624)	\$ 75,596,743
Issuance of common stock, net of issuance costs	356,000	356	1,581,694	—	1,582,050
Issuance of restricted stock	5,000	5	(5)	—	—
Stock-based compensation expense	—	—	1,323,352	—	1,323,352
Net loss	—	—	—	(12,337,829)	(12,337,829)
Balance at March 31, 2020	23,572,391	23,572	229,314,197	(163,173,453)	66,164,316
Issuance of common stock, net of issuance costs	5,682,784	5,683	27,240,793	—	27,246,476
Stock-based compensation expense	—	—	1,347,433	—	1,347,433
Net loss	—	—	—	(20,332,761)	(20,332,761)
Balance at June 30, 2020	29,255,175	29,255	257,902,423	(183,506,214)	74,425,464
Issuance of restricted stock	194,000	194	(194)	—	—
Stock-based compensation expense	—	—	1,262,625	—	1,262,625
Net loss	—	—	—	(9,048,531)	(9,048,531)
Balance at September 30, 2020	29,449,175	\$ 29,449	\$ 259,164,854	\$ (192,554,745)	\$ 66,639,558

	Nine months ended September 30, 2019				
	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2018	17,626,873	\$ 17,627	\$ 175,476,075	\$ (117,892,041)	\$ 57,601,661
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)
Balance at March 31, 2019	21,074,996	21,075	195,048,717	(127,039,058)	68,030,734
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)
Balance at June 30, 2019	23,198,010	23,198	223,734,452	(138,174,243)	85,583,407
Stock-based compensation expense	—	—	1,376,225	—	1,376,225
Net loss	—	—	—	(1,946,390)	(1,946,390)
Balance at September 30, 2019	23,198,010	\$ 23,198	\$ 225,110,677	\$ (140,120,633)	\$ 85,013,242

See accompanying notes to unaudited consolidated financial statements.

**ZYNERBA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)**

	Nine months ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (41,719,121)	\$ (22,228,592)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	147,253	98,207
Stock-based compensation	3,933,410	4,354,222
Changes in operating assets and liabilities:		
Incentive and tax receivables	6,396,274	(10,002,361)
Prepaid expenses and other assets	(1,727,805)	1,046,133
Right-of-use assets	(333)	(5,723)
Accounts payable	(1,270,587)	(1,163,454)
Accrued expenses	(86,366)	548,454
Net cash used in operating activities	<u>(34,327,275)</u>	<u>(27,353,114)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(383,223)	(81,051)
Net cash used in investing activities	<u>(383,223)</u>	<u>(81,051)</u>
Cash flows from financing activities:		
Proceeds from the issuance of common stock	29,766,385	46,813,364
Payment of financing fees and expenses	(807,924)	(1,785,142)
Proceeds from the exercise of stock options	—	189,700
Net cash provided by financing activities	<u>28,958,461</u>	<u>45,217,922</u>
Net (decrease) increase in cash and cash equivalents	<u>(5,752,037)</u>	<u>17,783,757</u>
Cash and cash equivalents at beginning of period	70,063,242	59,763,773
Cash and cash equivalents at end of period	<u>\$ 64,311,205</u>	<u>\$ 77,547,530</u>
Supplemental disclosures of cash flow information:		
Deferred financing costs included in accounts payable and accrued expenses at end of period	\$ —	\$ 62,357
Property and equipment acquired but unpaid at end of period	\$ 13,418	\$ 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 individual syndromes from a heterogeneous group of rare and ultra-rare epilepsies known as developmental and epileptic encephalopathies.

The Company has incurred losses and negative cash flows from operations since inception and has an accumulated deficit of \$192.6 million as of September 30, 2020. 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.

In August 2019, the Company entered into a Controlled Equity Offering Sales AgreementSM (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. In 2019, the Company sold and issued 13,381 shares of its common stock in the open market at a weighted-average selling price of \$7.00 per share, for gross and net proceeds of \$0.1 million. In the first quarter of 2020, the Company sold and issued 356,000 shares of its common stock in the open market at a weighted-average selling price of \$5.10 per share, for gross proceeds of \$1.8 million and net proceeds, after deducting commissions and offering expenses, of \$1.6 million. In the second quarter of 2020, the Company sold and issued 5,682,784 shares of its common stock in the open market at a weighted-average selling price of \$4.92 per share, for gross proceeds of \$27.9 million and net proceeds, after deducting commissions and offering expenses, of \$27.2 million. The Company did not sell and issue any shares of its common stock pursuant to the 2019 Sales Agreement during the third quarter of 2020.

In June 2017, the Company entered into an Open Market Sales Agreement (the “2017 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 2017 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 2017 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 2017 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 2017 Sales Agreement, which was terminated pursuant to its terms.

Management believes that current cash and cash equivalents are sufficient to fund operations and capital requirements until late in the fourth quarter 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. The Company's ability to raise sufficient additional financing depends on many factors beyond its control, including the current volatility in the capital markets as a result of the COVID-19 pandemic. 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 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.

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

(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, 2019 included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019 (“2019 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, 2020 its results of operations for the three and nine months ended September 30, 2020 and 2019 and cash flows for the nine months ended September 30, 2020 and 2019. 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 2019 Annual Report.

Certain prior period balances have been reclassified to conform to the current year presentation.

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 (“ATO”), 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 estimates the amount of cash refund it expects to receive related to the Australian research and development tax incentive program and records the incentives when it is probable 1) the Company will comply with relevant conditions of the program and 2) the incentive will be received.

Certain research and development expenses incurred with respect to Zygel outside of Australia may also be eligible for the Australian research and development tax incentive program. To receive a cash refund with respect to such expenses incurred outside of Australia, the expenses must have been for eligible research and development activities, as determined by AusIndustry, and the expenditures must have a scientific link to the Australian activities, be unable to be conducted in Australia and be less than the expenditures for activities conducted in Australia, as determined by the ATO. In December 2018, the Company submitted an Advance Overseas Finding (“AOF”) application to AusIndustry for a determination that the Company’s activities are eligible research and development activities, which was approved by AusIndustry in July 2019.

As a result of this finding, the Company believes it is eligible to receive a cash refund from the ATO for qualifying expenditures related to its research and development activities 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, 2020, incentive and tax receivables included \$8.4 million related to the AOF. The increase of \$0.1 million was due to unrealized foreign currency gains related to the remeasurement of the Subsidiary’s assets and liabilities.

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

The Company evaluates its eligibility under tax incentive programs as of each balance sheet date based on the most current and relevant data available. If the Company is deemed to be ineligible or unable to receive the Australian research and development tax credit, or the Australian government significantly reduces or eliminates the tax credit, the actual cash refund the Company receives may materially differ from its estimates. In June 2020, the ATO informed the Company that it may not qualify for the AOF program based on their interpretation of certain eligibility requirements. Although the Company continues to believe that it complies with the relevant conditions of the AOF program that were in place when the Company received its original approval from AusIndustry, the Company determined it was no longer probable that the AOF claim would be received. As a result, during the three months ended June 30, 2020, the Company recorded a full reserve against the AOF receivable.

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 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, 2020, incentive and tax receivables included \$0.4 million for refundable GST on expenses incurred with Australian vendors during the three months ended September 30, 2020.

Current incentive and tax receivables consisted of the following as of September 30, 2020 and December 31, 2019:

	September 30, 2020	December 31, 2019
Research and development incentive (non-AOF) for the period 1/1/18 - 12/31/18	\$ 3,178,601	\$ 3,126,750
Research and development incentive (non-AOF) for the period 1/1/19 - 12/31/19	2,961,731	2,913,417
Research and development incentive (AOF) for the period 1/1/18 - 12/31/19	8,393,335	8,256,416
Goods and services tax	392,747	317,386
Total incentive and tax receivables before reserve for AOF	\$ 14,926,414	\$ 14,613,969
Reserve for research and development incentive (AOF) for the period 1/1/18 - 12/31/19	(8,393,335)	—
Total incentive and tax receivables - current assets	\$ 6,533,079	\$ 14,613,969

As of September 30, 2020, the Company’s estimate of the amount of cash refund it expects to receive in 2020 for 2019 and 2018 eligible spending as part of this incentive program was \$6.1 million and was recorded as a current asset. The Company’s estimate of the amount of cash refund it expects to receive in 2021 for 2020 eligible spending through September 30, 2020 was \$1.7 million and was recorded as a non-current asset.

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.

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

The following table summarizes research and development expenses for the three and nine months ended September 30, 2020 and 2019:

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Research and development expenses - before R&D incentive	\$ 6,177,830	\$ 7,381,241	\$ 23,526,911	\$ 23,380,269
Research and development incentive (non-AOF)	(371,882)	(715,631)	(1,596,024)	(2,184,164)
Research and development expenses (before impact of AOF)	5,805,948	6,665,610	21,930,887	21,196,105
AOF - cumulative change in estimate for the period 1/1/18 through 12/31/19	—	(8,270,009)	—	(8,270,009)
Amounts reserved against AOF refund	—	—	8,107,695	—
Total research and development expenses	<u>\$ 5,805,948</u>	<u>\$ (1,604,399)</u>	<u>\$ 30,038,582</u>	<u>\$ 12,926,096</u>

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, 2020 and 2019 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:

	<u>September 30,</u>	
	<u>2020</u>	<u>2019</u>
Stock options	4,710,201	3,990,623
Unvested restricted stock	205,800	11,600
	<u>4,916,001</u>	<u>4,002,223</u>

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 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 could 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.

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

(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, 2020 and December 31, 2019:

	Carrying amount as of September 30, 2020	Fair Value Measurement as of September 30, 2020		
		Level 1	Level 2	Level 3
Cash equivalents (money market accounts)	\$ 64,013,545	\$ 64,013,545	\$ —	\$ —
	<u>\$ 64,013,545</u>	<u>\$ 64,013,545</u>	<u>\$ —</u>	<u>\$ —</u>

	Carrying amount as of December 31, 2019	Fair Value Measurement as of December 31, 2019		
		Level 1	Level 2	Level 3
Cash equivalents (money market accounts)	\$ 69,686,350	\$ 69,686,350	\$ —	\$ —
	<u>\$ 69,686,350</u>	<u>\$ 69,686,350</u>	<u>\$ —</u>	<u>\$ —</u>

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of September 30, 2020 and December 31, 2019:

	September 30, 2020	December 31, 2019
Prepaid development expenses	\$ 1,332,887	\$ 957,814
Prepaid insurance	2,312,693	841,858
Deferred financing costs	—	193,505
Other current assets	267,532	385,635
Total prepaid expenses and other current assets	<u>\$ 3,913,112</u>	<u>\$ 2,378,812</u>

ZYNERBA PHARMACEUTICALS, INC.
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**(5) Property and Equipment**

Property and equipment consisted of the following as of September 30, 2020 and December 31, 2019:

	Estimated useful life (in years)	September 30, 2020	December 31, 2019
Equipment	2-5	\$ 674,234	\$ 263,829
Computer equipment	3-5	30,319	30,319
Furniture and fixtures	3-5	311,355	311,355
Leasehold improvements	various	68,881	68,881
Construction in process		49,409	78,773
Total cost		1,134,198	753,157
Less accumulated depreciation		(537,686)	(390,433)
Property and equipment, net		<u>\$ 596,512</u>	<u>\$ 362,724</u>

Depreciation expense was \$57,790 and \$36,027 for the three months ended September 30, 2020 and 2019, respectively, and \$147,253 and \$98,207 for the nine months ended September 30, 2020 and 2019, respectively.

(6) Accrued Expenses

Accrued expenses consisted of the following as of September 30, 2020 and December 31, 2019:

	September 30, 2020	December 31, 2019
Accrued compensation	\$ 1,892,084	\$ 2,340,533
Accrued research and development	4,642,490	4,343,322
Other	453,079	389,651
Total accrued expenses	<u>\$ 6,987,653</u>	<u>\$ 7,073,506</u>

(7) Common Stock

In August 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. In 2019, the Company sold and issued 13,381 shares of its common stock in the open market at a weighted-average selling price of \$7.00 per share, for gross and net proceeds of \$0.1 million. In the first quarter of 2020, the Company sold and issued 356,000 shares of its common stock in the open market at a weighted-average selling price of \$5.10 per share, for gross proceeds of \$1.8 million and net proceeds, after deducting commissions and offering expenses, of \$1.6 million. In the second quarter of 2020, the Company sold and issued 5,682,784 shares of its common stock in the open market at a weighted-average selling price of \$4.92 per share, for gross proceeds of \$27.9 million and net proceeds, after deducting commissions and offering expenses, of \$27.2 million. The Company did not sell and issue any shares of its common stock pursuant to the 2019 Sales Agreement during the third quarter of 2020.

In the first quarter of 2019, the Company sold and issued 3,439,523 shares of common stock under the 2017 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 2017 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 2017 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 2017 Sales Agreement, which has terminated pursuant to its terms.

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

(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, 2020, 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 total number of shares of common stock available for issuance under the 2014 Plan to 7,804,869 shares. As of September 30, 2020, 2,347,292 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 primarily 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, 2020, 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, 2020, 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.

In September 2020, the Company granted 194,000 restricted stock awards that contain both performance-based and service-based conditions. These awards vest on the earlier of: (a) meeting the performance condition or (b) service provided for one-year from the grant date. Awards with both performance and service conditions are being expensed over the service period, with an acceleration of the remaining compensation expense, if the performance-based criteria is met before the end of the service condition.

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

For the nine months ended September 30, 2020 and 2019, 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	
	2020	2019	2020	2019	2020	2019
Research and development	\$ 1,548,971	\$ 1,893,441	\$ 41,314	\$ 22,137	\$ 1,590,285	\$ 1,915,578
General and administrative	2,331,520	2,438,644	11,605	—	2,343,125	2,438,644
	<u>\$ 3,880,491</u>	<u>\$ 4,332,085</u>	<u>\$ 52,919</u>	<u>\$ 22,137</u>	<u>\$ 3,933,410</u>	<u>\$ 4,354,222</u>

The following table summarizes the stock option activity for the nine months ended September 30, 2020:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Life (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2019	3,988,716	\$ 10.83		
Granted	840,480	5.09		
Forfeited	(118,995)	12.90		
Outstanding as of September 30, 2020	<u>4,710,201</u>	<u>9.75</u>	<u>7.01</u>	<u>\$ —</u>
Exercisable as of September 30, 2020	<u>2,943,333</u>	<u>11.47</u>	<u>6.06</u>	<u>\$ —</u>
Vested and expected to vest as of September 30, 2020	<u>4,626,921</u>	<u>\$ 9.72</u>		

The weighted-average grant date fair values of options granted during the nine months ended September 30, 2020 and 2019 were \$3.58 and \$4.19, 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,	
	2020	2019
Weighted-average risk-free interest rate	1.27%	2.38%
Expected term of options (in years)	6.18	6.16
Expected stock price volatility	82.00%	80.00%
Expected dividend yield	0%	0%

As of September 30, 2020, excluding performance-based stock options that have not been deemed probable, there was \$6.5 million of unrecognized stock-based compensation expense related to stock options, which is expected to be recognized over a weighted-average period of 2.25 years.

The following table summarizes the restricted stock award activity under the 2014 Plan for the nine months ended September 30, 2020:

	Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2019	8,600	\$ 4.42
Granted	199,000	3.58
Vested	(1,800)	3.65
Unvested as of September 30, 2020	<u>205,800</u>	<u>\$ 3.62</u>

As of September 30, 2020, excluding performance-based restricted stock awards that have not been deemed probable, there was \$667,385 of unrecognized stock-based compensation expense related to unvested restricted stock awards, which is expected to be recognized over a weighted-average period of 0.95 years. The Company expects that all 200,800 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. On November 11, 2019, the Company extended its original five-year lease for one additional year until May 31, 2021. 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 a right-of-use asset of \$312,859, which was recorded net of a pre-existing deferred rent liability of \$12,824. As of November 11, 2019, the effective date of the lease modification, the Company remeasured the lease liability for the remaining portion of the lease and adjusted the lease liability to \$392,822 and right-of-use assets to \$386,609, which was recorded net of a deferred rent liability of \$6,213. As of September 30, 2020, the Company's right-of-use asset, net of amortization, was \$166,889.

Other operating lease information as of September 30, 2020:

Weighted-average remaining lease term - operating leases	0.7 years
Weighted-average discount rate - operating leases	6.6 %

The following is a maturity analysis of the annual undiscounted cash flows of the operating lease liabilities as of September 30, 2020:

<u>Year ended:</u>	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
December 31, 2020	\$ 66,903	\$ 259,864
December 31, 2021	111,506	111,506
Total minimum lease payments	178,409	371,370
Less: imputed lease interest	(4,336)	(18,004)
Total lease liabilities	<u>\$ 174,073</u>	<u>\$ 353,366</u>

Lease expense for the nine months ended September 30, 2020 and 2019 was comprised of the following:

	<u>Nine months ended September 30,</u>	
	<u>2020</u>	<u>2019</u>
Operating lease expense	\$ 192,628	\$ 178,773
Variable lease expense	44,023	44,023
Total lease expense	<u>\$ 236,651</u>	<u>\$ 222,796</u>

Cash payments related to operating leases were \$192,961 and \$184,496 for the nine months ended September 30, 2020 and 2019, respectively.

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, 2019 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our 2019 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 2019 Annual Report.

Overview

Company Overview

We are 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.

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

Zygel is the first and only pharmaceutically-produced Cannabidiol formulated as a permeation-enhanced gel for transdermal delivery, and the formulation is patent protected through 2030. Five additional patents expiring in 2038 are directed to methods of use relating to Zygel, including methods of treating FXS and ASD.

In preclinical animal studies, Zygel's permeation enhancer increased delivery of Cannabidiol 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 Cannabidiol when delivered transdermally. In addition, an *in vitro* study published in *Cannabis and Cannabinoid Research* in April 2016 demonstrated that Cannabidiol 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 Cannabidiol is delivered orally and may be avoided with the transdermal delivery of Zygel, which maintains Cannabidiol in a neutral pH. Zygel, which is being developed as a clear gel with once- or twice-daily dosing, is targeting treatment of behavioral symptoms of FXS, ASD and 22q and the reduction of seizures in patients with DEE syndromes. We have been granted orphan drug designations from United States Food and Drug Administration, or FDA, for the use of Cannabidiol for the treatment of FXS and for the treatment of 22q. 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 the FDA in order to get new important drugs to the patient earlier.

As of October 2020, the Zygel safety database across all clinical studies conducted by us includes data from 905 volunteers and patients. Across these clinical studies, Zygel has been well tolerated and consistent with previously reported data.

In April 2018, we initiated the exploratory Phase 2 BELIEVE (Open Label Study to Assess the Safety and Efficacy of Zygel 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 Zygel in children and adolescents (age three through 17 years) with DEE as classified by the International League Against Epilepsy, or ILAE (Scheffer et al. 2017). In September 2019, we reported positive top-line results from the BELIEVE 1 trial. In September 2020, we concluded iterative discussions with the FDA using their "Written Response Only" meeting format regarding the clinical pathway for Zygel in DEE. While FDA supports a development

program which would evaluate the treatment of focal-impaired awareness and convulsive seizures, based on FDA feedback suggesting that the Company pursue an individual syndrome rather than considering DEE patients as a single disorder or condition due to the heterogeneity of DEE patients, we are evaluating specific DEE syndromes as possible clinical targets and expect to provide an update around year-end 2020.

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 designed to assess the efficacy and safety of Zylgel in children and adolescents ages three through 17 years who have full mutation of the FMR1 gene. In June 2020, we announced that Zylgel did not achieve statistical significance versus placebo in the primary endpoint of improvement in the Social Avoidance subscale of the Aberrant Behavior Checklist – Community FXS ($ABC-C_{FXS}$). Zylgel also did not demonstrate statistical significance versus placebo in the three key secondary endpoints, which were the change from baseline to the end of the treatment period in the Irritability subscale score of the $ABC-C_{FXS}$, the Socially Unresponsive/Lethargic subscale score of the $ABC-C_{FXS}$ and Improvement in Clinical Global Impression (CGI-I). A pre-planned ad hoc analysis of the most severely impacted patients in the trial as defined by patients having at least 90% methylation (“full methylation”) of the impacted FMR1 gene, or FMet patients, demonstrated that FMet patients receiving Zylgel achieved statistical significance in the primary endpoint of improvement at 12 weeks of treatment in the Social Avoidance subscale of the $ABC-C_{FXS}$ compared to placebo ($p=0.020$). This group comprised 80% of the patients enrolled in the CONNECT-FX study. In July 2020, the Company presented an overview of its Fragile X development program at the 17th NFXF International Fragile X Conference Research Roundup, including additional caregiver-reported data from the CONNECT-FX trial. The results of the Caregiver Global Impression – Change survey show a broad shift toward global improvement from baseline to week 12 for FMet patients with three of the four behavioral domains (social avoidance and isolation, irritable and disruptive behaviors, and social interactions) showing a statistically significant change in favor of patients on Zylgel and the fourth domain (overall behavior) trending toward significance. These data support the statistically significant improvement observed in the CONNECT-FX primary endpoint of social avoidance in FMet patients who received Zylgel compared to placebo. In October 2020, we presented additional results from the CONNECT-FX trial at the 16th International Child Neurology Congress & 49th Annual Child Neurology Society Meeting (CNS-ICNC) including the results of psychometric analyses that defined clinically meaningful treatment response over 12 weeks of treatment as an improvement of ≥ 3 points for the Social Avoidance subscale of the $ABC-C_{FXS}$ and ≥ 9 points for the Irritability subscale. Through this analysis, we determined that 58.2% of FMet patients receiving Zylgel achieved a clinically meaningful change in their socially avoidant behavior compared to 40.6% of placebo patients ($p=0.031$), and 40.3% of FMet patients receiving Zylgel achieved a clinically meaningful change in Irritability compared to 23.8% of placebo patients ($p=0.036$). In the fourth quarter of 2020, we expect to announce the outcome of our discussions with the FDA regarding the CONNECT-FX trial and the regulatory path forward for Zylgel in pediatric and adolescent patients with fully methylated FMR1 gene.

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) clinical trial, a 14-week open label clinical trial designed to assess the safety, tolerability and efficacy of Zylgel for the treatment of pediatric and adolescent patients with ASD. In May 2020, we reported positive top-line results of this trial and we now expect to discuss a path forward with the FDA in the first half of 2021. The trial evaluated multiple efficacy assessments, including the Aberrant Behavior Checklist – Community, or ABC-C, Autism Parenting Stress Index, Patient Reported Anxiety Scale – Autism Spectrum Disorder, or PRAS-ASD, Autism Impact Measure, or AIM, Clinical Global Impression – Severity, or CGI-S, and the Clinical Global Impression – Improvement, or CGI-I. Patients treated with Zylgel demonstrated statistically significant improvement at week 14 from baseline for each ABC-C subscale (Irritability, Inappropriate Speech, Stereotypy, Social Withdrawal, and Hyperactivity). The results of the other efficacy assessments are consistent with the results demonstrated in the ABC-C. In October 2020, we presented new data describing statistically significant results from the Phase 2 BRIGHT trial at the CNS-ICNC meeting. Patients receiving Zylgel achieved statistically significant caregiver-reported improvements compared to baseline across all subscales of the AIM: Atypical behavior ($p<0.001$), Communication ($p<0.001$), Peer Interaction ($p<0.001$), Repetitive Behavior ($p<0.001$), and Social Reciprocity ($p=0.0053$). In addition, statistically significant improvements compared to baseline were observed at week 14 of treatment with Zylgel in the Autism Parenting Stress Index ($p<0.0001$).

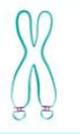
In May 2019, we initiated the open-label Phase 2 INSPIRE (Assessing the Impact of Zylgel [Transdermal CBD Gel] on Pediatric Behavioral and Emotional Symptoms of 22q11.2 Deletion Syndrome) clinical trial, a 14-week open label clinical trial designed to assess the safety, tolerability and efficacy of Zylgel for treatment of behavioral symptoms of 22q. We expect to enroll approximately 20 male and female patients (age six through 17 years). Recruitment into the

INSPIRE trial has been delayed due to the impact of COVID-19 in Australia and resulting travel restrictions. As a result of the uncertainty of the scope, duration and impact of the COVID-19 pandemic in Australia, the Company has withdrawn its guidance on the timing of data from this trial, and will provide updated guidance as soon as possible. In September 2020, we were granted orphan drug designation from the FDA for the use of Cannabidiol for the treatment of 22q.

Zygel Clinical Development Timelines

The COVID-19 pandemic continues to evolve and we are closely monitoring the situation, including its potential impact on our clinical development plans and timelines going forward. In response to COVID-19, for our current clinical development programs, we implemented multiple measures consistent with the FDA’s guidance on the conduct of clinical trials of medical products during the COVID-19 pandemic, including remote site monitoring and patient visits using telemedicine where needed, direct to patient drug shipment from investigator sites, and local community study related clinical laboratory collection. Except with respect to our Phase 2 open-label INSPIRE trial, timelines for delivery of top-line results for our clinical trials were not adversely impacted by COVID-19.

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

	1Q 2020	2Q 2020	3Q 2020	4Q 2020
 FXS		✓ Report pivotal CONNECT-FX topline results		Discuss results in FMet pts with FDA & disclose outcome
 DEE			✓ Results of FDA discussions on clinical path	Provide update on path forward around Y/E 2020
 ASD		✓ Report Ph. 2 BRIGHT topline results		
 22q	Enrollment delayed due to COVID-19 travel restrictions in Australia. Topline results timeline to be determined following lifting of restrictions			

We have never been profitable and have incurred net losses since inception. Our net losses were \$41.7 million and \$22.2 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, our accumulated deficit was \$192.6 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.

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;

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- 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, or ATO, 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. We estimate the amount of cash refund we expect to receive related to the Australian research and development tax incentive program and record the incentives when it is probable 1) we will comply with relevant conditions of the program and 2) the incentive will be received.

Certain research and development expenses incurred with respect to Zygel outside of Australia may also be eligible for the Australian research and development tax incentive program. To receive a cash refund with respect to such expenses incurred outside of Australia, the expenses must have been for eligible research and development activities, as determined by AusIndustry, and the expenditures must have a scientific link to the Australian activities, be unable to be conducted in Australia and be less than the expenditures for activities conducted in Australia, as determined by the ATO. In December 2018, the Subsidiary submitted an AOF application to AusIndustry for a determination that its activities are eligible research and development activities, which was approved by AusIndustry in July 2019.

As a result of this finding, we believe the Subsidiary is eligible to receive a cash refund from the ATO for qualifying expenditures related to its research and development activities outside of Australia in 2018, 2019 and 2020. During the three months ended September 30, 2019, we 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, 2020, incentive and tax receivables included \$8.4 million related to the AOF. The increase of \$0.1 million was due to unrealized foreign currency gains related to the remeasurement of the Subsidiary's assets and liabilities.

We evaluate the Subsidiary's eligibility under tax incentive programs as of each balance sheet date based on the most current and relevant data available. If the Subsidiary is deemed to be ineligible or unable to receive the Australian research and development tax credit, or the Australian government significantly reduces or eliminates the tax credit, the actual cash refund we receive may materially differ from our estimates. In June 2020, the ATO informed us that we may not qualify for the AOF program based on their interpretation of certain eligibility requirements. Although we continue to believe that we comply with the relevant conditions of the AOF program that were in place when we received our original approval from AusIndustry, we have determined it is no longer probable that the AOF claim will be received. As a result, during the three months ended June 30, 2020, we recorded a full reserve against the AOF receivable.

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The following table summarizes research and development expenses for the three and nine months ended September 30, 2020 and 2019:

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Research and development expenses - before R&D incentive	\$ 6,177,830	\$ 7,381,241	\$ 23,526,911	\$ 23,380,269
Research and development incentive (non-AOF)	(371,882)	(715,631)	(1,596,024)	(2,184,164)
Research and development expenses (before impact of AOF)	5,805,948	6,665,610	21,930,887	21,196,105
AOF - cumulative change in estimate for the period 1/1/18 through 12/31/19	—	(8,270,009)	—	(8,270,009)
Amounts reserved against AOF refund	—	—	8,107,695	—
Total research and development expenses	<u>\$ 5,805,948</u>	<u>\$ (1,604,399)</u>	<u>\$ 30,038,582</u>	<u>\$ 12,926,096</u>

Excluding the 2020 and 2019 change in research and development expenses related to the AOF, we expect research and development expenses to slightly increase in 2020 as compared to 2019 as we continue to advance our clinical trials for Zygel. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of our 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 Gain (Loss)

Foreign exchange gain (loss) 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 2019 Annual Report under Part II, Item 7, "Critical Accounting Policies and Use of Estimates." During the nine months ended September 30, 2020, there have been no material changes to the critical accounting estimates or critical accounting policies discussed in our 2019 Annual Report.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

Research and Development Expenses

	Three months ended September 30,	
	2020	2019
Research and development expenses (before impact of AOF)	\$ 5,805,948	\$ 6,665,610
AOF - cumulative change in estimate for the period 1/1/18 through 12/31/19	—	(8,270,009)
Total research and development expenses	<u>\$ 5,805,948</u>	<u>\$ (1,604,399)</u>

Excluding the \$8.3 million reduction in research and development expenses recorded during the three months ended September 30, 2019 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 \$0.9 million, or 13%, to \$5.8 million for the three months ended September 30, 2020 from \$6.7 million for the three months ended September 30, 2019. The decrease was primarily related to decreased clinical trial and manufacturing costs associated with our Zygel program; partially offset by a reduction in the non-AOF Australian research and development incentive.

General and Administrative Expenses

General and administrative expenses decreased by \$0.1 million, or 3%, to \$3.4 million for the three months ended September 30, 2020 from \$3.5 million for the three months ended September 30, 2019. The decrease was primarily related to decreases in pre-commercialization expense for our product candidates partially offset by an increase in directors and officers liability insurance.

Other Income (Expense)

During the three months ended September 30, 2020 and 2019, we recognized \$10,781 and \$0.4 million, respectively, in interest income. The decrease in interest income was primarily related to lower average interest rates earned on our investments. During the three months ended September 30, 2020 and 2019, we recognized a foreign currency gain of \$0.2 million and a foreign currency loss of \$0.5 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, 2020 and 2019*Research and Development Expenses*

	Nine months ended September 30,	
	2020	2019
Research and development expenses (before impact of AOF)	\$ 21,930,887	\$ 21,196,105
AOF - cumulative change in estimate for the period 1/1/18 through 12/31/19	—	(8,270,009)
Amounts reserved against AOF refund	8,107,695	—
Total research and development expenses	<u>\$ 30,038,582</u>	<u>\$ 12,926,096</u>

Excluding AOF activity for the nine months ended September 30, 2020 and 2019, research and development expenses increased by \$0.7 million, or 3%, to \$21.9 million for the nine months ended September 30, 2020 from \$21.2 million for the nine months ended September 30, 2019. The increase was primarily related to increased clinical trial costs associated with our Zygel program, an increase in employee-related costs and a reduction in the non-AOF Australian research and development incentive; partially offset by decreases in manufacturing costs related to our Zygel program and stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses increased by \$1.9 million, or 19%, to \$11.8 million for the nine months ended September 30, 2020 from \$10.0 million for the nine months ended September 30, 2019. The increase was primarily related to increases in pre-commercialization expense for our product candidates, directors and officers liability insurance, legal fees and higher employee-related costs, including recruiting costs.

Other Income (Expense)

During the nine months ended September 30, 2020 and 2019, we recognized \$0.2 million and \$1.2 million, respectively, in interest income. The decrease in interest income was primarily related to lower average interest rates earned on our investments. During the nine months ended September 30, 2020 and 2019, we recognized foreign currency losses of \$0.1 million and \$0.6 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.

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 initial public offering, our follow-on public offerings and sales under our "at-the-market" offering) 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, 2020, our principal sources of liquidity were our cash and cash equivalents of \$64.3 million. Our working capital was \$64.2 million as of September 30, 2020.

Management believes that current cash and cash equivalents are sufficient to fund operations and capital requirements until late in the fourth quarter of 2021. However, the economic effects of the COVID-19 pandemic remain fluid and management will continue to closely monitor the situation to ensure our cash and cash equivalents will help us manage the impact of the COVID-19 pandemic on our business and related liquidity needs. 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. Our ability to access the capital markets or otherwise raise such capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

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Equity Financings

In August 2019, we entered into a Controlled Equity Offering Sales AgreementSM, 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. In 2019, we sold and issued 13,381 shares of our common stock in the open market at a weighted-average selling price of \$7.00 per share, for gross and net proceeds of \$0.1 million. In the first quarter of 2020, we sold and issued 356,000 shares of our common stock in the open market at a weighted-average selling price of \$5.10 per share, for gross proceeds of \$1.8 million and net proceeds, after deducting commissions and offering expenses, of \$1.6 million. In the second quarter of 2020, we sold and issued 5,682,784 shares of our common stock in the open market at a weighted-average selling price of \$4.92 per share, for gross proceeds of \$27.9 million and net proceeds, after deducting commissions and offering expenses, of \$27.2 million. We did not sell and issue any shares of our common stock pursuant to the 2019 Sales Agreement during the third quarter of 2020.

In June 2017, we entered into an Open Market Sales Agreement, or the 2017 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 2017 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 2017 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. From June 2017 through May 16, 2019, we had cumulative gross proceeds of \$50.0 million from shares sold in the open market under the 2017 Sales Agreement. The last sale under the 2017 Sales Agreement was made on May 16, 2019, following which the 2017 Sales Agreement terminated pursuant to its terms.

Debt

We had no debt outstanding as of September 30, 2020 or December 31, 2019.

Future Capital Requirements

During the nine months ended September 30, 2020, net cash used in operating activities was \$34.3 million, and our accumulated deficit as of September 30, 2020 was \$192.6 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.

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;

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- 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;
- 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;
- the extent to which health epidemics and other outbreaks of communicable diseases, including the ongoing COVID-19 pandemic, could disrupt our operations or materially and adversely affect our business and financial conditions; and
- the timing and outcome of the ATO's review regarding our eligibility to receive tax credits related to the AOF.

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, 2020 and 2019.

	<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>
Statement of Cash Flows Data:		
Total net cash (used in) provided by:		
Operating activities	\$ (34,327,275)	\$ (27,353,114)
Investing activities	(383,223)	(81,051)
Financing activities	28,958,461	45,217,922
Net (decrease) increase in cash and cash equivalents	<u>\$ (5,752,037)</u>	<u>\$ 17,783,757</u>

Operating Activities

For the nine months ended September 30, 2020, cash used in operating activities was \$34.3 million compared to \$27.4 million for the nine months ended September 30, 2019. The increase from the comparable 2019 period was primarily the result of increased prepaid expenses, increased general and administrative expenses and an increase in research and development expenses related to clinical trial costs of our Zygel program.

Excluding any cash that may be received from the July 2019 AOF application, we expect cash used in operating activities to increase in 2020 as compared to 2019, as we continue to advance our clinical trials for Zygel.

Investing Activities

For the nine months ended September 30, 2019, cash used in investing activities represented the cost of expenditures made for manufacturing equipment.

Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2020 consisted of \$29.0 million in net proceeds from sales of our shares of common stock under the 2019 Sales Agreement. Cash provided by financing activities for the nine months ended September 30, 2019 consisted primarily of \$45.0 million in net proceeds from sales of our shares of common stock under the 2017 Sales Agreement.

Contractual Obligations

Our material contractual obligations consist of commitments under operating lease agreements and the related amounts of our obligations as of December 31, 2019 were disclosed in “Contractual Obligations” in Part II, Item 7 in our 2019 Annual Report. Since December 31, 2019, no material changes in our contractual obligations have occurred.

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 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.

We are also a “smaller reporting company,” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. We would cease to be a smaller reporting company if we have a public float in excess of \$250 million, or have annual revenues in excess of \$100 million and a public float in excess of \$700 million, determined on an annual basis. Consequently, even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

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, 2020, we had cash and cash equivalents of \$64.3 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, Canada and the United Kingdom and to conduct clinical trials for our product candidates in the United States, 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, however, our financial statements are reported in U.S. dollars and changes in foreign currency exchange rates could significantly affect our financial condition, results of operations, or cash flows. 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, 2020. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under 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, 2020, 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, 2020 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, with an amended complaint filed on March 9, 2020. This action was purportedly 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 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 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. The Company’s motion to dismiss the plaintiffs’ complaint is currently pending.

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On April 23, 2020, the Company and the individual defendants filed a motion to dismiss the complaint with prejudice. On April 24, 2020, a stockholder derivative complaint, captioned Philip Quartararo v. Armando Anido, et al., was filed against the Company, its current and former directors (Armando Anido, John P. Butler, Warren D. Cooper, William J. Federici, Thomas L. Harrison, Daniel L. Kisner, Kenneth I. Moch, and Pamela Stephenson), and its Chief Financial Officer, James E. Fickenscher. The complaint generally alleges breach of fiduciary duty, corporate waste and violations of Section 14 (a) of the Exchange Act in connection with the Company's disclosures around the BELIEVE I clinical trial. These proceedings are currently stayed pending resolution of the Company's motion to dismiss in the putative class action.

We believe that the claims asserted in these lawsuits are without merit, and we intend to defend these actions vigorously. There is no assurance, however, that we will be successful in the defense of these lawsuits, or any associated appeals, or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of these actions. Moreover, we are unable to predict the outcome or reasonably estimate a range of possible losses at this time. A resolution of these lawsuits in a manner adverse to us, however, could have a material effect on our financial position and results of operations in the period in which a particular lawsuit is resolved.

Item 1A. Risk Factors.

You should carefully consider the risk factors described in our 2019 Annual Report and our 2020 Quarterly Reports, under the caption "Item 1A. "Risk Factors." There have been no material changes in our risk factors included in our 2019 Annual Report or our 2020 Quarterly Reports. The risks described in our 2019 Annual Report and 2020 Quarterly Reports are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

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

<u>Exhibit No.</u>	<u>Exhibit</u>
31.1	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).
31.2	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).
32.1	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).
32.2	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).
101 INS	Inline XBRL Document (filed herewith).
101 SCH	Inline XBRL Taxonomy Extension Schema (filed herewith).
101 CAL	Inline XBRL Taxonomy Extension Schema Calculation Linkbase (filed herewith).
101 DEF	Inline XBRL Taxonomy Extension Schema Definition Linkbase (filed herewith).
101 LAB	Inline XBRL Taxonomy Extension Schema Label Linkbase (filed herewith).
101 PRE	Inline XBRL Taxonomy Extension Schema Presentation Linkbase (filed herewith).
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in exhibit 101)

CERTIFICATION

I, Armando Anido, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Zynserba 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

Dated: November 9, 2020

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 9, 2020

**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 Zynherba Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2020 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 9, 2020

**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 Zynherba Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2020 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 9, 2020
