
**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 June 30, 2016

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)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if a
smaller reporting company)

Smaller reporting company

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 August 9, 2016 there were 9,199,919 shares of Common Stock, \$0.001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

- our estimates regarding expenses, future revenue, capital requirements and timing and availability of and the need for additional financing;
- the success and timing of our preclinical studies and clinical trials;
- the potential results of preclinical studies and clinical trials for ZYN002 and ZYN001;
- our dependence on third parties in the conduct of our preclinical studies and clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of ZYN002 and ZYN001;
- our plans and ability to develop and commercialize ZYN002 and ZYN001;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- the size and growth of the potential markets for ZYN002 and ZYN001, the rate and degree of market acceptance of ZYN002 and ZYN001 and our ability to serve those markets;
- legal and regulatory developments in the United States and foreign countries;
- our ability to limit our exposure under product liability lawsuits;
- the success of competing therapies and products that are or become available;
- our exposure to additional scrutiny as a public company;
- our use of the proceeds from our initial public offering (“IPO”);
- obtaining and maintaining intellectual property protection for ZYN002 and ZYN001;
- recently enacted and future legislation regarding the healthcare system;
- the performance of third parties upon which we depend, including third-party contract research organizations (“CROs”) and third-party manufacturers;
- our ability to recruit or retain key scientific or management personnel or to retain our executive officers; and
- the other risks, uncertainties and factors discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (“2015 Annual Report”) under the caption “Item 1.A 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. Consequently, there can be no assurance that actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Given these uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. 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)**

	<u>June 30, 2016</u>	<u>December 31, 2015</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,133,048	\$ 41,513,060
Incentive and tax receivables	1,692,315	356,718
Prepaid expenses and other current assets	1,768,994	1,545,917
Total current assets	<u>35,594,357</u>	<u>43,415,695</u>
Property and equipment, net	209,287	227,646
Other assets	200	200
Total assets	<u>\$ 35,803,844</u>	<u>\$ 43,643,541</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,681,122	\$ 823,401
Accrued expenses	1,517,048	2,272,991
Deferred grant revenue	833,975	841,225
Total current liabilities	<u>5,032,145</u>	<u>3,937,617</u>
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; 9,199,919 shares issued and outstanding at June 30, 2016 and December 31, 2015	9,200	9,200
Additional paid-in capital	63,853,317	62,276,779
Accumulated deficit	<u>(33,090,818)</u>	<u>(22,580,055)</u>
Total stockholders' equity	<u>30,771,699</u>	<u>39,705,924</u>
Total liabilities and stockholders' equity	<u>\$ 35,803,844</u>	<u>\$ 43,643,541</u>

See accompanying notes to unaudited consolidated financial statements.

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

	Three months ended		Six months ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Revenue	\$ —	\$ 15,390	\$ 7,250	\$ 30,218
Operating expenses:				
Research and development	4,807,177	1,010,989	7,376,167	1,864,693
General and administrative	1,476,357	631,474	3,156,487	1,285,247
Total operating expenses	<u>6,283,534</u>	<u>1,642,463</u>	<u>10,532,654</u>	<u>3,149,940</u>
Loss from operations	(6,283,534)	(1,627,073)	(10,525,404)	(3,119,722)
Other income (expense):				
Interest income	18,118	697	30,496	1,377
Foreign exchange loss	(20,250)	—	(43,398)	—
Total other income (expense)	<u>(2,132)</u>	<u>697</u>	<u>(12,902)</u>	<u>1,377</u>
Loss before income taxes	(6,285,666)	(1,626,376)	(10,538,306)	(3,118,345)
Income tax benefit	(56,277)	—	(27,543)	—
Net loss	<u>\$ (6,229,389)</u>	<u>\$ (1,626,376)</u>	<u>\$ (10,510,763)</u>	<u>\$ (3,118,345)</u>
Net loss per share basic and diluted	<u>\$ (0.70)</u>	<u>\$ (1.12)</u>	<u>\$ (1.19)</u>	<u>\$ (2.15)</u>
Basic and diluted weighted average shares outstanding	<u>8,860,592</u>	<u>1,449,865</u>	<u>8,842,271</u>	<u>1,449,865</u>

See accompanying notes to unaudited consolidated financial statements.

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

	Six months ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (10,510,763)	\$ (3,118,345)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	27,450	4,542
Stock-based compensation	1,576,538	—
Changes in operating assets and liabilities:		
Incentive and tax receivables	(1,335,597)	—
Prepaid expenses and other assets	(223,077)	(497,148)
Deferred grant revenue	(7,250)	(30,218)
Accounts payable	1,877,165	761,930
Accrued expenses	(755,943)	(608,747)
Net cash used in operating activities	<u>(9,351,477)</u>	<u>(3,487,986)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(28,535)	(46,300)
Net cash used in investing activities	<u>(28,535)</u>	<u>(46,300)</u>
Cash flows from financing activities:		
Payment of offering costs	—	(53,631)
Net cash used in financing activities	<u>—</u>	<u>(53,631)</u>
Net decrease in cash and cash equivalents	(9,380,012)	(3,587,917)
Cash and cash equivalents at beginning of period	41,513,060	9,330,681
Cash and cash equivalents at end of period	<u>\$ 32,133,048</u>	<u>\$ 5,742,764</u>
Supplemental disclosures of cash flow information:		
Deferred offering costs included in accounts payable and accrued expenses	—	1,897,290

See accompanying notes to unaudited consolidated financial statements

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

(1) Nature of Business and Liquidity

Zynerba Pharmaceuticals, Inc. and its subsidiary (the “Company”, “we”) is a clinical stage specialty pharmaceutical company dedicated to developing and commercializing innovative transdermal cannabinoid treatments for patients with high unmet needs. The Company was incorporated on January 31, 2007 under the laws of the State of Delaware as AllTranz, Inc. and changed its name to Zynerba Pharmaceuticals, Inc. in August 2014.

The Company has incurred losses and negative cash flows from operations since inception and has an accumulated deficit of \$33.1 million as of June 30, 2016. 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 convertible promissory notes and equity securities.

In August 2015, the Company completed its Initial Public Offering (“IPO”) of common stock selling 3,450,000 shares at an offering price of \$14.00 per share, resulting in net proceeds of \$42.1 million. Management believes that current cash and cash equivalents are sufficient to fund operations through the end of 2017 and five Phase 2 studies. Substantial additional financings will be needed by the Company to fund its operations, to complete clinical development of and to commercially develop its product candidates. There is no assurance that such financing will be available when needed or on acceptable terms.

The Company is subject to those risks associated with any clinical stage pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees and consultants.

(2) Summary of Significant Accounting Policies

a. Basis of Presentation

The accompanying unaudited interim consolidated financial statements of the Company and its subsidiary 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 or Regulation S-X. 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 financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2016 and its results of operations and cash flows for the six months ended June 30, 2016 and 2015. 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 financial statements should be read in conjunction with the financial statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015 (“2015 Annual Report”), filed with the Securities and Exchange Commission (“SEC”).

b. Use of Estimates

The preparation of 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 revenue and 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 may obtain a cash refund from the Australian Taxation Office for a percentage of the research and development costs expended by the Subsidiary in Australia. The Company's estimate of the amount of cash refund it expects to receive related to the Australian research and development tax incentive program is included in “Incentive and

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

tax receivables” on the accompanying consolidated balance sheets for the amount expected to be collected in the next twelve months. As of June 30, 2016, the Company estimates it will collect \$1.5 million as part of this incentive program.

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 paid is included in “Incentive and tax receivables” on the accompanying consolidated balance sheets for the amount expected to be collected in the next twelve months. As of June 30, 2016, the Company estimates it will collect \$0.2 million for GST paid to Australian vendors through that date.

d. Revenue

Revenue consists of state and federal research grants. Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Grant revenue received is deferred until the related expenditures are incurred.

e. 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 (“CROs”), 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. Beginning in the fourth quarter of 2015, research and development costs are reduced by the Australian research and development incentive recorded in the respective period.

f. Net Loss per Share

Basic loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during each period. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, restricted stock, and stock options, which would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	Three and six months ended June 30,	
	2016	2015
Convertible preferred stock	—	6,964,053
Stock options	1,757,399	606,379
Unvested restricted stock	326,185	579,882
	<u>2,083,584</u>	<u>8,150,314</u>

The Company has corrected the net loss per share basic and diluted and basic and diluted weighted average shares outstanding calculations for the three and six months ended June 30, 2015 to exclude contingently redeemable shares. The Company had previously disclosed \$0.80 and \$1.54 net loss per share basic and diluted for the three and six months ended June 30, 2015, respectively, in the Company’s Form 10-Q for the quarterly period ended June 30, 2015.

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

g. Reclassification

Certain amounts in the prior year financial statements have been reclassified to conform to the current-year presentation. The impact of the reclassifications made to prior year amounts is not material.

h. Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standard Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, which defines management’s responsibility to assess an entity’s ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Company’s consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which requires that lease arrangements longer than 12 months result in an entity recognizing an asset and liability. The pronouncement is effective for interim and annual periods beginning after December 15, 2018 with early adoption permitted. The Company is currently evaluating the impact this guidance is expected to have on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which is intended to simplify the accounting and reporting for employee share-based payment transactions. The pronouncement is effective for interim and annual periods beginning after December 31, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Company’s consolidated financial statements.

(3) Fair Value Measurements

The Company utilizes a valuation hierarchy that prioritizes fair value measurements based on the types of inputs used for the various valuation techniques related to its financial assets and financial liabilities. The three levels of inputs used to measure fair value are described as follows:

Level 1 — Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs and quoted prices in active markets for similar assets and liabilities.

Level 3 — Unobservable inputs and models that are supported by little or no market activity.

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

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:

	Carrying value as of June 30, 2016	Fair Value Measurement as of June 30, 2016		
		Level 1	Level 2	Level 3
Cash equivalents (money market accounts)	\$31,362,847	\$31,362,847	\$ —	\$ —
Certificate of deposit (included in prepaid expenses and other current assets)	20,000	20,000	—	—
	<u>\$31,382,847</u>	<u>\$31,382,847</u>	<u>\$ —</u>	<u>\$ —</u>

	Carrying value as of December 31, 2015	Fair Value Measurement as of December 31, 2015		
		Level 1	Level 2	Level 3
Cash equivalents (money market accounts)	\$ 41,032,351	\$41,032,351	\$ —	\$ —
Certificate of deposit (included in prepaid expenses and other current assets)	20,000	20,000	—	—
	<u>\$ 41,052,351</u>	<u>\$41,052,351</u>	<u>\$ —</u>	<u>\$ —</u>

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following as June 30, 2016 and December 31, 2015:

	June 30, 2016	December 31, 2015
Prepaid development expenses	\$ 1,666,975	\$ 1,211,668
Prepaid insurance	76,523	282,440
Other	25,496	51,809
Total prepaid expenses and other current assets	<u>\$ 1,768,994</u>	<u>\$ 1,545,917</u>

Included in prepaid development expenses above is research and grant revenue remitted to third-party research organizations of \$0.8 million and \$0.8 million as of June 30, 2016 and December 31, 2015, respectively, that will be recognized as research projects progress and expenses are incurred.

(5) Property and Equipment

Property and equipment consisted of the following:

	Estimated useful life (in years)	June 30, 2016	December 31, 2015
Equipment	5	\$139,526	\$ 139,526
Computer equipment	3	27,111	23,632
Furniture and fixtures	5	99,731	94,118
Total cost		266,368	257,276
Less accumulated depreciation		(57,081)	(29,630)
Property and equipment, net		<u>\$209,287</u>	<u>\$ 227,646</u>

Depreciation expense was \$13,892 and \$3,095 for the three months ended June 30, 2016 and 2015, respectively. Depreciation expense was \$27,450 and \$4,542 for the six months ended June 30, 2016 and 2015, respectively.

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

(6) Accrued Expenses

Accrued expenses consisted of the following:

	June 30, 2016	December 31, 2015
Accrued compensation	\$ 636,093	\$ 1,047,530
Accrued research and development	716,151	943,295
Other	164,804	282,166
Total accrued expenses	<u>\$ 1,517,048</u>	<u>\$ 2,272,991</u>

(7) Stock-Based Compensation

The Company maintains the Amended and Restated 2014 Omnibus Incentive Compensation Plan, as amended (“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 purchase an aggregate of 2,450,000 shares of the Company’s common stock to employees, officers, directors, consultants, and advisors, 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, commencing on January 1, 2017, equal to the lesser of 1.5 million shares and 10% of the number of shares of common stock outstanding on the last trading day of December of the preceding year. In addition, the 2014 Plan provides selected executive employees with the opportunity to receive bonus awards that are considered qualified performance-based compensation. As of June 30, 2016 96,762 shares are available for 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.

During the six months ended June 30, 2016, the Company recorded stock-based compensation expense related to its stock option grants and restricted stock awards, as follows:

	Research and Development	General and Administrative	Total
Stock option grants	\$ 558,922	\$ 897,696	\$ 1,456,618
Restricted stock awards	64,729	55,191	119,920
	<u>\$ 623,651</u>	<u>\$ 952,887</u>	<u>\$ 1,576,538</u>

Vesting of the stock option grants and restricted stock awards issued prior to the Company’s IPO in August 2015 was contingent upon the closing of the Company’s IPO. Accordingly, prior to the Company’s IPO in August 2015, no expense had been recorded for the stock option grants and restricted stock awards.

The following table summarizes the stock option activity under the 2014 Plan for the six-month period ended June 30, 2016:

	Options	Weighted Average Grant Date Fair Value	Weighted Average Exercise Price
Outstanding as of December 31, 2015	1,637,399	\$ 6.47	\$ 10.49
Granted	120,000	\$ 5.50	\$ 8.35
Outstanding as of June 30, 2016	<u>1,757,399</u>	\$ 6.40	\$ 10.34

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

During the three months ended June 30, 2016, the Company granted a total of 120,000 stock options to non-management members of the Company's Board of Directors and a new employee. The stock options granted to the non-management directors vest on the earlier of the one-year anniversary of the grant date, or the date of the Company's 2017 annual stockholders' meeting. The stock options granted to the Company's new employee vest 25% upon the first anniversary of the grant date and quarterly over three years thereafter.

The weighted average grant date fair value of stock options granted during the three months ended June 30, 2016 was estimated using the Black-Scholes option pricing model with the following ranges of assumptions: expected volatility of 77%, risk free interest rate of 1.43% to 1.62%, expected term of 5.5 years to 6.25 years and 0% expected dividend yield.

As of June 30, 2016, there was \$8.5 million of unrecognized stock-based compensation expense related to stock options, which is expected to be recognized over a weighted-average period of 2.81 years. As of June 30, 2016, 415,029 stock options with a weighted average grant date fair value of \$3.98 were exercisable, and the Company expects an additional 1,342,370 stock options to vest.

The following table summarizes the restricted stock award activity under the 2014 Plan for the six-month period ended June 30, 2016:

	<u>Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Unvested as of December 31, 2015	398,671	\$ 1.65
Vested	<u>(72,486)</u>	\$ 1.65
Unvested as of June 30, 2016	<u>326,185</u>	\$ 1.65

As of June 30, 2016, there was \$0.5 million of unrecognized stock-based compensation expense related to unvested restricted stock awards as of June 30, 2016, which is expected to be recognized over a weighted-average period of 2.09 years. The Company expects all 326,185 unvested restricted stock awards to vest.

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 consolidated financial statements and related notes appearing elsewhere in this quarterly report and the audited financial statements and notes thereto for the year ended December 31, 2015 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our 2015 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 2015 Annual Report.

Overview

Company Overview

We are a clinical stage specialty pharmaceutical company dedicated to developing and commercializing innovative transdermal synthetic cannabinoid treatments for patients with high unmet needs. We are evaluating two patent protected product candidates, ZYN002 and ZYN001, in five indications. We are studying ZYN002 in adult patients with refractory focal seizures, and intend to study ZYN002 in patients with osteoarthritis, or OA, and fragile X syndrome, or FXS. We intend to study ZYN001 in patients with fibromyalgia and peripheral neuropathic pain. We believe these product candidates will provide new treatment options for patients, as well as additional treatment options for patients not currently receiving adequate relief from current treatment regimens. In June 2016, we completed two Phase 1 clinical trials for ZYN002 in healthy volunteers and patients with epilepsy, initiated a third Phase 1 clinical trial to evaluate different concentrations of ZYN002 in healthy volunteers and initiated a Phase 2 clinical trial for ZYN002 in adult patients with refractory focal seizures. We announced the randomization and dosing of the first patients in this Phase 2 study on August 1, 2016. We expect to initiate Phase 2 clinical trials for ZYN002 in patients with OA and FXS in the second half of 2016. We expect to initiate Phase 1 clinical trials for ZYN001 in the second half of 2016.

Cannabinoids are a class of compounds derived from *Cannabis* plants. The two primary cannabinoids contained in *Cannabis* are cannabidiol, or CBD, and Δ^9 -tetrahydrocannabinol, or THC. Clinical and preclinical data suggest that CBD has positive effects on treating refractory epilepsy, arthritis and FXS, and THC has positive effects on treating pain. In addition to ZYN002 and ZYN001 potentially offering first-line therapies to patients suffering from OA, FXS, fibromyalgia and peripheral neuropathic pain, we believe ZYN002 may provide a complementary treatment for patients suffering from epilepsy who are refractory to their current treatment regimens.

ZYN002 is the first and only synthetic CBD formulated as a permeation-enhanced gel for transdermal delivery, and is patent-protected through 2030. CBD is the primary non-psychoactive component of *Cannabis*. In preclinical animal studies, ZYN002's permeation enhancer increased delivery of CBD through the layers of the skin and into the circulatory system. These preclinical studies suggest increased bioavailability, consistent plasma levels and the avoidance of first-pass liver metabolism. In addition, an *in vitro* study published in *Cannabis and Cannabinoid Research* in April 2016 demonstrated that CBD is degraded to THC in an acidic environment such as the stomach. We believe such degradation may lead to increased psychoactive effects and may be avoided with the transdermal delivery of ZYN002, which maintains CBD in a neutral pH. ZYN002, which is being developed as a clear gel with once- or twice-daily dosing, is targeting treatment of refractory epilepsy, OA and FXS, which collectively affect millions of patients using treatments that currently comprise a multi-billion dollar market. We have been granted orphan drug designation from the U.S. Food and Drug Administration, or FDA, for ZYN002 for the treatment of FXS.

ZYN001 is a pro-drug of THC that enables effective transdermal delivery via a patch and is patent-protected through 2031. A pro-drug is a drug administered in an inactive or less active form and designed to enable more effective delivery, which is then converted into an active form through a normal metabolic process. In addition, we expect that ZYN001 will be classified by the FDA as a new chemical entity. In our preclinical animal studies, ZYN001 demonstrated effective skin permeation with sustained delivery and rapid conversion of ZYN001 to THC. These preclinical studies suggest increased bioavailability, consistent plasma levels and the avoidance of first-pass liver metabolism. In addition, preclinical testing conducted has shown no genotoxicity findings and safety pharmacology findings consistent with those seen with THC. ZYN001 is targeting two pain indications, fibromyalgia and peripheral neuropathic pain.

In June 2016, we completed two Phase 1 clinical trials for ZYN002 in healthy volunteers and patients with epilepsy. The first Phase 1 single rising dose clinical trial for ZYN002 in healthy human subjects and in patients with refractory epilepsy evaluated the tolerability and pharmacokinetic, or PK, profile of ZYN002. Results from this clinical trial demonstrated that ZYN002 was safe and well-tolerated at all tested dose levels and the incidence of adverse events associated with ZYN002 was similar to placebo for both healthy subjects and epilepsy patients. The second Phase 1 clinical trial was a randomized, double-blind, placebo controlled multiple rising dose clinical trial for ZYN002 in twenty-four healthy volunteers and twelve patients with epilepsy to evaluate the PK profile, pharmacodynamics, or PD, and tolerability of multiple doses (200, 250, and 500 mg) of ZYN002. Each volunteer and patient received seven days of either ZYN002 or placebo. Top line results from this clinical trial demonstrated that ZYN002 was safe and well-tolerated at all dose levels. The twice daily dosing provided a more favorable PK profile with comparable results between healthy volunteers and epilepsy patients. Transdermal application of ZYN002 was very well tolerated with minimal skin erythema. Skin dryness at the application site was common for both ZYN002 and placebo gel. Overall, the incidence of adverse events associated with ZYN002 was similar to placebo in both healthy volunteers and adult epilepsy patients. There were no reports of somnolence or fatigue and a very low incidence of gastrointestinal events was observed. There were no serious adverse events or discontinuations for healthy volunteers and epilepsy patients receiving ZYN002. One healthy volunteer receiving placebo gel developed a serious adverse event suspected to be a catheter infection and was discontinued from the study. In addition, healthy volunteers and epilepsy patients had no drug related changes in performance on the Trail Making Test, a test of visual attention, psychomotor ability, and task switching; a divided attention task; and the Paced Auditory Serial Addition Task, or PASAT, a test that measures working memory and focused attention. These results indicate that ZYN002 did not produce impairment in critical areas of cognitive functioning often impacted by central nervous system drugs. No changes in mood symptoms as assessed by the Inventory of Depression and Anxiety Symptoms, or IDAS, and the Positive and Negative Affect Schedule, or PANAS were observed for ZYN002 suggesting that ZYN002 is not associated with declines in psychological health.

In June 2016, we initiated a third Phase 1 clinical trial for ZYN002 which was randomized, double-blind and placebo controlled in 42 healthy volunteers. The volunteers received a range of ZYN002 doses from 395 mg to 504 mg daily in 2.5% and 4.2% ZYN002 formulations for fourteen days. Results from this clinical trial demonstrated that ZYN002 was very well tolerated with minimal skin erythema. The 4.2% formulation demonstrated a comparable PK and tolerability profile to the 2.5% concentration and was easier to use due to the lower volume. There were no serious adverse events or discontinuations from this clinical trial.

In the Phase 1 studies, ZYN002 was safe and well tolerated, provided a favorable CBD PK profile, and no THC was detected in plasma or urine.

In June 2016, we initiated a Phase 2 randomized, multi-center, multi-dose clinical trial designed to evaluate the efficacy and safety of ZYN002 in adult patients with refractory focal seizures, which we refer to as the STAR 1 (Synthetic Transdermal Cannabidiol for the Treatment of Epilepsy). Approximately 180 patients will be enrolled in the trial and will be followed for 8 weeks during the baseline phase. After the baseline phase, patients are randomized (1:1:1) to receive one of two doses (390 mg or 195 mg daily) of ZYN002 or placebo for 12 weeks. The primary endpoint of the study is median percentage change in seizure frequency at 12 weeks. On August 1, 2016, we announced that the first patients were randomized and dosed in STAR 1, and we expect to report preliminary top line results in the first half of 2017.

We plan to evaluate the tolerability and PK profile of ZYN001 in a Phase 1 single rising dose clinical trial in healthy human subjects in the second half of 2016. Subsequent to the single rising dose clinical trials, we intend to conduct a Phase 1 multiple rising dose clinical trial to examine the tolerability, PK and PD of multiple doses of ZYN001 in healthy human subjects and in patients with fibromyalgia.

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Our key development programs and expected timelines for the development of ZYN002 and ZYN001 are shown in the table below:

<u>Product Candidate</u>	<u>Target Indication</u>	<u>Delivery Method</u>	<u>Current Development Status</u>	<u>Expected Next Steps</u>
ZYN002	Refractory Epilepsy Osteoarthritis Fragile X Syndrome	Permeation-enhanced Gel	Phase 2	1H17: TopLine Results 2H16: Initiate Phase 2 2H16: Initiate Phase 2
ZYN001	Fibromyalgia Peripheral Neuropathic Pain	Transdermal Patch	Preclinical	2H16: Initiate Phase 1 1H17: Initiate Phase 2

We have never been profitable and have incurred net losses since inception. Our net losses were \$10.5 million for the six months ended June 30, 2016. 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.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was signed into law. 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 and "emerging growth company," whichever occurs first.

Financial Operations Overview

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

Revenue

Our revenue consists of state and federal research grants and, historically, fees received from research services for third-party product development. We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Grant revenue received is deferred until the related expenditures are incurred. Revenue in each of the periods presented is related to work performed in connection with grants received.

Research and Development Expenses

Our research and development expenses consist of expenses incurred in development, preclinical studies and clinical trials relating to our product candidates, including:

- 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, contractor laboratories and independent contractors; and
- depreciation, maintenance and other facility-related expenses.

We expense all research and development costs as incurred. Preclinical and clinical development expenses for our product candidates are a significant component of our current research and development expenses. 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. From time to time, we use third-party CROs, 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 trial or study completed at the end of each reporting period.

We incurred research and development expenses of \$4.8 million and \$1.0 million for the three months ended June 30, 2016 and 2015, respectively. Research and development expenses for the three months ended June 30, 2016 are net of a \$0.8 million Australian tax incentive, which we expect will result in a refund of \$0.8 million of certain research and development costs incurred in Australia. Research and development expenses for the three months ended June 30, 2016 are also net of a \$0.2 million tax refund, which we expect will result in a refund of \$0.2 million of GST paid on research and development costs provided by Australian vendors.

We incurred research and development expenses of \$7.4 million and \$1.9 million for the six months ended June 30, 2016 and 2015, respectively. Research and development expenses for the six months ended June 30, 2016 are net of a \$1.1 million Australian tax incentive, which we expect will result in a refund of \$1.1 million of certain research and development costs incurred in Australia. Research and development expenses for the six months ended June 30, 2016 are also net of a \$0.2 million tax refund, which we expect will result in a refund of \$0.2 million of GST paid on research and development costs provided by Australian vendors.

We expect research and development expenses in future years to continue to increase as we continue our clinical trials and begin new phases for each of our product candidates as a result of the work needed for completion of our Phase 2 clinical trials of ZYN002, initiated in June 2016, and the expected initiation of our Phase 1 clinical trials for ZYN001 in the second half of 2016. 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 ZYN002 and ZYN001. As a result of the difficulties of forecasting research and development costs of ZYN002 and ZYN001 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, accounting, legal and human resource functions. Our general and administrative expenses also include facility and related costs not included in research and development

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expenses, professional fees for legal services, including patent-related expenses, consulting, tax and accounting services, insurance and general corporate expenses. We expect that our general and administrative expenses will increase with the continued development and potential commercialization of our product candidates.

We expect that our general and administrative expenses in 2016 and for the next several years will be higher than in past years as we increase our headcount. We also anticipate increased expenses relating to our operations as a public company, including increased costs for the hiring of additional personnel, and for payment to outside consultants, including lawyers and accountants, to comply with additional regulations, corporate governance, internal control and similar requirements applicable to public companies, as well as increased costs for insurance.

Interest Income

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

Results of Operations

Comparison of the Three Months Ended June 30, 2016 and June 30, 2015

Revenues

Revenues decreased by \$15,390, or 100%, and were zero for the three months ended June 30, 2016, compared to \$15,390 for the three months ended June 30, 2015. Revenues in the 2015 period were entirely related to work performed in connection with grants received. The decrease from 2015 reflected reduced research activities associated with our remaining grant.

Research and Development Expenses

Research and development expenses increased by \$3.8 million or 373%, to \$4.8 million for the three months ended June 30, 2016 from \$1.0 million for the three months ended June 30, 2015. The increase was primarily the result of increases in expense of approximately \$3.9 million related to an increase in the number and size of our non-clinical studies and clinical trials for ZYN002 and ZYN001, active pharmaceutical ingredient, or API, development and production, as well as an increase in personnel costs of approximately \$0.9 million related to increased headcount, stock-based compensation and travel costs, partially offset by \$0.8 million for an Australian tax incentive and \$0.2 million for the expected refund of Australian GST.

Our expenditures associated with ZYN002, ZYN001 and other research and development projects for the three months ended June 30, 2016 were \$3.6 million (including an offset of \$1.0 million for an Australian tax incentive and GST refund), \$0.5 million and \$0.7 million, respectively. Our expenditures associated with ZYN002, ZYN001 and our other projects in the three months ended June 30, 2015 were \$0.5 million, \$0.3 million and \$0.2 million, respectively. The increase in the expenses from prior year relates to the initiation of clinical trials and an increase in preclinical studies for ZYN002 and an increase in preclinical studies for ZYN001.

General and Administrative Expenses

General and administrative expenses increased by \$0.9 million, or 134%, to \$1.5 million for the three months ended June 30, 2016 from \$0.6 million for the three months ended June 30, 2015. The increase was primarily the result of an increase in personnel costs of approximately \$0.5 million, as well as increases in insurance, franchise taxes and professional service fees of approximately \$0.4 million in aggregate.

The increases in personnel costs related primarily to stock-based compensation expense in the 2016 period, and increases in professional service fees and insurance were largely the result of on-going costs associated with being a public company and costs associated with establishing an infrastructure to support our product development activities.

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Other Income (Expense)

During the three months ended June 30, 2016 and 2015, the Company recognized \$18,118 and \$697, respectively, in interest income. During the three month period ended June 30, 2016, the Company recognized foreign currency losses of \$20,250. There was no foreign currency gain or loss for the same period in 2015.

Income Tax Benefit

During the three months ended June 30, 2016, we reversed \$56,277 of income tax expense associated with our Australian subsidiary.

Comparison of the Six Months Ended June 30, 2016 and June 30, 2015

Revenue

Revenue decreased by \$22,968 or 76%, to \$7,250 for the six months ended June 30, 2016 from \$30,218 for the six months ended June 30, 2015. The decrease from 2015 reflected reduced research activities associated with our remaining grants.

Research and Development Expenses

Research and development expenses increased by \$5.5 million, or 296% to \$7.4 million for the six months ended June 30, 2016 from \$1.9 million for the six months ended June 30, 2015. The increase was primarily the result of increases in expense of approximately \$5.4 million related to an increase in the number and size of our non-clinical studies and clinical trials for ZYN002 and ZYN001, active pharmaceutical ingredient, or API, development and production, as well as an increase in personnel costs of approximately \$1.4 million related to increased headcount, stock-based compensation and travel costs, partially offset by \$1.1 million for an Australian tax incentive and \$0.2 million for the expected refund of Australian GST.

Our expenditures associated with ZYN002, ZYN001 and other general research and development for the six months ended June 30, 2016 were \$5.2 million (including an offset of \$1.3 million for an Australian tax incentive and GST refund), \$0.9 million and \$1.3 million, respectively. Our expenditures associated with ZYN002, ZYN001 and other general research and development for the six months ended June 30, 2015 were \$0.8 million, \$0.7 million and \$0.4 million, respectively. The increase in the expenses from prior year relates to the initiation of clinical trials and an increase in preclinical studies for ZYN002 and an increase in preclinical studies for ZYN001.

General and Administrative Expenses

General and administrative expenses increased by \$1.9 million, or 146% to \$3.2 million for the six months ended June 30, 2016 from \$1.3 million for the six months ended June 30, 2015. The increase primarily relates to increases in personnel costs and travel expenses of \$1.2 million, an increase in professional services fees of approximately \$0.4 million, an increase in insurance costs of approximately \$0.2 million and an increase in franchise taxes of \$0.1 million in the current-year period.

The increases in personnel costs related primarily to stock-based compensation expense in the 2016 period, and increases in professional service fees and insurance were largely the result of on-going costs associated with being a public company and costs associated with establishing an infrastructure to support our product development activities.

Other Income (Expense)

During the six months ended June 30, 2016, the Company recognized interest income of \$30,496, compared to interest income of \$1,377 for the six months ended June 30, 2015. Also during the six months ended June 30, 2016, the Company recognized a loss of \$43,398 associated with foreign currency transactions related to our clinical trials in Australia. There was no foreign currency gain or loss in 2015 for the same period.

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Income Tax Benefit

During the six months ended June 30, 2016, we reversed \$27,543 of income tax expense associated with our Australian subsidiary.

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 recent IPO, which raised \$42.1 million of net proceeds) 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 June 30, 2016, our principal sources of liquidity were our cash and cash equivalents, which totaled \$32.1 million. Our working capital was \$30.6 million as of June 30, 2016.

Based on our current operating plans, we expect that the net proceeds from our IPO and our existing cash and cash equivalents will be sufficient to fund our operations and capital requirements through the end of 2017. We believe that these available funds will be sufficient to become Phase 3 ready, completing Phase 1 clinical trials for each of our product candidates and Phase 2a clinical trials for each of our five indications. However, it is difficult to predict our spending for our product candidates prior to obtaining FDA approval. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

Equity Financings

In August 2015 we completed our IPO, selling 3,450,000 shares of common stock at an offering price of \$14.00 per share, resulting in gross proceeds of \$48.3 million. Net proceeds received after deducting underwriting discounts and commissions and offering expenses were \$42.1 million. In connection with the closing of the IPO, all outstanding shares of our Series 1 convertible preferred stock were converted into an aggregate of 3,704,216 shares of common stock.

Debt

We had no debt outstanding as of June 30, 2016 or December 31, 2015.

Future Capital Requirements

During the six months ended June 30, 2016, net cash used in operating activities was \$9.4 million, and our accumulated deficit as of June 30, 2016 was \$33.1 million. Our expectations regarding future cash requirements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we make in the future. We have no current understandings, agreements or commitments for any material acquisitions or licenses of any products, businesses or technologies. We may need to raise substantial additional capital in order to engage in any of these types of transactions.

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 either of our product candidates, we will incur significant sales, marketing and outsourced 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 applicable to us as a public 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;

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- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the United States Drug Enforcement Agency (“DEA”), 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, including patent infringement actions brought by third parties against us;
- costs and timing of the implementation of commercial scale manufacturing activities; and
- the cost of establishing, or outsourcing, sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

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. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

Cash Flows

The following table summarizes our cash flows from operating, investing and financing activities for the six months ended June 30, 2016 and June 30, 2015.

	<u>Six Months Ended June 30,</u>	
	<u>2016</u>	<u>2015</u>
Statement of Cash Flows Data:		
Total net cash used in:		
Operating activities	\$(9,351,477)	\$(3,487,986)
Investing activities	(28,535)	(46,300)
Financing activities	—	(53,631)
Decrease in cash and cash equivalents	<u>\$(9,380,012)</u>	<u>\$(3,587,917)</u>

Operating Activities

For the six months ended June 30, 2016, cash used in operating activities was \$9.4 million compared to \$3.5 million for the six months ended June 30, 2015. The increase from the comparable 2015 period was primarily the result of increased research and development activities related to the non-clinical studies and clinical trials of ZYN002 and ZYN001, as well as an increase in the number of employees hired to support our research and development and general and administrative activities, and an increase in receivables, primarily related to an incentive associated with research and development costs in Australia and the expected refund of GST paid to Australian vendors.

We expect cash used in operating activities to continue to increase in 2016 as compared to 2015 due to an expected

increase in our operating losses associated with ongoing development of our product candidates.

Investing Activities

For the six months ended June 30, 2016 and June 30, 2015, cash used in investing activities represented the cost of computer equipment and furniture and fixtures associated with our corporate headquarters.

Financing Activities

Cash used in financing activities in the six months ended June 30, 2015 represented offering costs associated with our IPO.

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.

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 and do not believe we are exposed to material market risk with respect to our cash and cash equivalents.

We have contracted with third parties to manufacture our product candidates in Canada and to conduct Phase 1 and Phase 2a clinical trials in Australia. Manufacturing and research costs related to these activities are paid for in a combination of U.S. dollars and local currencies. Accordingly, we are subject to limited foreign currency exchange rate risk. For example, for the six months ended June 30, 2016, we recognized a loss of \$43,398 related to foreign currency transactions. We do not believe foreign currency exchange rate risk is a material risk at this time due to the limited extent of our operations, however, as we continue to 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.

As of June 30, 2016, we had cash and cash equivalents of \$32.1 million consisting primarily of cash and money market accounts. We do not engage in any hedging activities against changes in interest rates or foreign currency exchange rates. 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 material impact on the realized value of our investments.

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 June 30, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (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 SEC’s rules and forms. 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 June 30, 2016, 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

No change in our internal control over financial reporting occurred during the fiscal quarter ended June 30, 2016 that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any legal proceedings.

Item 1A. Risk Factors.

You should carefully consider the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (“2015 Annual Report”) under the caption “Item 1.A “Risk Factors”. There have been no material changes to the risk factors disclosed in our 2015 Annual Report.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Our IPO was effected through a Registration Statement on Form S-1 (File No. 333-205355) that was declared effective by the SEC on August 4, 2015, which registered an aggregate of 3,450,000 shares of our common stock. On August 10, 2015, 3,450,000 shares of common stock were sold on our behalf at an IPO price of \$14.00 per share, including 450,000 shares of common stock upon the exercise by the underwriters of their option to purchase additional shares at the IPO price, for aggregate gross proceeds of \$48.3 million. As of the date of filing this report, the offering has terminated, and all of the securities registered pursuant to the offering have been sold prior to termination. Jefferies LLC and Piper Jaffray & Co. acted as joint book-running managers in the IPO, and Canaccord Genuity Inc. and Oppenheimer & Co. Inc. acted as co-managers in the IPO.

On August 10, 2015 we received proceeds from the IPO of \$44.8 million, which was net of underwriting discounts and commissions of approximately \$3.5 million. Of this amount, we paid offering expenses of approximately \$2.7 million. All of the foregoing expenses were direct or indirect payments to persons other than (i) our directors, officers or any of their associates; (ii) persons owning 10% or more of our common stock; or (iii) our affiliates.

As of June 30, 2016, we have used approximately \$10.0 million of the net offering proceeds from our IPO to fund the development efforts of ZYN002 (including funding of our Phase 1 and Phase 2 clinical trials), development efforts of ZYN001, working capital, research and development and general corporate purposes. None of the net proceeds have been paid directly or indirectly to (i) our directors, officers or any of their associates; (ii) persons owning 10% or more of our common stock; or (iii) our affiliates.

There has been no material change in the use of proceeds from the IPO as described in the Prospectus under “Use of Proceeds.”

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.

None.

Item 5. Other Information.

Not applicable

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

- 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 The following financial information from this Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, formatted in XBRL (Extensible Business Reporting Language) and furnished electronically herewith: (i) the Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015 (Unaudited); (ii) the Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2016 and 2015 (Unaudited); (iii) the Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2016 and 2015 (Unaudited) and (iv) the Notes to Unaudited Consolidated Financial Statements, tagged in detail.

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)) 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) 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
 - (c) 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: August 11, 2016

CERTIFICATION

I, Richard A. Baron, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Zynerba 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)) 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) 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
 - (c) 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/ Richard A. Baron

Name: Richard A. Baron

Title: Chief Financial Officer and Treasurer

Dated: August 11, 2016

**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 Zynerba Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended June 30, 2016 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: August 11, 2016

**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 Zynerba Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended June 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard A. Baron, Chief Financial Officer and Treasurer 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/ Richard A. Baron

Richard A. Baron
Chief Financial Officer and Treasurer

Dated: August 11, 2016
