# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K/A

# (Amendment No.1)

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): October 10, 2023

# HARMONY BIOSCIENCES HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-39450 (Commission File Number) 82-2279923 (IRS Employer Identification No.)

630 W. Germantown Pike, Suite 215 Plymouth Meeting, PA 19462

(Address of principal executive offices) (Zip Code)

(484) 539-9800

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

	Trading	Name of each exchange
Title of each class	Symbol(s)	on which registered
Common Stock, \$0.00001 par value	HRMY	The Nasdaq Global Market
per share		

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

# **Explanatory Note**

On October 10, 2023, Harmony Biosciences Holdings, Inc. (the "Company"), completed its previously announced acquisition of Zynerba Pharmaceuticals, Inc. ("Zynerba"), pursuant to an Agreement and Plan of Merger, dated as of August 14, 2023, and amended on October 4, 2023 (the "Merger Agreement"), by and among Zynerba, the Company and Xylophone Acquisition Corp. (the "Purchaser").

On October 11, 2023, the Company filed its Current Report on Form 8-K (the "Original 8-K") to report the completion of the acquisition on October 10, 2023.

Under Item 9.01 of the Original 8-K, the Company stated that (a) the financial statements of the business acquired required by Item 9.01 would be filed by amendment to the Original 8-K no later than 71 calendar days after the date on which the Original 8-K was required to be filed, and (b) the pro forma financial information required by Item 9.01 would be filed by amendment to the Original 8-K no later than 71 calendar days after the date on which the Original 8-K was required to be filed. Accordingly, this Current Report on Form 8-K/A amends Item 9.01 of the Original 8-K to present certain financial statements and certain pro forma financial information. Except for this Explanatory Note, the filing of the financial statements and the pro forma financial information required by Item 9.01, filed herewith as Exhibits 99.1, 99.2 and 99.3, and the consent of KPMG LLP. filed herewith as Exhibit 23.1, there are no changes to the Original 8-K.

#### Item 9.01. Financial Statements and Exhibits

(a) Financial statements of business acquired

The audited consolidated financial statements of Zynerba Pharmaceuticals, Inc. as of and for the year ended December 31, 2022 are filed as Exhibit 99.1 and incorporated by reference herein.

The unaudited condensed consolidated financial statements of Zynerba Pharmaceuticals, Inc. as of and for the nine months ended September 30, 2023 are filed as Exhibit 99.2 and incorporated by reference herein.

# (b) Pro forma financial information

The unaudited pro forma condensed combined financial statements of Harmony Biosciences Holdings, Inc. as of and for the nine months ended September 30, 2023 and for the year ended December 31, 2022, and notes related thereto, are filed as Exhibit 99.3 and incorporated by reference herein.

- (d) Exhibits
  - 23.1 Consent of KPMG LLP
  - 99.1 <u>Audited consolidated financial statements of Zynerba Pharmaceuticals, Inc. as of and for</u> the year ended December 31, 2022.
  - 99.2 Unaudited condensed consolidated financial statements of Zynerba Pharmaceuticals, Inc. as of and for the nine months ended September 30, 2023.
  - 99.3 <u>Unaudited pro forma condensed combined financial statements of Harmony Biosciences</u> <u>Holdings, Inc. as of and for the nine months ended September 30, 2023 and for the year</u> <u>ended December 31, 2022.</u>
  - 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

# SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HARMONY BIOSCIENCES HOLDINGS, INC.

Date: December 7, 2023

By: <u>/s/ Sandip Kapadia</u> Sandip Kapadia Chief Financial Officer and Chief Administrative Officer

# **Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statements No. 333-260905 on Form S-3 and Nos. 333-248243 and 333-263077 on Form S-8 of Harmony Biosciences Holdings, Inc. of our report dated March 28 2023, with respect to the consolidated financial statements of Zynerba Pharmaceuticals, Inc., appearing in this Current Report on Form 8-K/A of Harmony Biosciences Holdings, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania December 7, 2023

# Zynerba Pharmaceuticals, Inc. Consolidated Financial Statements

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The following financial statements are filed as a part of this Annual Report on Form 10-K:

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#### **Report of Independent Registered Public Accounting Firm**

To the Stockholders and Board of Directors Zynerba Pharmaceuticals, Inc.:

#### Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Zynerba Pharmaceuticals, Inc. and subsidiary (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2022, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

# Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.



#### Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of prepaid development expenses and accrued research and development expenses

As discussed in Notes 2, 4 and 6 to the consolidated financial statements, research and development costs are expensed as incurred, which include accrued external research and development expenses incurred under arrangements with third parties, such as contract research organizations (CROs) that conduct clinical trials and contract manufacturing organizations (CMOs). 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, considering factors such as the number of patients enrolled in studies, milestones achieved and other criteria related to the efforts of its vendors. 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. The prepaid development expenses and accrued research and development expenses were \$0.7 million and \$4.2 million, respectively, as of December 31, 2022.

We identified the evaluation of prepaid development expenses and accrued research and development expenses for CROs and CMOs as a critical audit matter. Evaluating the sufficiency of audit evidence obtained over research and development costs, including the factors described above, required especially subjective auditor judgment due to the nature of evidence available regarding the cost of research and development activities incurred as of year-end under the arrangements with CROs and CMOs.

The following are the primary procedures we performed to address this critical audit matter. For a sample of contracts with CROs and CMOs, we examined the provisions in the contracts, invoices and communications received from third parties related to the project status, and management's analysis of costs incurred as of year-end. For these contracts, we evaluated the relevant factors used in determining the costs incurred for CROs and CMOs as of year-end. We also compared the Company's estimate of costs incurred as of year-end to a selection of third-party invoices and communication from third parties received after year-end. We assessed the sufficiency of audit evidence obtained related to prepaid development expenses and accrued research and development costs incurred by CROs and CMOs by evaluating the cumulative results of the audit procedures.

/s/ KPMG LLP

We have served as the Company's auditor since 2014.

Philadelphia, Pennsylvania March 28, 2023

# ZYNERBA PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS

		December 31, 2022	December 31, 2021
Assets			
Current assets:			
Cash and cash equivalents	\$	50,640,993	\$ 67,808,000
Incentive and tax receivables		1,225,383	9,580,468
Prepaid expenses and other current assets		2,908,731	2,831,392
Total current assets		54,775,107	80,219,860
Property and equipment, net		409,572	385,833
Right-of-use assets		336,215	565,814
Total assets	\$	55,520,894	\$ 81,171,507
Liabilities and Stockholders' Equity	_		
Current liabilities:			
Accounts payable	\$	1,942,830	\$ 1,798,813
Accrued expenses		7,014,882	7,896,598
Lease liabilities		214,901	 209,068
Total current liabilities		9,172,613	9,904,479
Lease liabilities, long-term		119,524	 353,694
Total liabilities		9,292,137	10,258,173
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; 47,895,687 shares issued and outstanding at December 31, 2022 and 41,217,537 shares issued and			
outstanding at December 31, 2021		47,896	41,218
Additional paid-in capital		320,698,146	310,353,595
Accumulated deficit		(274,517,285)	 (239,481,479)
Total stockholders' equity		46,228,757	 70,913,334
Total liabilities and stockholders' equity	\$	55,520,894	\$ 81,171,507

See accompanying notes to consolidated financial statements.

# ZYNERBA PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,			
	2022	2021	2020	
Operating expenses:				
Research and development	\$ 21,099,666	\$ 21,424,489 \$	35,654,994	
General and administrative	14,151,874	15,345,901	16,407,548	
Total operating expenses	35,251,540	36,770,390	52,062,542	
Loss from operations	(35,251,540)	(36,770,390)	(52,062,542)	
Other income (expense):				
Interest income	846,860	21,047	243,992	
Foreign exchange (loss) gain	(631,126)	(559,681)	481,719	
Total other income (expense)	215,734	(538,634)	725,711	
Net loss	\$ (35,035,806)	\$ (37,309,024)	\$ (51,336,831)	
Net loss per share basic and diluted	\$ (0.82)	\$ (0.95)	\$ (1.90)	
Basic and diluted weighted average shares outstanding	42,662,770	39,259,495	27,022,931	

See accompanying notes to consolidated financial statements.

# ZYNERBA PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY YEARS ENDED DECEMBER 31, 2020, 2021 and 2022

I EARS ENDED DEC	-ENIDER 31	, 2020, 202	1 and 2022		
	Common stock Additional			Accumulated	Total stockholders'
	Shares	Amount	<u>paid-in capital</u>	deficit	equity
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	6,596,873	6,597	30,699,492	_	30,706,089
Issuance of restricted stock	167,000	167	(167)	_	
Stock-based compensation expense	_	_	5,177,527	_	5,177,527
Net loss	—	—		(51,336,831)	(51,336,831)
Balance at December 31, 2020	29,975,264	29,975	262,286,008	(202,172,455)	60,143,528
Issuance of common stock, net of issuance costs	10,244,326	10,245	42,210,099	_	42,220,344
Issuance of restricted stock	984,822	985	(985)	_	_
Exercise of stock options	13,125	13	47,893		47,906
Stock-based compensation expense	_	_	5,810,580	_	5,810,580
Net loss	_	_	_	(37,309,024)	(37,309,024)
Balance at December 31, 2021	41,217,537	41,218	310,353,595	(239,481,479)	70,913,334
Issuance of common stock, net of issuance costs	4,958,274	4,958	6,014,544		6,019,502
Commitment shares issued under an equity purchase agreement	347,222	347	(347)	_	_
Issuance of restricted stock	1,372,654	1,373	(1,373)	_	
Stock-based compensation expense			4,331,727	_	4,331,727
Net loss	_	_	· · · —	(35,035,806)	(35,035,806)
Balance at December 31, 2022	47,895,687	\$ 47,896	\$ 320,698,146	\$ (274,517,285)	\$ 46,228,757

See accompanying notes to consolidated financial statements.

# ZYNERBA PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,			
	2022	2021	2020	
Cash flows from operating activities:				
Net loss	\$ (35,035,806)	\$ (37,309,024)	\$ (51,336,831)	
Adjustments to reconcile net loss to net cash used in operating				
activities:				
Depreciation	219,283	247,140	207,035	
Stock-based compensation	4,331,727	5,810,580	5,177,527	
Changes in operating assets and liabilities:				
Incentive and tax receivables	8,355,084	(537,882)	5,571,383	
Prepaid expenses and other assets	(58,998)	2,472,624	(2,981,094)	
Right-of-use assets and liabilities	1,263	(7,542)	(3,027)	
Accounts payable	70,568	(723,903)	(2,145,165)	
Accrued expenses	(910,071)	(3,409,469)	4,196,132	
Net cash used in operating activities	(23,026,950)	(33,457,476)	(41,314,040)	
Cash flows from investing activities:				
Purchases of property and equipment	(154,105)	(47,570)	(445,314)	
Net cash used in investing activities	(154,105)	(47,570)	(445,314)	
Cash flows from financing activities:				
Proceeds from the issuance of common stock	6,557,290	43,193,660	31,707,228	
Payment of financing fees and expenses	(543,242)	(1,085,707)	(853,929)	
Proceeds from the exercise of stock options	_	47,906	_	
Net cash provided by financing activities	6,014,048	42,155,859	30,853,299	
Net (decrease) increase in cash and cash equivalents	(17,167,007)	8,650,813	(10,906,055)	
Cash and cash equivalents at beginning of year	67,808,000	59,157,187	70,063,242	
Cash and cash equivalents at end of year	\$ 50,640,993	\$ 67,808,000	\$ 59,157,187	
i s				
Supplemental disclosures of cash flow information:				
Financing costs included in accounts payable and accrued expenses at				
end of year	\$ 55,387	\$ 42,500	\$ 17,275	
Property and equipment acquired but unpaid at end of year	\$ 88,917	\$	\$ —	

See accompanying notes to consolidated financial statements

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

Zynerba Pharmaceuticals, Inc., together with its subsidiary, Zynerba Pharmaceuticals Pty Ltd (collectively, "Zynerba," the "Company," or "we"), is a clinical stage specialty pharmaceutical company focused on the development of pharmaceutically-produced transdermal cannabinoid therapies for orphan neuropsychiatric disorders, including Fragile X syndrome ("FXS") and chromosome 22q11.2 deletion syndrome ("22q"). We have been granted orphan drug designations from the United States Food and Drug Administration ("FDA") and the European Commission for the use of cannabidiol for the treatment of FXS and 22q. In addition, we have received Fast Track designation from the FDA for treatment of behavioral symptoms associated with FXS. The Company has decided to prioritize its resources on FXS and 22q, both of which have no approved products. While we believe the data from the Company's autism spectrum disorder ("ASD") clinical development program to date are compelling, given the difficult financial market, the Company has decided to defer the start of the Phase 3 development program in ASD.

The Company has incurred losses and negative cash flows from operations since inception and has an accumulated deficit of \$274.5 million as of December 31, 2022. 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.

Management believes that the Company's cash and cash equivalents as of December 31, 2022 are sufficient to fund operations and capital requirements to mid-year 2024. Substantial additional financings will be needed by the Company to fund its operations, and 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 and ongoing 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.

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

#### a. Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and with the instructions to Form 10-K and Article 10 of Regulation S-X.

#### 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. Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash equivalents, accounts payable and accrued expenses approximate fair value given their short-term nature.

#### d. Cash and Cash Equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. As of December 31, 2022 and 2021, the Company invested a portion of its cash balances in money market funds that seek to maintain a stable net asset value. These investments have been included as cash equivalents on the consolidated balance sheets.

# e. 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) 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. 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 December 2018, the Company submitted an Advance Overseas Finding ("AOF") application to a division of the Australian Government's Department of Industry, Innovation and Science ("AusIndustry"), for a portion of the Company's research and development activities incurred outside of Australia, which was approved by AusIndustry in July 2019. During the year ended December 31, 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 December 31, 2019. 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 and, during the three months ended June 30, 2020, the Company determined it was no longer probable that the AOF claim would be received and the Company recorded a full reserve against the AOF receivable.

During the three months ended March 31, 2022, the Company concluded its conversations with the ATO on these matters and made the decision to no longer pursue the AOF claim, resulting in the write off of both the AOF receivable and the corresponding reserve during the period. During the three months ended March 31, 2022, the Company received a payment of \$8.0 million from the ATO for the non-AOF research and development incentive for the years ended December 31, 2018, 2019 and 2020.

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 December 31, 2022, incentive and tax receivables included \$0.2 million for refundable GST on expenses incurred with Australian vendors during the three months ended December 31, 2022.

Current incentive and tax receivables consisted of the following as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Research and development incentive (non-AOF) for the period 1/1/18 - 12/31/18	\$	\$ 3,144,152
Research and development incentive (non-AOF) for the period 1/1/19 - 12/31/19		2,914,931
Research and development incentive (non-AOF) for the period 1/1/20 - 12/31/20		1,993,038
Research and development incentive (non-AOF) for the period 1/1/21 - 12/31/21		1,226,688
Research and development incentive (non-AOF) for the period 1/1/22 - 12/31/22	977,714	—
Research and development incentive (AOF) for the period 1/1/18 - 12/31/19		8,566,843
Goods and services tax	247,669	301,659
Total incentive and tax receivables before reserve for AOF	1,225,383	18,147,311
Reserve for research and development incentive (AOF) for the period 1/1/18 - 12/31/19		(8,566,843)
Total incentive and tax receivables - current assets	\$ 1,225,383	\$ 9,580,468

#### f. Property and Equipment

Property and equipment are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives. Leasehold improvements are amortized over the estimated useful life of the assets or the remaining lease term at the time the asset is placed into service, whichever is shorter. Repairs and maintenance costs are expensed as incurred. When property and equipment are sold or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is included in other expenses.

#### g. Impairment of Long-Lived Assets

The Company assesses the recoverability of its long-lived assets, which include property and equipment, whenever significant events or changes in circumstances indicate an impairment may have occurred. If indicators of an impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the years ended December 31, 2022, 2021 and 2020, the Company determined that there was no impairment of its long-lived assets.

#### h. 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.

The following table summarizes research and development expenses for the years ended December 31, 2022, 2021, and 2020:

	Year ended December 31,						
		2022		2021		2020	
Research and development expenses - before R&D incentive	\$	22,101,576	\$	22,454,878	5	\$ 29,437,	,551
Research and development incentive (non-AOF)		(1,001,910)		(1,030,389)		(1,890,	,252)
Research and development expenses (before impact of AOF)		21,099,666		21,424,489	-	27,547,	,299
Amounts reserved against AOF refund		—		—		8,107,	,695
Total research and development expenses	\$	21,099,666	\$	21,424,489	S	\$ 35,654,	,994

# i. Stock-Based Compensation

The Company measures employee and nonemployee stock-based awards at grant-date fair value and records compensation expense on a straight-line basis over the requisite service period of the award. Stock-based compensation expense for 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, which were established by the Company's board of directors.

For grants of restricted stock the Company uses the closing price of the Company's common stock on the date of grant. The Company uses the Black-Scholes option pricing model to estimate the fair value of its stock option awards. Estimating the fair value of stock option awards requires management to apply judgment and make estimates, including the expected volatility of the Company's common stock, the expected term of the Company's stock options and the expected dividend yield. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected term of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post vesting employment termination behavior for its stock option grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For expected stock price volatility, the Company has historically used comparable public companies, in addition to the Company's historical volatility, as a basis for its expected volatility to calculate the fair value of option grants. For option grants issued beginning in 2022, the Company used its own stock price volatility, over the expected term of the award, as the basis for its expected volatility. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected term of the option.

#### j. Income Taxes

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities and the expected benefits of net operating loss carryforwards. The impact of changes in tax rates and laws on deferred taxes, if any, applied during the years in which temporary differences are expected to be settled, is reflected in the consolidated financial statements in the period of enactment. The carrying amount of deferred tax assets is reduced, if necessary, if, based on weight of the evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. As of December 31, 2022 and 2021, the Company has concluded that a full valuation allowance is necessary for its net deferred tax assets. The Company has no liability for unrecognized tax benefits or tax-related penalties or interest at December 31, 2022 and does not expect a significant change in the balance of unrecognized tax benefits within the next 12 months.

#### k. 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 December 31, 2022, 2021 and 2020 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:

		December 31,			
	2022	2021	2020		
Stock options	6,276,016	5,224,913	4,546,484		
Unvested restricted stock	2,114,512	989,822	173,800		
	8,390,528	6,214,735	4,720,284		

# 1. Foreign Currency

The Company has determined the functional currency of its Australian subsidiary to be the U.S. dollar. The Company records remeasurement gains and losses on monetary assets and liabilities, such as incentive and tax receivables and accounts payables, which are not in the functional currency of the operation. These remeasurement gains and losses are recorded in the consolidated statements of operations as they occur.

#### m. Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment.

#### n. Recent Accounting Pronouncements

In November 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2021-10, *Government Assistance (Topic 832): Disclosure by Business Entities about Government Assistance* ("ASU 2021-10"), which improves the transparency of government assistance received by most business entities by requiring the disclosure of: (1) the types of government assistance received; (2) the accounting for such assistance; and (3) the effect of the assistance on a business entity's financial statements. This guidance is effective for financial statements issued for annual periods beginning after 15 December 2021. The Company adopted ASU 2021-10 effective January 1, 2022, and the adoption did not have a material impact on its consolidated financial statements.

#### (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 December 31, 2022 and 2021:

	Ca	rrying amount	Fair Value I as of Decen		
	as of I	December 31, 2022	Level 1	Level 2	Level 3
Cash equivalents (money market accounts)	\$	44,663,395	\$ 44,663,395	\$ —	\$ —
	\$	44,663,395	\$ 44,663,395	\$ —	\$ —

	Ca	rrying amount	Fair Value I as of Decen		
	as of l	December 31, 2021	Level 1	Level 2	Level 3
Cash equivalents (money market accounts)	\$	67,709,279	\$ 67,709,279	\$ —	\$ —
	\$	67,709,279	\$ 67,709,279	\$ —	\$ —

# (4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Prepaid development expenses	\$ 668,096	\$ 543,897
Prepaid insurance	1,546,784	1,952,867
Deferred financing costs	155,956	137,615
Other current assets	537,895	197,013
Total prepaid expenses and other current assets	\$ 2,908,731	\$ 2,831,392

# (5) Property and Equipment

Property and equipment consisted of the following as of December 31, 2022 and 2021:

Estimated useful life (in years)	December 31, 2022	December 31, 2021
2-5	\$ 828,666	\$ 740,543
3-5	30,319	30,319
3-5	311,356	311,356
various	68,881	68,881
	234,241	79,342
	1,473,463	1,230,441
	(1,063,891)	(844,608)
	\$ 409,572	\$ 385,833
	useful life (in years) 2-5 3-5 3-5	useful life (in years) December 31, 2022   2-5 \$ 828,666   3-5 30,319   3-5 311,356   various 68,881   234,241 1,473,463   (1,063,891) (1,063,891)

Depreciation expense was \$219,283, \$247,140 and \$207,035 for the years ended December 31, 2022, 2021 and 2020, respectively.

#### (6) Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Accrued compensation	\$ 2,016,402	\$ 2,412,291
Accrued research and development	4,239,719	5,125,010
Other	758,761	359,297
Total accrued expenses	\$ 7,014,882	\$ 7,896,598

#### (7) Stockholders' Equity

#### Preferred Stock

The Company's board of directors are authorized to issue up to 10.0 million shares of preferred stock, with any rights, preferences and privileges as it may designate. As of December 31, 2022, no shares of preferred stock were issued.

#### Common Stock

#### a. At The Market Financing

In May 2021, the Company entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the "2021 Sales Agreement") with Cantor Fitzgerald & Co., Canaccord Genuity, LLC, H.C. Wainwright & Co. LLC and Ladenburg Thalmann & Co. Inc., as sales agents (collectively, the "2021 Sales Agents"), pursuant to which, under a prospectus filed by the Company in May 2022, the Company may sell, from time to time, up to \$75.0 million of its common stock. During the year ended December 31, 2022, the Company sold and issued 4,608,274 shares of common stock under the 2021 Sales Agreement in the open market at a weighted average selling price of \$1.35 per share, resulting in gross proceeds of \$6.2 million. Net proceeds after deducting commissions and offering expenses were \$5.8 million. From January 1, 2023 through March 22, 2023, the Company sold and issued 1,179,077 shares of its common stock in the open market at a weighted average selling price of \$0.56 per share, for gross proceeds of \$0.7 million and net proceeds, after deducting commissions and offering expenses, of \$0.6 million.

In August 2019, the Company entered into the 2019 Sales Agreement with the 2019 Sales Agents pursuant to which the Company sold \$75.0 million of its common stock. In 2021, the Company sold and issued 10,244,326 shares of common stock under the 2019 Sales Agreement in the open market at a weighted average selling price of \$4.22 per share, resulting in gross proceeds of \$43.2 million. Net proceeds after deducting commissions and offering expenses were \$42.2 million. In 2020, the Company sold and issued 6,596,873 shares of common stock in the open market at a weighted-average selling price of \$4.81 per share, for gross proceeds of \$31.7 million and net proceeds, after deducting commissions and offering expenses, of \$30.7 million. As of February 9, 2021, the Company utilized the entire \$75.0 million under the 2019 Sales Agreement.

#### b. Equity Purchase Agreement

On July 21, 2022 (the "Effective Date"), the Company entered into a Purchase Agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") pursuant to which Lincoln Park committed to purchase up to \$20.0 million of the Company's common stock. Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$20.0 million of the Company's common stock. Such sales of common stock will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on the Effective Date. The number of shares the Company may sell to Lincoln Park on any single business day in a regular purchase is

150,000, but that amount may be increased up to 300,000 shares, depending upon the market price of the Company's common stock at the time of sale and subject to a maximum limit of \$2.0 million per regular purchase. The purchase price per share for each such regular purchase will be based on prevailing market prices of the Company's common stock immediately preceding the time of sale as computed under the Purchase Agreement. In addition to regular purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases.

Pursuant to the terms of the Purchase Agreement, the Company issued 347,222 shares of its common stock to Lincoln Park as consideration for its commitment to purchase shares of the Company's common stock under the Purchase Agreement.

During the year ended December 31, 2022, the Company sold and issued 350,000 shares of common stock under the Purchase Agreement at a weighted average selling price of \$0.92 per share, resulting in gross of \$0.3 million and net proceeds, after deducting offering expenses, of \$0.2 million. From January 1, 2023 through March 22, 2023, the Company sold and issued 1,950,000 shares of common stock under the Purchase Agreement at a weighted average selling price of \$0.53 per share, resulting in gross and net proceeds of \$1.0 million.

#### (8) Stock-Based Compensation

The Company maintains the Amended and Restated 2014 Omnibus Incentive Compensation Plan, as amended (the "2014 Plan"), which allows for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, stock awards, stock units, performance units and other stock-based awards to employees, officers, non-employee directors, consultants and advisors. In addition, the 2014 Plan provides selected executive employees with the opportunity to receive bonus awards that are considered qualified performance-based compensation. The 2014 Plan is subject to automatic annual increases in the number of shares authorized for issuance under the 2014 Plan on the first trading day of January each year equal to the lesser of 1.5 million shares or 10% of the number of shares of common stock outstanding on the last trading day of December of the preceding year. As of January 1, 2023, 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 12,304,869 shares. As of December 31, 2022, 1,442,876 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.

Stock-based compensation expense for 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, which were established by the Company's board of directors. The Company's board of directors determines if the performance conditions have been met.

During 2021, the Company granted 551,911 time-based restricted stock awards to employees and non-employee directors of which 474,911 restricted stock awards remained outstanding as of December 31, 2022. In addition, during 2021, the Company granted 506,911 performance-based restricted stock awards to employees of which 187,964 restricted stock awards have fully vested and 281,947 restricted stock awards remained outstanding as of December 31, 2022. The performance-based conditions for these performance-based grants were deemed probable of achievement during 2021 and, as of December 31, 2022, the Company has recorded \$1.7 million in stock-based compensation expense related to these grants. As of December 31, 2022, there was \$13,565 of unrecognized stock-based compensation

expense related to these performance-based awards, which will be expensed over the estimated service period related to each performance condition.

During 2022, the Company granted 841,654 time-based restricted stock awards to employees, non-employee directors and consultants of which 804,654 restricted stock awards remained outstanding as of December 31, 2022. In addition, during 2022, the Company granted 556,500 performance-based restricted stock awards to employees of which 548,000 restricted stock awards remained outstanding as of December 31, 2022. As of December 31, 2022, satisfaction of the related performance conditions has not been deemed probable of being achieved and there was \$1.1 million of unrecognized stock-based compensation expense related to these performance-based awards, which will be expensed over the estimated service period related to each performance condition once the performance conditions have been deemed probable.

During the years ended December 31, 2022, 2021 and 2020, the Company recorded \$4,331,727, \$5,810,580, and \$5,177,527, respectively, in stock-based compensation expense related to its stock option grants and restricted stock awards, as follows:

	8	Stock Option Grants			on Grants Restricted stock awards		
	2022	2021	2020	2022	2021	2020	
Research and development	\$ 1,032,267	\$ 1,479,681	\$ 2,053,675	\$ 940,627	\$ 1,348,290	\$ 141,213	
General and administrative	1,243,842	1,696,490	2,922,620	1,114,991	1,286,119	60,019	
	\$ 2,276,109	\$ 3,176,171	\$ 4,976,295	\$ 2,055,618	\$ 2,634,409	\$ 201,232	

The following table summarizes the Company's stock option activity:

	Number	Weighted- Average Exercise	Weighted- Average Contractual	Aggregate Intrinsic
	of Shares	Price	Life (in Years)	Value
Outstanding as of December 31, 2020	4,546,484	\$ 9.76		
Granted	869,867	3.71		
Exercised	(13,125)	3.65		
Forfeited	(178,313)	10.69		
Outstanding as of December 31, 2021	5,224,913	8.74		
Granted	1,136,728	2.17		
Forfeited	(85,625)	10.97		
Outstanding as of December 31, 2022	6,276,016	7.52	5.92	\$ _
Exercisable as of December 31, 2022	4,441,441	9.41	4.82	\$ —
Vested and expected to vest as of December 31, 2022	6,276,016	\$ 7.52		

The weighted-average grant date fair value of options granted during the years ended December 31, 2022, 2021, and 2020 was \$1.74, \$2.86, and \$3.58, respectively.

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

	Year ended December 31,			
	2022	2020		
Weighted-average risk-free interest rate	2.02%	0.40%	1.27%	
Expected term of options (in years)	6.11	6.21	6.18	
Expected stock price volatility	100.23%	95.94%	82.00%	
Expected dividend yield	0%	0%	0%	

As of December 31, 2022, there was \$3.3 million of unrecognized stock-based compensation expense related to stock options, which is expected to be recognized over a weighted-average period of 2.26 years. During the year ended December 31, 2021, the Company received \$47,906 in cash from the exercise of employee stock options.

The following table summarizes the restricted stock award activity under the 2014 Plan:

	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Unvested as of December 31, 2020	173,800	\$ 3.64	
Granted	1,058,822	3.61	
Forfeited	(74,000)	3.58	
Vested	(168,800)	3.60	
Unvested as of December 31, 2021	989,822	3.62	
Granted	1,398,154	2.17	
Forfeited	(25,500)	2.41	
Vested	(247,964)	3.61	
Unvested as of December 31, 2022	2,114,512	\$ 2.86	\$ 1,120,691
Expected to vest as of December 31, 2022	1,561,512	\$ 2.85	\$ 827,601

As of December 31, 2022, there was \$1.1 million of unrecognized stock-based compensation expense related to unvested restricted stock awards, which is expected to be recognized over a weighted-average period of 0.56 years.

# (9) Operating Lease Obligations

The Company adopted Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842), Accounting Standards Codification 842* ("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 March 1, 2021, the Company extended its lease for three additional years until May 31, 2024. 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 March 1, 2021, 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 \$755,085 and right-of-use assets to \$752,391, which was recorded net of a deferred rent liability of \$2,694. As of December 31, 2022, the Company's right-of-use asset, net of amortization, was \$336,215.

Other operating lease information as of December 31, 2022:

Weighted-average remaining lease term - operating leases	1.4 years
Weighted-average discount rate - operating leases	2.76 %

The following is a maturity analysis of the annual undiscounted cash flows of the operating lease liabilities as of December 31, 2022:

<u>Year ending:</u>	December 31, 2022	
December 31, 2023	\$ 240,420	
December 31, 2024	100,175	
Total minimum lease payments	 340,595	
Less: imputed lease interest	(6,170)	
Total lease liabilities	\$ 334,425	

Lease expense for the years ended December 31, 2022, 2021, and 2020 was comprised of the following:

		Year ended December 31,				
	20	2022 2021				
Operating lease expense	\$ 241	,683 \$	244,209	\$	256,837	
Variable lease expense	61	,625	60,864		58,697	
Total lease expense	\$ 303	,308 \$	305,073	\$	315,534	

Total cash payments related to leases for the years ended December 31, 2022, 2021, and 2020 were \$302,045, \$310,448 and \$318,561, respectively.

# (10) Defined Contribution Retirement Plan

The Company offers a tax-qualified defined contribution retirement plan, which we refer to as our 401(k) plan, to eligible employees, including our current named executive officers. Our 401(k) plan permits eligible employees to defer their annual eligible compensation subject to the limitations imposed by the Internal Revenue Service. The Company may, but is not required to, make discretionary employer matching contributions on behalf of eligible employees under this plan. The Company provides an employer match on the first 6% of employee contributions and employer matching contributions vest immediately. For the years ended December 31, 2022, 2021 and 2020, the Company provided an employer match of 67%, 33% and 33%, respectively. For the years ended December 31, 2022, 2021, and 2020, the Company's contributions to the plan were \$240,833, \$111,258 and \$111,846, respectively.

#### (11) Income Taxes

The Company's U.S. and foreign loss before income taxes are set forth below:

	Ye	Year ended December 31,			
	2022	2022 2021			
United States	\$ (33,308,897)	\$ (34,729,615)	\$ (40,407,933)		
Foreign	(1,726,909)	(2,579,409)	(10,928,898)		
Total	\$ (35,035,806)	\$ (37,309,024)	\$ (51,336,831)		

The Company had \$170.1 million and \$160.6 million of federal net operating loss carryforwards and \$5.7 million and \$4.7 million of U.S. research tax credit carryforwards as of December 31, 2022 and 2021, respectively. The U.S. federal net operating loss carryforwards and research tax credit carryforwards begin to expire in 2028 and 2027, respectively. Federal net operating losses that were generated after December 31, 2017 carryforward indefinitely. The Company has \$170.2 million and \$160.6 million of state net operating loss carryforwards as of December 31, 2022 and 2021, respectively. The state net operating loss carryforwards begin to expire in 2028. As of December 31, 2022 and 2021, the

Company had \$2.8 million and \$3.0 million, respectively, of Australian net operating loss carryforwards, which have an indefinite life.

The Tax Reform Act of 1986 (the Act) provides for limitation on the use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could limit the Company's ability to utilize these carryforwards. The Company may have experienced various ownership changes, as defined by the Act, as a result of past financings. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore, the Company may not be able to take full advantage of these carryforwards for federal income tax purposes.

The components of the net deferred income tax asset as of December 31, 2022 and 2021 are as follows:

	December 31, 2022		Decen		De	cember 31, 2021
Deferred tax assets:						
Net operating loss carry forwards	\$	49,832,469	\$	46,999,701		
Research and development credit carry forwards		5,687,207		4,761,598		
Research and development expenditure capitalization		5,436,581		—		
Stock-based compensation		9,277,449		8,656,457		
Property and equipment		39,703		16,839		
Other		786,861		703,134		
Gross deferred tax assets		71,060,270	_	61,137,729		
Less valuation allowance		(71,060,270)		(61,137,729)		
Net deferred tax asset	\$	_	\$			

The Tax Cuts and Jobs Act passed in 2017 included a provision which requires taxpayers to capitalize and amortize U.S.based research or experimental expenditures ("R&E") over a period of five years and non-U.S. R&E over 15 years effective for tax years beginning after December 31, 2021, pursuant to Internal Revenue Code Section 174.

In assessing the realizability of deferred tax assets, the Company considers whether it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance against its net deferred tax assets as of December 31, 2022 and 2021, respectively, because the Company has determined that is it more likely than not that these assets will not be fully realized due to historic net operating losses incurred. The valuation allowance increased by \$9.9 million and \$6.6 million during the years ended December 31, 2022 and 2021, respectively, due primarily to the generation of net operating loss carryforwards during those years and the capitalization of R&E in 2022.

The Company does not have unrecognized tax benefits as of December 31, 2022 and 2021, respectively. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

A reconciliation of income tax expense (benefit) at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

	Year ended December 31,			
	2022	2021	2020	
Federal income tax benefit at statutory rate	21.0 %	21.0 %	21.0 %	
State income tax, net of federal benefit	7.1	7.1	6.4	
Nondeductible research and development expenses	(0.7)	(1.1)	(4.6)	
Other permanent differences	(1.6)	(0.8)	0.2	
Research and development credit benefit	2.8	2.6	2.2	
Adjustment of prior years' income taxes	(0.3)	(11.0)	(0.1)	
Change in valuation allowance	(28.3)	(17.8)	(25.1)	
Effective income tax rate	%	%	%	

The Company and its subsidiaries are subject to income taxes in the U.S. federal jurisdiction, various state jurisdictions and Australia. The Company's U.S. tax returns for the tax years 2011 to 2022 remain open and subject to examination.

# (12) Commitments and Contingencies

a. Leases

The Company is a party to a noncancelable operating lease for office space, under a long-term lease arrangement. As of December 31, 2022, future minimum lease commitment for the Company's noncancelable lease was \$423,750.

#### b. Employment Agreements

The Company has entered into employment contracts and subsequent amendments with its officers and certain employees that provide for severance and continuation of benefits in the event of termination of employment either by the Company without cause or by the employee for good reason, both as defined in the agreements. In addition, in the event of termination of employment following a change in control, as defined in the employee's stock options and/or restricted stock awards become immediately vested.

c. Litigation

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. Legal fees are expensed as incurred.

# ZYNERBA PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS AS OF AND FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023

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# ZYNERBA PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,818,895	\$ 50,640,993
Incentive and tax receivables	1,041,864	1,225,383
Prepaid expenses and other current assets	2,458,674	2,908,731
Total current assets	30,319,433	54,775,107
Property and equipment, net	379,879	409,572
Right-of-use assets	159,843	336,215
Total assets	\$ 30,859,155	\$ 55,520,894
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 543,820	\$ 1,942,830
Accrued expenses	11,315,367	7,014,882
Lease liabilities	159,001	214,901
Total current liabilities	12,018,188	9,172,613
Lease liabilities, long-term	—	119,524
Total liabilities	12,018,188	9,292,137
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;		
53,939,431 shares issued and outstanding at September 30, 2023 and		
47,895,687 shares issued and outstanding at December 31, 2022	53,940	47,896
Additional paid-in capital	324,922,231	320,698,146
Accumulated deficit	(306,135,204)	(274,517,285)
Total stockholders' equity	18,840,967	46,228,757
Total liabilities and stockholders' equity	\$ 30,859,155	\$ 55,520,894

See accompanying notes to unaudited consolidated financial statements.

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

	Th	Three months ended September 30,		Nine months ended			d September 30,	
		2023		2022		2023		2022
Operating expenses:								
Research and development	\$	6,261,551	\$	5,039,228	\$	20,506,340	\$	15,632,150
General and administrative		4,696,537		3,453,648		12,059,130		10,933,411
Total operating expenses		10,958,088		8,492,876		32,565,470		26,565,561
Loss from operations		(10,958,088)		(8,492,876)		(32,565,470)		(26,565,561)
Other income (expense):								
Interest income		360,500		251,855		1,242,533		439,590
Foreign exchange loss		(130,423)		(435,128)		(294,982)		(893,803)
Total other income								
(expense)		230,077		(183,273)		947,551		(454,213)
Net loss	\$	(10,728,011)	\$	(8,676,149)	\$	(31,617,919)	\$	(27,019,774)
Net loss per share basic and								
diluted	\$	(0.21)	\$	(0.20)	\$	(0.64)	\$	(0.65)
Basic and diluted weighted								
average shares outstanding		50,378,937		43,746,878		49,295,103		41,831,998
							_	

See accompanying notes to unaudited consolidated financial statements.

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

	Nine months ended September 30, 2023						
	Common stock Shares Amount		Additional paid-in capital	Accumulated deficit	Total stockholders' equity		
Balance at December 31, 2022	47,895,687	\$ 47,896	\$ 320,698,146	\$ (274,517,285)	\$ 46,228,757		
Issuance of common stock, net							
of issuance costs	3,279,077	3,279	1,747,000	—	1,750,279		
Issuance of restricted stock	1,896,167	1,896	(1,896)	—	—		
Common stock issued in lieu of annual bonus	431,556	432	278,940	_	279,372		
Stock-based compensation	,		,				
expense	_	_	821,986	_	821,986		
Net loss			_	(10,113,843)	(10,113,843)		
Balance at March 31, 2023	53,502,487	53,503	323,544,176	(284,631,128)	38,966,551		
Issuance of common stock, net							
of issuance costs	150,000	150	61,350	_	61,500		
Issuance of restricted stock	286,944	287	(287)	_	_		
Stock-based compensation							
expense	—	—	768,584	—	768,584		
Net loss				(10,776,065)	(10,776,065)		
Balance at June 30, 2023	53,939,431	53,940	324,373,823	(295,407,193)	29,020,570		
Issuance of common stock, net							
of issuance costs	—	—	(189,865)	—	(189,865)		
Stock-based compensation							
expense	—	—	738,273	—	738,273		
Net loss				(10,728,011)	(10,728,011)		
Balance at September 30, 2023	53,939,431	\$ 53,940	\$ 324,922,231	\$ (306,135,204)	\$ 18,840,967		

	Nine months ended September 30, 2022						
	Commor	l stock	Additional	Accumulated	Total stockholders'		
	Shares	Amount	paid-in capital	deficit	equity		
Balance at December 31, 2021	41,217,537	\$ 41,218	\$ 310,353,595	\$ (239,481,479)	\$ 70,913,334		
Issuance of common stock, net							
of issuance costs	857,060	857	1,582,916	—	1,583,773		
Issuance of restricted stock	1,249,500	1,249	(1,249)	—	—		
Stock-based compensation							
expense	—	—	1,160,482	—	1,160,482		
Net loss	—	—	—	(8,490,619)	(8,490,619)		
Balance at March 31, 2022	43,324,097	43,324	313,095,744	(247,972,098)	65,166,970		
Issuance of common stock, net							
of issuance costs	488,892	489	818,877	_	819,366		
Issuance of restricted stock	123,154	123	(123)	_	_		
Stock-based compensation							
expense	_	—	1,108,543	—	1,108,543		
Net loss		—	—	(9,853,006)	(9,853,006)		
Balance at June 30, 2022	43,936,143	43,936	315,023,041	(257,825,104)	57,241,873		
Issuance of common stock, net							
of issuance costs	2,779,346	2,780	3,147,150	_	3,149,930		
Issuance of restricted stock	347,222	347	(347)	_	_		
Stock-based compensation							
expense	_		1,041,100	_	1,041,100		
Net loss	—		_	(8,676,149)	(8,676,149)		
Balance at September 30, 2022	47,062,711	\$ 47,063	\$ 319,210,944	\$ (266,501,253)	\$ 52,756,754		

See accompanying notes to unaudited consolidated financial statements.

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

	Nine months ended September 3			
		2023		2022
Cash flows from operating activities:				
Net loss	\$	(31,617,919)	\$	(27,019,774)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation		167,934		165,920
Stock-based compensation		2,328,843		3,310,125
Changes in operating assets and liabilities:				
Incentive and tax receivables		183,520		7,449,915
Prepaid expenses and other assets		294,101		(637,578)
Right-of-use assets and liabilities		947		947
Accounts payable		(1,328,200)		(256,554)
Accrued expenses		4,527,144		(354,500)
Net cash used in operating activities		(25,443,630)		(17,341,499)
Cash flows from investing activities:				
Purchases of property and equipment		(100,951)		(146,705)
Net cash used in investing activities		(100,951)		(146,705)
Cash flows from financing activities:				
Proceeds from the issuance of common stock		1,827,512		6,059,511
Payment of financing fees and expenses		(105,029)		(444,816)
Net cash provided by financing activities		1,722,483		5,614,695
Net decrease in cash and cash equivalents		(23,822,098)		(11,873,509)
Cash and cash equivalents at beginning of period		50,640,993		67,808,000
Cash and cash equivalents at end of period	\$	26,818,895	\$	55,934,491
Supplemental disclosures of cash flow information:				
Financing costs included in accounts payable and accrued expenses				
at end of period	\$		\$	122,782
Property and equipment acquired but unpaid at end of period	\$	126,207	\$	53,245

See accompanying notes to unaudited consolidated financial statements

# (1) Nature of Business and Liquidity

### a. Nature of Business

Zynerba Pharmaceuticals, Inc., together with its subsidiary, Zynerba Pharmaceuticals Pty Ltd (collectively, "Zynerba," the "Company," or "we"), is a clinical stage specialty pharmaceutical company focused on the development of pharmaceutically-produced transdermal cannabinoid therapies for orphan neuropsychiatric disorders, including Fragile X syndrome ("FXS") and chromosome 22q11.2 deletion syndrome ("22q"). We have been granted orphan drug designations from the United States Food and Drug Administration ("FDA") and the European Commission for the use of cannabidiol for the treatment of FXS and 22q. In addition, we have received Fast Track designation from the FDA for treatment of behavioral symptoms associated with FXS. The Company has decided to prioritize its resources on FXS and 22q, both of which have no approved products. While we believe the data from the Company's autism spectrum disorder ("ASD") clinical development program to date are compelling, given the difficult financial market, the Company has decided to defer the start of the Phase 3 development program in ASD.

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.

# b. Merger Agreement

On August 14, 2023, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Harmony Biosciences Holdings, Inc. ("Harmony") and Xylophone Acquisition Corp., a wholly owned subsidiary of Harmony ("Merger Sub"). Pursuant to the Merger Agreement, and upon the terms and subject to the conditions therein, Harmony will commence a tender offer (the "Tender Offer") to acquire all of the issued and outstanding shares of common stock, par value \$0.001 per share, of the Company ("Zynerba Common Stock"), for (i) approximately \$1.1059 per share of Zynerba Common Stock (the "Common Cash Amount"), in cash, subject to any applicable withholding of taxes and without interest, plus (ii) one contingent value right per share of Zynerba Common Stock (the "Common CVR Amount"), which represents the right to receive up to approximately \$2.5444 per share of Zynerba Common Stock in the form of one or more potential contingent payments, in cash, subject to any applicable withholding of taxes and without interest, upon the achievement of certain milestones as set forth in, and subject to and in accordance with the terms and conditions of, the Contingent Value Rights Agreement (the Common Cash Amount plus the Common CVR Amount, collectively, or any different amount per share paid pursuant to the Tender Offer to the extent permitted by the Merger Agreement, being the "Offer Price"). Following the consummation of the Tender Offer, upon the terms and conditions set forth in the Merger Agreement, Merger Sub will merge with and into the Company (the "Merger"), with the Company continuing as the surviving corporation in the Merger.

#### c. Liquidity

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, Presentation of Financial Statements - Going Concern ("ASC 205-40"), requires management to assess the Company's ability to continue as a going concern for one year after the date the financial statements are issued. This standard requires management to 1) identify and disclose if there are initial conditions indicating substantial doubt about the Company's ability to continue as a going concern within one year of the issuance date of the financial statements, 2) disclose the principal conditions that gave rise to substantial doubt, 3) disclose management's evaluation of the significance of those conditions in

relation to the Company's ability to meet its obligations and 4) disclose management's plans that are intended to mitigate the adverse conditions. In accordance with the accounting standard, when considering management's plans to mitigate the conditions giving rise to substantial doubt, management can only consider those plans which are probable to be successfully implemented.

As of September 30, 2023, the Company had cash and cash equivalents of \$26.8 million and an accumulated deficit of \$306.1 million. For the nine months ended September 30, 2023, the Company reported a net loss of \$31.6 million and cash used in operating activities of \$25.4 million. The Company expects that its existing cash and cash equivalents will be sufficient to enable the Company to fund its operating expenses and capital expenditure requirements to mid-year 2024, but not more than one year after the date of the filing of this Quarterly Report, and therefore management has concluded that substantial doubt exists about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management believes that the Company's liquidity position as of the date of this filing provides sufficient runway to achieve important research and development milestones. Management intends to raise additional capital through equity offerings and/or debt financings, or from other potential sources of liquidity, which may include new collaborations, licensing or other commercial agreements for one or more of the Company's research programs or patent portfolios or divestitures of the Company's assets. The Company's ability to access the capital markets or otherwise raise such capital may be adversely impacted by geopolitical tensions and macroeconomic events and the recent disruptions to, and volatility in, financial markets in the United States and globally resulting from multiple factors such as COVID-19, inflationary pressures, banking instability, rising interest rates and the ongoing conflict in Ukraine. There is no assurance that such financing will be available when needed or on acceptable terms. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce, or eliminate its research and development programs or other operations. If any of these events occur, the Company's ability to achieve its operational goals would be adversely affected.

The interim consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

# (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, 2022 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 (the "2022 Annual Report"), filed with the Securities and Exchange Commission (the "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, 2023 its results of operations for the three and nine months ended September 30, 2023 and 2022 and cash flows for the nine months ended September 30, 2023 and 2022. 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 2022 Annual Report.

# b. Use of Estimates

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

# c. Incentive and Tax Receivables

The Company's subsidiary, Zynerba Pharmaceuticals Pty Ltd (the "Subsidiary"), is incorporated in Australia. The Subsidiary is eligible to participate in an Australian research and development tax incentive program. As part of this program, the Subsidiary is eligible to receive a cash refund from the Australian Taxation Office for a percentage of the research and development costs expended by the Subsidiary in Australia. The cash refund is available to eligible companies with an annual aggregate revenue of less than \$20.0 million (Australian) 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. 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 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, 2023, incentive and tax receivables included \$0.3 million for refundable GST on expenses incurred with Australian vendors during the three months ended September 30, 2023.

Current incentive and tax receivables consisted of the following as of September 30, 2023 and December 31, 2022:

	Se	otember 30, 2023	December 31, 2022		
Research and development incentive	\$	791,494	\$	977,714	
Goods and services tax		250,370		247,669	
Total incentive and tax receivables - current assets	\$	1,041,864	\$	1,225,383	

As of September 30, 2023, the Company's estimate of the amount of cash refund it expects to receive for 2023 eligible spending as part of this incentive program was \$0.8 million and was recorded as a 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.

The following table summarizes research and development expenses for the nine months ended September 30, 2023 and 2022:

	Nine months ended September 30,				
		2023		2022	
Research and development expenses - before R&D incentive	\$	21,432,694	\$	16,450,619	
Research and development incentive		(926,354)		(818,469)	
Total research and development expenses	\$	20,506,340	\$	15,632,150	

# 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, 2023 and 2022 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:

	Septer	September 30,			
	2023 2				
Stock options	6,706,432	6,276,016			
Unvested restricted stock	3,336,775	2,119,512			
	10,043,207	8,395,528			

f. Recent Accounting Pronouncements

In November 2021, the FASB issued Accounting Standards Update No. 2021-10, *Government Assistance* (*Topic 832*): *Disclosure by Business Entities about Government Assistance* ("ASU 2021-10"), which improves the transparency of government assistance received by most business entities by requiring the disclosure of: (1) the types of government assistance received; (2) the accounting for such assistance; and (3) the effect of the assistance on a business entity's financial statements. This guidance is effective for financial statements issued for annual periods beginning after December 15, 2021. The Company adopted ASU 2021-10 effective January 1, 2022, and the adoption did not have a material impact on its consolidated financial statements.

# (3) Fair Value Measurements

The Company measures certain assets and liabilities at fair value in accordance with Accounting Standards

Codification ("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, 2023 and December 31, 2022:

	Car	rying amount	Fair Value as of Sep	-			
	as of Se	eptember 30, 2023	Level 1	Le	vel 2	el 2 Level	
Cash equivalents							
(money market							
accounts)	\$	22,517,394	\$ 22,517,394	\$	—	\$	—
	\$	22,517,394	\$ 22,517,394	\$		\$	_

	Ca	rrying amount	Fair Value Measurement as of December 31, 2022							
	as of D	ecember 31, 2022	Level 1	Le	evel 2 Leve		vel 3			
Cash equivalents										
(money market										
accounts)	\$	44,663,395	\$ 44,663,395	\$	_	\$	—			
	\$	44,663,395	\$ 44,663,395	\$	_	\$				

# (4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of September 30, 2023 and December 31, 2022:

	Se	ptember 30, 2023	De	ecember 31, 2022
Prepaid development expenses	\$	887,001	\$	668,096
Prepaid insurance		933,515		1,546,784
Deferred financing costs		—		155,956
Other current assets		638,158		537,895
Total prepaid expenses and other current assets	\$	2,458,674	\$	2,908,731

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

# (5) Property and Equipment

Property and equipment consisted of the following as of September 30, 2023 and December 31, 2022:

	Estimated useful life (in years)	Se	ptember 30, 2023	D	ecember 31, 2022
Equipment	2-5	\$	1,165,570	\$	828,666
Computer equipment	3-5		30,319		30,319
Furniture and fixtures	3-5		311,356		311,356
Leasehold improvements	various		68,881		68,881
Construction in process			35,578		234,241
Total cost			1,611,704	_	1,473,463
Less accumulated depreciation			(1,231,825)		(1,063,891)
Property and equipment, net		\$	379,879	\$	409,572

Depreciation expense was \$167,934 and \$165,920 for the nine months ended September 30, 2023 and 2022 respectively.

# (6) Accrued Expenses

Accrued expenses consisted of the following as of September 30, 2023 and December 31, 2022:

	Se	eptember 30, 2023	December 31, 2022		
Accrued compensation	\$	2,141,866	\$	2,016,402	
Accrued research and development		7,293,673		4,239,719	
Other		1,879,828		758,761	
Total accrued expenses	\$	11,315,367	\$	7,014,882	

## (7) Common Stock

## a. At-The-Market Financing

On May 11, 2021, the Company entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the "2021 Sales Agreement") with Cantor Fitzgerald & Co., Canaccord Genuity, LLC, H.C. Wainwright & Co. LLC and Ladenburg Thalmann & Co. Inc., as sales agents, pursuant to which, under a prospectus filed by the Company in May 2022, the Company may sell, from time to time, up to \$75.0 million of its common stock. We are currently subject to General Instruction I.B.6 of Form S-3, and the amount of funds we can raise through primary public offerings of securities in any twelve-month period using our existing registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates. We will be subject by this limit until such time as our public float exceeds \$75.0 million.

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

During the nine months ended September 30, 2023, the Company sold and issued 1,179,077 shares of common stock under the 2021 Sales Agreement in the open market at a weighted average selling price of \$0.56 per share, resulting in gross proceeds of \$0.7 million. Net proceeds after deducting commissions and offering expenses were \$0.5 million.

## b. Equity Purchase Agreement

On July 21, 2022 (the "Effective Date"), the Company entered into a Purchase Agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") pursuant to which Lincoln Park committed to purchase up to \$20.0 million of the Company's common stock. Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$20.0 million of the Company's common stock. Such sales of common stock will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on the Effective Date. The number of shares the Company may sell to Lincoln Park on any single business day in a regular purchase is 150,000, but that amount may be increased up to 300,000 shares, depending upon the market price of the Company's common stock at the time of sale and subject to a maximum limit of \$2.0 million per regular purchase. The purchase price per share for each such regular purchase will be based on prevailing market prices of the Company's common stock immediately preceding the time of sale as computed under the Purchase Agreement. In addition to regular purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases.

Pursuant to the terms of the Purchase Agreement, in July 2022, the Company issued 347,222 shares of its common stock to Lincoln Park as consideration for its commitment to purchase shares of the Company's common stock under the Purchase Agreement.

During the nine months ended September 30, 2023, the Company sold and issued 2,250,000 shares of common stock under the Purchase Agreement at a weighted average selling price of \$0.52 per share, resulting in gross and net proceeds of \$1.2 million.

# (8) Stock-Based Compensation

The Company's board of directors adopted the 2023 Zynerba Pharmaceuticals, Inc. Stock Option and Incentive Plan (the "2023 Plan") in April 2023, which was subsequently approved by the stockholders in June 2023, under which the Company may grant incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, cash-based awards, and dividend equivalent rights to employees, officers, non-employee directors, consultants, and advisors. The number of shares available for issuance under awards granted pursuant to the 2023 Plan was 6,900,000 shares of the Company's common stock. Shares of common stock underlying awards granted under the 2023 Plan that are forfeited, canceled or otherwise terminated (other than by exercise) will be added back to the share reserve available for issuance under the 2023 Plan. Notwithstanding the foregoing, the following shares shall not be added to the share reserve authorized for grant under the 2023 Plan: shares tendered or held back upon exercise of an option or shares subject to a stock appreciation right that are not issued in connection with the stock settlement of the stock appreciation right upon exercise thereof. Further, shares reacquired by the Company on the open market will not be added to the share reserve authorized for issuance under the 2023 Plan.

The Company also maintained 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

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

awards to employees, officers, non-employee directors, consultants, and advisors. In addition, the 2014 Plan provides selected employees with the opportunity to receive bonus awards that are considered "qualified performance-based compensation" under Section 162(m) of the Internal Revenue Code. As of June 6, 2023, no additional awards will be granted under the 2014 Plan.

Options issued under the 2023 and 2014 Plans 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 one day before 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.

a. Time-Based Restricted Stock Awards:

During 2022, the Company granted 841,654 time-based restricted stock awards to employees, nonemployee directors and consultants, of which 595,664 restricted stock awards remain outstanding as of

September 30, 2023. During the nine months ended September 30, 2023, the Company granted 1,554,944 time-based restricted stock awards to employees and non-employee directors, which all remain outstanding as of September 30, 2023.

b. Restricted Stock Awards in Lieu of Bonus:

During the nine months ended September 30, 2023, the Company granted 431,556 fully vested stock awards to certain employees in lieu of their earned annual bonus. The fair value of those vested stock awards was \$0.3 million and was recorded against accrued compensation that existed as of December 31, 2022.

c. Performance-Based Restricted Stock Awards:

Stock-based compensation expense for 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, which were established by the Company's board of directors. The Company's board of directors determines if the performance conditions have been met.

During 2021, the Company granted 506,911 performance-based restricted stock awards to employees, of which 469,911 restricted stock awards have fully vested and no restricted stock awards remained outstanding as of September 30, 2023. The performance-based conditions for these performance-based grants were deemed probable of achievement during the nine months ended September 30, 2021 and, as of September 30, 2023, the Company had recorded \$1.7 million in stock-based compensation expense related to these grants.

During 2022, the Company granted 556,500 performance-based restricted stock awards to employees, of which 548,000 restricted stock awards remained outstanding as of September 30, 2023. During the nine months ended September 30, 2023, the Company granted 628,167 performance-based restricted stock

awards to employees. As of September 30, 2023, satisfaction of the related performance conditions for both the 2022 and 2023 grants have not been deemed probable of being achieved and there was \$1.1 million and \$0.3 million, respectively, of unrecognized stock-based compensation expense related to

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

these performance-based awards, which will be expensed over the estimated service period related to each performance condition once the performance conditions have been deemed probable.

For the nine months ended September 30, 2023 and 2022, the Company recorded stock-based compensation expense related to its stock option grants and restricted stock awards, as follows:

	Stock Opt	ion Grants	Restricted	stock awards	5 Total			
	2023	2022	2023	2022	2023	2022		
Research and development	\$ 615,406	\$ 776,809	\$ 443,359	\$ 723,638	\$1,058,765	\$ 1,500,447		
General and administrative	744,099	941,321	525,979	868,357	1,270,078	1,809,678		
	\$1,359,505	\$1,718,130	\$ 969,338	\$ 1,591,995	\$2,328,843	\$ 3,310,125		

The following table summarizes the Company's stock option activity for the nine months ended September 30, 2023:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Contractual Life (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31,				
2022	6,276,016	\$ 7.52		
Granted	430,416	0.35		
Outstanding as of September 30,				
2023	6,706,432	\$ 7.06	5.47	\$ 461,988
Exercisable as of September 30,				
2023	5,308,214	\$ 8.33	4.69	\$ 57,859
Vested and expected to vest as of				
September 30, 2023	6,706,432	\$ 7.06		

The weighted-average grant date fair values of options granted during the nine months ended September 30, 2023 and 2022 were \$0.25 and \$1.74, 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 end	ed September 30,
	2023	2022
Weighted-average risk-free interest rate	3.99%	2.02%
Expected term of options (in years)	5.50	6.11
Expected stock price volatility	87.35%	100.23%
Expected dividend yield	0%	0%

As of September 30, 2023, there was \$2.1 million of unrecognized stock-based compensation expense related to stock options.

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

The following table summarizes the Company's restricted stock award activity under the 2014 Plan for the nine months ended September 30, 2023:

	Shares	Weighted Average Aggregate Grant Date Intrinsic Fair Value Value
Unvested as of December 31, 2022	2,114,512	\$ 2.86
Granted	2,614,667	0.56
Vested	(1,392,404)	3.11
Unvested as of September 30, 2023	3,336,775	\$ 0.97 \$ 4,254,388
Expected to vest as of September 30, 2023	2,160,608	\$ 1.10 \$ 2,754,775

As of September 30, 2023, excluding performance-based restricted stock awards that have not been deemed probable, there was \$1.0 million of unrecognized stock-based compensation expense related to unvested restricted stock awards.

## (9) Operating Lease Obligations

The Company adopted Accounting Standards Update No. 2016-02, *Leases (Topic 842), Accounting Standards Codification 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 March 1, 2021, the Company extended its lease for three additional years until May 31, 2024. 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 March 1, 2021, 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 \$755,085 and right-of-use assets to \$752,391, which was recorded net of a deferred rent liability of \$2,694. As of September 30, 2023, the Company's right-of-use asset, net of amortization, was \$159,843.

Other operating lease information as of September 30, 2023:

Weighted-average remaining lease term - operating leases	0.7 years
Weighted-average discount rate - operating leases	2.76 %

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

The following is a maturity analysis of the annual undiscounted cash flows of the operating lease liabilities as of September 30, 2023:

	September 30,				
Year ending:		2023			
December 31, 2023	\$	60,105			
December 31, 2024		100,175			
Total minimum lease payments		160,280			
Less: imputed lease interest		(1,279)			
Total lease liabilities	\$	159,001			

Lease expense for the nine months ended September 30, 2023 was comprised of the following:

	Nine months ended September 30,				
		2022			
Operating lease expense	\$	181,262	\$	181,262	
Variable lease expense		54,780		46,951	
Total lease expense	\$	236,042	\$	228,213	

Total cash payments related to leases were \$235,095 and \$227,266 for the nine months ended September 30, 2023 and 2022, respectively.

## **10) Subsequent Events**

On October 10, 2023, Harmony completed a Tender Offer to acquire all of the outstanding shares of common stock of the Company. Under the terms of the Tender Offer, the Harmony paid (i) \$1.1059 per share of Zynerba Common Stock, plus (ii) one contingent value right (each, a "CVR") per share of Zynerba Common Stock for each holder of Zynerba Common Stock upon the closing of the Tender Offer, which represents the right to receive up to approximately \$2.5444 per share of Zynerba Common Stock, subject to the achievement of certain clinical, regulatory and sales-based milestones. Both the Common Cash Amount and Common CVR Amount are to be paid in cash, subject to any applicable withholding of taxes and without interest.

### UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

On October 10, 2023, Harmony Biosciences Holdings, Inc. (the "Company" or "Harmony") completed the previously announced acquisition ("Transaction") of Zynerba Pharmaceuticals, Inc. ("Zynerba"), pursuant to an Agreement and Plan of Merger, dated as of August 14, 2023, and amended on October 4, 2023 (the "Merger Agreement"), by and among Zynerba, the Company and Xylophone Acquisition Corp, ("Purchaser").

Under the terms of the Merger Agreement, the Company paid (i) \$1.1059 per share of Zynerba Common Stock (the "Common Cash Amount"), plus (ii) one contingent value right (each, a "CVR") per share of Zynerba Common Stock (the "Common CVR Amount") for each holder of Zynerba Common Stock upon the closing of the Tender Offer, which represents the right to receive up to approximately \$2.5444 per share of Zynerba Common Stock, subject to the achievement of certain clinical, regulatory and sales-based milestones. Both the Common Cash Amount and Common CVR Amount were paid in cash, subject to any applicable withholding of taxes and without interest. The aggregate consideration paid by the Company to acquire the Zynerba Common Stock upon completion of the Tender Offer was \$60.0 million, exclusive of transaction related fees. The Company financed the acquisition with cash on hand.

The presentation of the unaudited pro forma condensed combined balance sheet as of September 30, 2023 gives effect to the Transaction as if it had occurred on September 30, 2023. The presentation of the unaudited pro forma condensed combined statements of operations and comprehensive income for the nine months ended September 30, 2023 and year ended December 31, 2022 reflects the combined results of operations as if the Transaction had occurred on January 1, 2022, the beginning of the Company's 2022 fiscal year. The unaudited pro forma condensed combined financial statements include adjustments that reflect the accounting for the Transaction in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

The unaudited pro forma condensed combined financial information was derived from and should be read in conjunction with the following historical consolidated financial statements and accompanying notes:

- The historical audited consolidated financial statements of the Company as of and for the year ended December 31, 2022 included in its Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 21, 2023;
- The historical unaudited condensed consolidated financial statements of the Company as of and for the nine months ended September 30, 2023 included in its Quarterly Report on Form 10-Q filed with the SEC on October 31, 2023;
- The historical audited consolidated financial statements of Zynerba as of and for the year ended December 31, 2022 included in its Annual Report on Form 10-K filed with the SEC on March 28, 2023; and
- The historical unaudited condensed consolidated financial statements of Zynerba as of and for the nine months ended September 30, 2023 included as Exhibit 99.2 in the Company's Current Report on Form 8-K/A to which this Exhibit 99.3 is attached.

The unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X, as amended. The unaudited pro forma condensed combined financial information should be read in conjunction with the accompanying notes to the unaudited pro forma combined financial information. In addition, the unaudited pro forma combined financial information was derived from and should be read in conjunction with the other exhibits in the Company's Current Report on Form 8-K/A to which this Exhibit 99.3 is attached.

The unaudited pro forma condensed combined financial information has been prepared by Harmony using the acquisition method of accounting in accordance with U.S. generally accepted accounting principles ("GAAP"). Harmony has been treated as the acquirer in the Transaction for accounting purposes. The pro forma adjustments are based upon available information and certain assumptions that we believe are reasonable. The unaudited pro forma condensed combined financial information is provided for

informational purposes only and is not necessarily indicative of results that would have occurred had the acquisition been completed as of the dates indicated. In addition, the unaudited pro forma condensed combined financial information does not purport to be indicative of the future financial position or operating results of the combined operations and does not reflect the costs of any integration activities or benefits that may result from realization of future cost savings from operating efficiencies or revenue synergies expected to result from the Transaction.

# HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET As of September 30, 2023 (in thousands)

	Harmony Historical	Histor	Zynerba rical Adjusted classifications	Trans	saction Accounting Adjustments	Note	Pro forma
ASSETS					•		
CURRENT ASSETS:							
Cash and cash equivalents	\$ 324,603	\$	26,819	\$	(63,806)	3(A)(i)	\$ 287,616
Investments, short-term	46,071		—		_		46,071
Trade receivables, net	67,264		—		—		67,264
Inventory, net	5,087		_		_		5,087
Prepaid expenses	14,269		1,939		124	3(A)	16,332
Other current assets	5,704		1,542		8,746	3(A), 4	15,992
Total current assets	462,998		30,300		(54,936)		438,362
NONCURRENT ASSETS:							
Property and equipment, net	428		380		(380)	3(A)	428
Restricted cash	250		20				270
Investments, long-term	67,700		—				67,700
Intangible assets, net	143,069		_		_		143,069
Deferred tax asset	100,485		—			3(A)(ii), 4	
Other noncurrent assets	2,836		160		(160)	3(A)	2,836
Total noncurrent assets	314,768		560		35,886		351,214
TOTAL ASSETS	\$ 777,766	\$	30,860	\$	(19,050)		\$ 789,576
LIABILITIES AND STOCKHOLDERS' EQUITY CURRENT LIABILITIES:							
Trade payables	\$ 6.539	\$	544	\$	4.451	3(A)	\$ 11,534
Accrued compensation	10,322	Ψ	2.132	Ψ	, -	3(A),3(B)	
Accrued expenses	72,761		9,184		(2,818)	3(A)	79,127
Current portion of long-term debt	15,000				(_,0.0)	•()	15,000
Other current liabilities	7,786		159		(6,104)	4	1,841
Total current liabilities	112,408		12.019		2.751		127,178
NONCURRENT LIABILITIES:			,		, -		
Long-term debt, net	182,131		_		_		182,131
Other noncurrent liabilities	1,895		_				1,895
Total noncurrent liabilities	184,026		_				184,026
TOTAL LIABILITIES	296,434		12.019		2.751		311,204
COMMITMENTS AND CONTINGENCIES			,•••	·			
STOCKHOLDERS' EQUITY:							
Common Stock	1		54		(54)	3(C)	1
Additional paid in capital	651,731		324,922		(324,922)	3(C)	651,731
Accumulated other comprehensive (loss) income	(516)		_		_		(516)
Accumulated deficit	(169,884)		(306,135)		303,175	3(C)	(172,844)
TOTAL STOCKHOLDERS' EQUITY	481,332		18,841		(21,801)		478,372
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 777,766	\$	30,860	\$	(19,050)		\$ 789,576

# HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS AND COMPREHENSIVE INCOME Year ended December 31, 2022

(in thousands, except share and per share data)

		Harmony	F	Zynerba listorical Adjusted	Tra	ansaction Accounting		
		Historical		r Reclassifications	Adjustments		Note	Pro forma
Net product revenues	\$	437,855	\$	_	\$	_		\$ 437,855
Cost of product sold		83,481		—		—		83,481
Gross profit		354,374				_		354,374
Operating expenses:								
Research and								
development		70,886		21,100		18,924	3(A)(iii)	110,910
Sales and marketing		79,285				—		79,285
General and								
administrative		84,017		14,152		7,241	3(B)	105,410
Total operating								
expenses		234,188		35,252		26,165		295,605
Operating income		120,186		(35,252)		(26,165)		58,769
Loss on debt extinguishment		_		—		—		—
Other income (expense), net		169		(631)		—		(462)
Interest expense, net		(15,669)		847		—		(14,822)
Income before income taxes		104,686		(35,036)		(26,165)		43,485
Income tax benefit		76,782		—		15,300	4	92,082
Net income	\$	181,468	\$	(35,036)	\$	(10,865)		\$ 135,567
Unrealized income (loss) on								
investments		(151)		—		—		(151)
Comprehensive income	\$	181,317	\$	(35,036)	\$	(10,865)		\$ 135,416
EARNINGS PER SHARE:	_		_					
Basic	\$	3.07						\$ 2.29
Diluted	\$	2.97						\$ 2.22
Weighted average								
number of shares of								
common stock - basic		59,173,121						59,173,121
Weighted average								
number of shares of								
common stock - diluted		61,097,045						61,097,045

# HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS AND COMPREHENSIVE INCOME Nine months ended September 30, 2023 (in thousands, except share and per share data)

				Zynerba				
		Harmony Historical		storical Adjusted Reclassifications	Tra	nsaction Accounting Adjustments	Note	Pro forma
Net product revenues	\$	413,610	\$	_	\$	_	\$	413,610
Cost of product sold		78,084		—		—		78,084
Gross profit	_	335,526		_				335,526
Operating expenses:								
Research and development		45,757		20,506		—		66,263
Sales and marketing		70,518		—		—		70,518
General and administrative		67,417		12,059		—		79,476
Total operating expenses		183,692		32,565				216,257
Operating income		151,834		(32,565)		_		119,269
Loss on debt extinguishment		(9,766)		_		—		(9,766)
Other (expense) income, net		(34)		(295)		—		(329)
Interest expense, net		(8,327)		1,242		—		(7,085)
Income before income taxes	_	133,707		(31,618)		_		102,089
Income tax (expense) benefit		(31,461)		_		7,905	4	(23,557)
Net income	\$	102,246	\$	(31,618)	\$	7,905	\$	78,533
Unrealized income (loss) on								
investments		(365)		_		_		(365)
Comprehensive income	\$	101,881	\$	(31,618)	\$	7,905	\$	78,168
EARNINGS PER SHARE:		<u> </u>	-	<u> </u>	-			
Basic	\$	1.71					\$	1.31
Diluted	\$	1.68					\$	1.29
Weighted average number of shares of common stock - basic	;	59,863,102						59,863,102
Weighted average number of shares of common stock - diluted		60.681.676						60.681.676
	,	00,001,070						00,001,070

# NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

# Note 1 – Basis of Presentation

The unaudited pro forma condensed combined financial information has been prepared by the Company in accordance with Article 11 of Regulation S-X, is subject to change and is not necessarily indicative of the results that would have been achieved had the acquisition been completed as of the dates indicated or that may be achieved in future periods. The Company believes that its calculation of fair value recognized for the assets acquired is based on reasonable estimates and assumptions. Preliminary fair value estimates may change as additional information becomes available. There can be no assurance that the final determination will not result in material changes from these preliminary amounts.

The financial statements included in the unaudited pro forma condensed combined financial information have been prepared in accordance with U.S. GAAP. The historical financial statements have been adjusted in the unaudited pro forma condensed combined financial information to give effect to pro forma events that reflect the accounting for the Transaction in accordance with U.S. GAAP.

The unaudited pro forma condensed combined financial information has been compiled in a manner consistent with the accounting policies adopted by the Company. The accounting policies of Zynerba have been determined to be similar in all material respects to the Company's accounting policies. As a result, no adjustments for accounting policy differences have been reflected in the unaudited pro forma condensed combined financial information.

#### Note 2 – Reclassifications

Certain reclassifications have been made to the historical presentation of Zynerba to conform to the financial statement presentation of Harmony as indicated in the tables below:

a) The reclassification adjustments to conform Zynerba's balance sheet presentation to that of Harmony's have no impact on net assets and are summarized below:

Financial Statements Line Item	Zynerba Historical Adjusted for Reclassifcations	Zynerba Historical
Other current assets	1,042	-
Incentive and tax receivables	-	(1,042)
Prepaid and other current assets	2,459	-
Prepaid expenses	-	(1,939)
Restricted cash	-	(20)
Other current assets	-	(500)
Other noncurrent assets	160	-
Right of use assets	-	(160)
Accounts payable	-	544
Trade payables	(544)	-
Accrued expenses	-	11,315
Accrued compensation	(2,132)	-
Accrued expenses	(9,183)	-
Other current liabilities	(159)	-
Lease Liabilities		159

As of September 30, 2023 (in thousands):

b) The reclassification adjustments to conform Zynerba's statement of operations presentation to that of Harmony's have no impact on net income and are summarized below:

For the year ended December 31, 2022 (in thousands):

Financial Statements Line Item	Zynerba Historical Adjusted for Reclassifcations	Zynerba Historical
Interest income		847
Interest expense, net	(847)	-
Foreign exchange (loss) gain	-	(631)
Other expense (income), net	631	-

#### For the year ended September 30, 2023 (in thousands):

Financial Statements Line Item	Presentation in Zynerba Financial Statements (in thousands)	Presentation in Harmony Financial Statements (in thousands)
Interest income		1,242
Interest expense, net	(1,242)	-
Foreign exchange (loss) gain	-	(295)
Other expense (income), net	295	-

#### Note 3 – Transaction Accounting Adjustments

Harmony has accounted for the acquisition of Zynerba as an acquisition of assets in accordance with Financial Accounting Standards Board Accounting Standards Codification (ASC) 805, *Business Combinations*, and Accounting Standards Update (ASU) No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, whereby the Company recognized assets acquired based on their estimated fair values on the acquisition date. Due to the screen test as required by ASU 2017-01, the acquisition does not meet the definition of a business as, based on the final terms of the Transaction on the closing date, substantially all the fair value of the gross assets acquired is concentrated in a single identifiable asset, Zygel, a pharmaceutically produced transdermal cannabinoid therapy.

### Pro Forma Adjustments

## (A) Purchase consideration

#### Total purchase consideration

On October 10, 2023, the Company completed the previously announced Merger Agreement to acquire all of the outstanding shares of common stock of Zynerba Pharmaceuticals, Inc. a clinical-stage pharmaceutical company focused on innovative pharmaceutically produced transdermal cannabidiol therapies for orphan neuropsychiatric disorders, including Fragile X syndrome. The aggregate consideration paid by the Company to acquire the Zynerba Common Stock upon completion of the Merger Agreement was \$60.0 million, exclusive of transaction costs of approximately \$2.6 million. The Company financed the acquisition with cash on hand.

The following table summarizes the components of the purchase consideration:

(in thousands)	Pro	Pro forma adjustment	
Closing cash payment	\$	60,000	
Transaction costs		2,645	
Total purchase consideration	\$	62,645	

## **Net Assets Acquired**

The transaction was accounted for as an asset acquisition under ASC Topic 805 because substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable IPR&D asset, Zygel, a pharmaceutically produced transdermal cannabinoid therapy.

The following table summarizes the preliminary allocation of purchase consideration based on the relative fair value of assets acquired and liabilities assumed by the Company as recognized in Harmony's unaudited pro forma condensed combined balance sheet as of September 30, 2023:

		Opening		
	Ba	lance Sheet	Less: Zynerba	Pro Forma
(in thousands)		(iv)	(Historical)	 Adjustment
Assets:				
Cash and cash equivalents (i)	\$	25,658	(26,819)	\$ (1,161)
Prepaid expenses		2,063	(1,939)	124
Other current assets		1,477	(1,542)	(65)
Property and equipment, net		-	(380)	(380)
Deferred tax asset (ii)		44,800	-	44,800
Restricted cash		20	(20)	-
Acquired in-process research and development (iii)		2,260	-	2,260
Other noncurrent assets		-	(160)	(160)
Total assets acquired	\$	76,278	(30,860)	\$ 45,418
Liabilities assumed:	-			
Accounts payable		4,995	(544)	4,451
Accrued compensation		2,113	(2,132)	(19)
Accrued expenses		6,366	(9,184)	(2,818)
Other current liabilities		159	(159)	-
Total liabilities assumed		13,633	(12,019)	1,614
Net assets acquired	\$	62,645	(18,841)	\$ 43,804

- (i) The total adjustment to cash and cash equivalents in the pro forma condensed combined balance sheet as of September 30, 2023 represents the reduction in Zynerba's historical cash and cash equivalents balance from September 30, 2023 to October 10, 2023 of \$1.2 million and the total purchase price consideration of \$62.6 million.
- (ii) Acquired deferred tax assets were primarily the result of net operating loss carryforwards ("NOLs") and capitalized research and development costs. Harmony determined that there was sufficient positive evidence to conclude that it is more likely than not that the deferred tax assets are realizable and did not record a valuation allowance against the deferred tax assets. The Company reduced the \$44.8 million in deferred tax assets by \$16.7 million related to NOLs that would not have been realized if the Transaction occurred on January 1, 2022.
- (iii) The acquired in-process research and development charge included in net assets acquired is net of allocating the preliminary excess fair value of net assets acquired over the purchase price consideration. This charge was adjusted due to reduction in deferred tax assets noted in Item (ii) above and is reflected as a research and development expense in the pro forma condensed combined statement of operations for the year ended December 31, 2022 and an adjustment to retained earnings in the pro forma condensed combined balance sheet as of September 30, 2023.
- (iv)Represents the preliminary purchase price allocation as of October 10, 2023, the date of the Transaction.

## (B) Accrued compensation

Represents a one-time post Transaction expense consisting of severance and other separation benefits in connection with the termination of certain employees of Zynerba. Zynerba employees are entitled to severance benefits pursuant to either employment agreement or Zynerba's change in control policy that include double-trigger provisions which require us to provide these benefits upon a change in control and termination. The amount is accrued in the pro forma condensed combined balance sheet and reflected as a general and administrative expense in the pro forma condensed combined statement of operations for the year ended December 31, 2022 and an adjustment to accrued compensation and retained earnings in the pro forma condensed combined statement of earnings in the pro forma condensed combined statement of earnings in the pro forma condensed compensation and retained earnings in the pro forma condensed combined statement of earnings in the pro forma condensed compensation and retained earnings in the pro forma condensed combined statement earnings in the pro forma condensed compensation and retained earnings in the pro forma condensed complexes and retained earnings in the pro forma condensed complexes and retained earnings in the pro forma condensed combined statement of earnings in the pro forma condensed complexes and retained earnings in the pro forma condensed complexes and retained earnings in the pro forma condensed complexes and retained earnings in the pro forma condensed combined statement earnings in the pro forma

# (C) Equity

Represents the elimination of Zynerba's historical equity balances, offset by the impact of adjustments included in items 3(A) (iii), 3(B) and 4.

### Note 4 – Income Taxes

The pro forma effect on income tax (expense) benefit was calculated using an estimated blended statutory rate of 25.0% for federal and state income taxes for both the year ended December 31, 2022 and the nine months ended September 30, 2023. The amounts are reflected as an income tax benefit in the pro forma condensed combined statement of operations for the year ended December 31, 2022 and the nine months ended September 30, 2023, and an adjustment to other current liabilities, other current assets, deferred tax assets and retained earnings in the pro forma condensed combined balance sheet as of September 30, 2023. The adjustments are summarized in the following tables:

Year ended December 31, 2022:

	-	Net Loss	Statutory	Income	
(in thousands, except tax rate)	Before	Income Taxes	Tax Rate	Tax Benefit	t
Combined pro forma adjustments to net (loss) income before					
income taxes	\$	(26,165)	25%	\$ 6,54	1
less: income tax benefit on Zynerba loss before taxes		(35,036)	25%	8,75	9
Pro forma adjustment				\$ 15,30	0

Nine months ended September 30, 2023:

(in thousands, except tax rate)	Net Loss Before Income Taxes	Statutory Tax Rate	Income Tax Benefit
Combined pro forma adjustments to net (loss) income before			
income taxes	\$-	25% \$	ş -
less: income tax benefit on Zynerba loss before taxes	(31,618)	25%	7,905
Pro forma adjustment		ç	\$ 7,905

As of September 30, 2023 (in thousands):

Financial Statements

Line Item	Pro forma adjustment		
Other current assets	8,811		
Deferred tax assets	8,290		
Other current liabilities	(6,104)		
Accumulated deficit	23,205		