UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the Transition Period From _____ to _____

Commission File Number: 001-36913

Zevra Therapeutics, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware **(State or Other Jurisdiction of Incorporation or Organization)**	**20-5894398** **(I.R.S. Employer Identification No.)**
1180 Celebration Boulevard, Suite 103, Celebration, FL **(Address of Principal Executive Offices)**	**34747** **(Zip Code)**

(321) 939-3416
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address, and Former Fiscal Year if Changed Since Last Report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	ZVRA	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

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

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

As of November 3, 2023, the registrant had 36,218,164 shares of common stock outstanding.

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ZEVRA THERAPEUTICS, INC.
FORM 10-Q

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements relate to future events or our future financial performance. We generally identify forward-looking statements by terminology such as "may," "will," "would," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "assume," "intend," "potential," "continue" or other similar words or the negative of these terms. We have based these forward-looking statements largely on our current expectations about future events and financial trends that we believe may affect our business, financial condition and results of operations. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in Part II, Item 1A. "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 7, 2023. Accordingly, you should not place undue reliance upon these forward-looking statements. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, the timing of events and circumstances and actual results could differ materially from those anticipated in the forward-looking statements. Forward-looking statements contained in this report include, but are not limited to, statements about:

- *the consummation of the Proposed Merger (as defined below);*
- *transaction fees and Merger-related costs in connection with the Proposed Merger;*
- *our ability to integrate Acer (as defined below) into our business successfully or realize the anticipated synergies and related benefits of the Proposed Merger;*
- *the progress of, outcome or and timing of any regulatory approval for any of our product candidates and the expected amount or timing of any payment related thereto under any of our collaboration agreements;*
- *the progress of, timing of and expected amount of expenses associated with our research, development and commercialization activities;*
- *our ability to raise additional funds on commercially reasonable terms, or at all, in order to support our continued operations;*
- *the sufficiency of our cash resources to fund our operating expenses and capital investment requirements for any period;*
- *the expected timing of our clinical trials for our product candidates and the availability of data and results of those trials;*
- *our expectations regarding federal, state and foreign regulatory requirements;*
- *the potential therapeutic benefits and effectiveness of our products and product candidates;*
- *the size and characteristics of the markets that may be addressed by our products and product candidates;*
- *our intention to seek to establish, and the potential benefits to us from, any strategic collaborations or partnerships for the development or sale of our products and product candidates; if approved;*
- *our expectations as to future financial performance, expense levels and liquidity sources;*
- *the timing of commercializing our products and product candidates, if approved;*
- *senior leadership and board member transitions and refreshments; and*
- *other factors discussed elsewhere in this report.*

The forward-looking statements made in this report relate only to events as of the date on which the statements are made. We have included or made reference to important factors in the cautionary statements included in this report, particularly in the section entitled "Risk Factors" where we make reference to Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 7, 2023, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. Except as required by law, we do not assume any intent to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

NOTE REGARDING COMPANY REFERENCE

Unless the context otherwise requires, we use the terms "Zevra," "Company," "we," "us" and "our" in this Quarterly Report on Form 10-Q to refer to Zevra Therapeutics, Inc., formerly known as KemPharm, Inc. prior to February 21, 2023. We have proprietary rights to a number of trademarks used in this Quarterly Report on Form 10-Q that are important to our business, including LAT® and the Zevra logo. All other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Quarterly Report on Form 10-Q are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

*On August 30, 2023, the Company and Aspen Z Merger Sub, Inc., an indirect wholly-owned subsidiary of Zevra ("Merger Sub") entered into an Agreemen and Plan of Merger (the "Merger Agreement") with Acer Therapeutics Inc. (the "*Proposed *Merger"). At the time the Merger becomes effective (the "Effective Time"), Merger Sub will merge with and into Acer, with Acer continuing as the surviving entity and as a wholly-owned subsidiary of Zevra. The Merger is*

subject to certain customary closing conditions, including stockholder approval by Acer's stockholders. Both companies will continue to operate their businesses independently until the close of the Merger. The Merger is expected to close in the fourth quarter of 2023.

PART I — FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ZEVRA THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and par value amounts)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 43,269	$ 65,466
Securities at fair value	39,672	16,900
Secured corporate notes	41,999	—
Short-term investments - other	485	481
Accounts and other receivables	9,927	8,299
Prepaid expenses and other current assets	1,661	1,877
Total current assets	137,013	93,023
Inventories	481	671
Property and equipment, net	642	794
Operating lease right-of-use assets	698	988
Long-term investments - other	—	20,000
Other long-term assets	148	53
Total assets	$ 138,982	$ 115,529
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 13,080	$ 6,169
Current portion of operating lease liabilities	433	480
Current portion of discount and rebate liabilities	7,890	4,655
Other current liabilities	311	422
Total current liabilities	21,714	11,726
Line of credit payable	38,801	12,800
Secured promissory note	5,073	—
Operating lease liabilities, less current portion	517	843
Discount and rebate liabilities, less current portion	4,987	4,327
Other long-term liabilities	420	26
Total liabilities	71,512	29,722
Commitments and contingencies (Note D)		
Stockholders’ equity:		
Preferred stock:		
Undesignated preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2023 or December 31, 2022	—	—
Common stock, $0.0001 par value, 250,000,000 shares authorized, 37,787,402 shares issued and 36,211,710 shares outstanding as of September 30, 2023; 35,450,257 shares issued and 34,540,304 shares outstanding as of December 31, 2022	3	3
Additional paid-in capital	418,138	401,799
Treasury stock, at cost	(10,983)	(7,536)
Accumulated deficit	(339,468)	(308,572)
Accumulated other comprehensive (loss) income	(220)	113
Total stockholders' equity	67,470	85,807
Total liabilities and stockholders' equity	$ 138,982	$ 115,529

See accompanying notes to unaudited condensed consolidated financial statements.

ZEVRA THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue, net	$ 2,895	$ 2,874	$ 14,244	$ 8,139
Operating expenses:				
Cost of revenue	144	141	946	200
Research and development	12,297	5,385	28,574	13,262
Selling, general and administrative	5,818	3,974	19,657	10,266
Acquired in-process research and development	—	—	—	17,663
Total operating expenses	18,259	9,500	49,177	41,391
Loss from operations	(15,364)	(6,626)	(34,933)	(33,252)
Other income (expense):				
Interest expense	(366)	(124)	(745)	(165)
Fair value adjustment related to derivative and warrant liability	—	22	—	295
Fair value adjustment related to investments	124	(139)	451	(634)
Interest and other income, net	1,738	218	4,331	482
Total other income (expense)	1,496	(23)	4,037	(22)
Loss before income taxes	(13,868)	(6,649)	(30,896)	(33,274)
Income tax (expense) benefit	(177)	33	—	752
Net loss	$ (14,045)	$ (6,616)	$ (30,896)	$ (32,522)
Basic and diluted net loss per share of common stock:				
Net loss	$ (0.40)	$ (0.19)	$ (0.90)	$ (0.94)
Weighted average number of shares of common stock outstanding:				
Basic and diluted	34,724,614	34,494,702	34,364,075	34,482,791

See accompanying notes to unaudited condensed consolidated financial statements.

ZEVRA THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Net loss	$ (14,045)	$ (6,616)	$ (30,896)	$ (32,522)
Other comprehensive loss:				
Foreign currency translation adjustment	5	201	(333)	201
Other comprehensive loss:	5	$ 201	(333)	201
Comprehensive loss	$ (14,040)	$ (6,415)	$ (31,229)	$ (32,321)

See accompanying notes to unaudited condensed consolidated financial statements.

ZEVRA THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock	Additional Paid-in Capital	Treasury Stock, at cost	Accumulated Deficit	Other Comprehensive Income (loss)	Total Stockholders' Equity
Balance as of January 1, 2023	$ 3	$ 401,799	$ (7,536)	$ (308,572)	$ 113	$ 85,807
Net loss	—	—	—	(11,767)	—	(11,767)
Stock-based compensation expense	—	591	—	—	—	591
Shares repurchased as part of the Share Repurchase Program	—	—	(3,447)	—	—	(3,447)
Issuance of common stock in exchange for consulting services	—	42	—	—	—	42
Severance expense	—	354	—	—	—	354
Other comprehensive loss	—	—	—	—	(176)	(176)
Balance as of March 31, 2023	$ 3	$ 402,786	$ (10,983)	$ (320,339)	$ (63)	$ 71,404
Net loss	—	—	—	(5,084)	—	(5,084)
Stock-based compensation expense	—	1,103	—	—	—	1,103
Issuance of common stock in exchange for consulting services	—	25	—	—	—	25
Severance expense	—	1,048	—	—	—	1,048
Issuance of common stock as part of the Employee Stock Purchase Plan	—	165	—	—	—	165
Other comprehensive loss	—	—	—	—	(162)	(162)
Balance as of June 30, 2023	$ 3	$ 405,127	$ (10,983)	$ (325,423)	$ (225)	$ 68,499
Net loss	—	—	—	(14,045)	—	(14,045)
Stock-based compensation expense	—	1,387	—	—	—	1,387
Issuance of common stock in connection with the Proposed Merger (Note K)	—	11,500	—	—	—	11,500
Issuance of common stock in exchange for consulting services	—	71	—	—	—	71
Severance expense	—	53	—	—	—	53
Other comprehensive loss	—	—	—	—	5	5
Balance as of September 30, 2023	$ 3	$ 418,138	$ (10,983)	$ (339,468)	$ (220)	$ 67,470

See accompanying notes to unaudited condensed consolidated financial statements.

ZEVRA THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY, CONTINUED
(in thousands)

	Common Stock	Additional Paid-in Capital	Treasury Stock, at cost	Accumulated Deficit	Other Comprehensive Income	Total Stockholders' Equity
Balance as of January 1, 2022	$ 4	$ 396,957	$ (2,814)	$ (267,029)	$ —	$ 127,118
Net loss	—	—	—	(1,864)	—	(1,864)
Stock-based compensation expense	—	918	—	—	—	918
Shares repurchased as part of the Share Repurchase Program	(1)	—	(4,722)	—	—	(4,723)
Issuance of common stock in exchange for consulting services	—	50	—	—	—	50
Balance as of March 31, 2022	$ 3	$ 397,925	$ (7,536)	$ (268,893)	$ —	$ 121,499
Net income	—	—	—	(24,042)	—	(24,042)
Stock-based compensation expense	—	1,510	—	—	—	1,510
Issuance of common stock in exchange for consulting services	—	50	—	—	—	50
Issuance of common stock as part of the Employee Stock Purchase Plan	—	216	—	—	—	216
Balance as of June 30, 2022	$ 3	$ 399,701	$ (7,536)	$ (292,935)	$ —	$ 99,233
Net loss	—	—	—	(6,616)	—	(6,616)
Stock-based compensation expense	—	911	—	—	—	911
Issuance of common stock in exchange for consulting services	—	65	—	—	—	65
Other comprehensive income	—	—	—	—	201	201
Balance as of September 30, 2022	$ 3	$ 400,677	$ (7,536)	$ (299,551)	$ 201	$ 93,794

See accompanying notes to unaudited condensed consolidated financial statements.

ZEVRA THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Nine months ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (30,896)	$ (32,522)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,081	3,339
Severance expense	1,401	—
Depreciation and amortization expense	219	644
Fair value adjustment related to derivative and warrant liability	—	(295)
Fair value adjustment related to investments	(451)	634
Loss on sublease and disposal of property and equipment	157	9
Consulting fees paid in common stock	138	165
Acquired in-process research and development	—	17,663
Gain on foreign currency exchange	(30)	—
Change in assets and liabilities:		
Accounts and other receivables	(1,628)	(4,646)
Prepaid expenses and other assets	216	(1,196)
Inventories	190	280
Operating lease right-of-use assets	243	82
Long-term investments - other	(93)	—
Accounts payable and accrued expenses	5,791	1,262
Discount and rebate liability	3,895	858
Operating lease liabilities	(326)	(160)
Other liabilities	716	(372)
Net cash used in operating activities	(17,377)	(14,255)
Cash flows from investing activities:		
Acquisitions, net	—	(14,090)
Purchases of property and equipment	(224)	(59)
Purchases of investments	(45,821)	(23,832)
Purchases of secured corporate notes	(25,426)	—
Maturities of investments	43,496	1,325
Net cash used in investing activities	(27,975)	(36,656)
Cash flows from financing activities:		
Proceeds from issuance of debt	38,801	12,800
Repayment of debt	(12,800)	—
Proceeds from insurance financing arrangements	1,256	1,273
Proceeds from Employee Stock Purchase Plan	219	216
Payments of principal on insurance financing arrangements	(564)	(876)
Payments to repurchase shares as part of the Share Repurchase Program	(3,447)	(4,723)
Payment of offering costs	—	(68)
Repayment of principal on finance lease liabilities	(5)	(13)
Net cash provided by financing activities	23,460	8,609
Effect of exchange rate changes on cash and cash equivalents	(305)	15
Net decrease in cash and cash equivalents	(22,197)	(42,287)
Cash and cash equivalents, beginning of period	65,466	112,346
Cash and cash equivalents, end of period	$ 43,269	$ 70,059
Supplemental cash flow information:		
Cash paid for interest	$ 456	$ 165
Supplemental disclosure of noncash investing activities:		
Issuance of common stock for Proposed Merger (Note K)	(11,500)	—
Supplemental disclosure of noncash investing activities:		
Issuance of secured promissory note for Proposed Merger (Note K)	(5,073)	—

See accompanying notes to unaudited condensed consolidated financial statements.

ZEVRA THERAPEUTICS, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

A. Description of Business, Basis of Presentation, and Significant Transactions

Organization

Zevra Therapeutics, Inc. (the "Company") is a rare disease company melding science, data and patient need to create transformational therapies for diseases with limited or no treatment options. The Company has a diverse portfolio of products and product candidates, which includes a combination of both a clinical stage pipeline and commercial stage assets. The Company's pipeline includes arimoclomol, an orally-delivered, first-in-class investigational product candidate being developed for Niemann-Pick disease type C ("NPC"), which has been granted orphan drug designation, Fast-track designation, Breakthrough Therapy designation and rare pediatric disease designation for the treatment of NPC by the U.S. Food and Drug Administration ("FDA") and orphan medical product designation for the treatment of NPC by the European Medicines Agency ("EMA"). KP1077 is the Company's lead clinical development product candidate which is being developed as a treatment for idiopathic hypersomnia ("IH"), a rare neurological sleep disorder, and narcolepsy. KP1077 is comprised solely of serdexmethylphenidate ("SDX"), the Company's proprietary prodrug of d-methylphenidate (“d-MPH”). The FDA has granted KP1077 orphan drug designation for the treatment of IH. The Company changed its name from KemPharm, Inc. to Zevra Therapeutics, Inc. effective as of February 21, 2023. On March 1, 2023, following its name change, the Company's common stock began trading on the Nasdaq Global Select Market under the ticker symbol "ZVRA".

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not include all of the information and related notes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included in the accompanying consolidated financial statements. Operating results for the three and nine months ended September 30, 2023, are not necessarily indicative of the results that may be expected for the full year ending December 31, 2023.

This interim information should be read in conjunction with the audited financial statements included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the United States Securities and Exchange Commission (“SEC”) on March 7, 2023.

Basis of Presentation

The Company prepared the unaudited condensed consolidated financial statements in accordance with U.S. GAAP and the rules and regulations of the SEC and, in the Company's opinion, reflect all adjustments, including normal recurring items that are necessary.

Acer Proposed Merger

On August 30, 2023, the Company and Aspen Z Merger Sub, Inc., a wholly-owned subsidiary of Zevra (“Merger Sub”), entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Acer Therapeutics Inc. (“Acer”), a pharmaceutical company focused on development and commercialization of therapies for rare and life-threatening diseases (the “Proposed Merger”). At the time the Proposed Merger becomes effective (the "Effective Time"), Merger Sub will merge with and into Acer, with Acer continuing as the surviving entity and as a wholly-owned subsidiary of Zevra. In connection therewith, Zevra has also purchased Acer’s secured debt from Nantahala Capital Management, LLC ("NCM”), certain of its affiliates and certain other parties (collectively with NCM, “Nantahala”) through a series of transactions and Zevra agreed to provide Acer with a bridge loan facility for up to $16.5 million ("Bridge Loan"), subject to certain terms and conditions. Both companies are deeply committed to developing and commercializing treatments for rare diseases with a strong focus on patients and remain dedicated to supporting communities with little or no existing therapeutic options. The merger is expected to expand Zevra's rare disease portfolio, as well as increase and diversify its revenues with the addition of a U.S. commercial asset, OLPRUVA, indicated for the treatment of urea cycle disorders ("UCDs"). The transaction is subject to certain customary closing conditions, including, but not limited to, approval by Acer’s stockholders. See Note K for further discussion related to the Proposed Merger.

Arimoclomol Acquisition

On May 15, 2022, the Company and Zevra Denmark A/S (formerly known as KemPharm Denmark A/S prior to February 21, 2023) (“Zevra DK”), a newly formed Danish company and wholly-owned subsidiary of the Company, entered into an asset purchase agreement (the “Arimoclomol Purchase Agreement”) with Orphazyme A/S in restructuring, a Danish public limited liability company (“Orphazyme”). The Arimoclomol Purchase Agreement closed on May 31, 2022. Under the terms of the Arimoclomol Purchase Agreement, Zevra DK purchased all of the assets and operations of Orphazyme related to arimoclomol and settled all of Orphazyme’s actual outstanding liabilities to its creditors with a cash payment of $12.8 million. In addition, Zevra DK agreed to assume an estimated reserve liability of $5.2 million related to revenue generated from Orphazyme’s Early Access Program in France.

The Company accounted for the arimoclomol acquisition as an asset acquisition as the majority of the value of the assets acquired related to the arimoclomol acquired in-process research and development (“IPR&D”) asset. The intangible asset associated with IPR&D relates to arimoclomol. The estimated fair value of $17.7 million was determined using the excess earnings valuation method, a variation of the income valuation approach. The excess earnings valuation method estimates the value of an intangible asset equal to the present value of the incremental after-tax cash flows attributable to that intangible asset over its remaining economic life. Some of the more significant assumptions utilized in the Company's asset valuations included projected revenues, probability of commercial success, and the discount rate. The fair value using the excess earnings valuation method was determined using an estimated weighted average cost of capital of 42%, which reflects the risks inherent in future cash flow projections and represents a rate of return that a market participant would expect for this asset. This fair value measurement was based on significant inputs not observable in the market and thus represent Level 3 fair value measurement.

In accordance with Accounting Standards Codification ("ASC"), Subtopic 730-10-25, *Accounting for Research and Development Costs*, the up-front payments to acquire a new drug compound, as well as future milestone payments when paid or payable, are immediately expensed as acquired IPR&D in transactions other than a business combination provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Therefore, the portion of the purchase price that was allocated to the IPR&D assets acquired was immediately expensed. Other assets acquired and liabilities assumed, were recorded at fair value. The Company also recorded a $0.8 million income tax benefit for the year ended December 31, 2022, related to research and development credits that are expected to be realized from the local jurisdiction in Denmark.

The following represents the consideration paid and purchase price allocation for the acquisition of arimoclomol (in thousands):

Cash	$	12,800
Assumed reserve liability		5,200
Total consideration	**$**	**18,000**
Total consideration	$	18,000
Direct transaction costs associated with the acquisition (1)		1,290
Total purchase price to be allocated	**$**	**19,290**
Property and equipment, inventory and assembled workforce acquired	$	1,627
IPR&D (2)		17,663
Total allocated purchase price	**$**	**19,290**

(1) As a result of the asset acquisition accounting, the transaction costs associated with the acquisition should be included in the costs of the assets acquired and allocated amongst qualifying assets using the relative fair value basis. The transaction costs primarily included financial advisor fees and legal expenses.
(2) The primary asset acquired, the IPR&D asset, was expensed and the allocated transaction related costs were included with and expensed with this asset.

Amendment to Registration Statement on Form S-3

On January 25, 2022, the Company filed an amendment to the registration statement on Form S-1 (File No. 333-250945) on Form S-3 covering the issuance of the shares of the Company's common stock issuable upon the exercise of the warrants issued in the Company's January 2021 underwritten public offering (the "Public Offering") and remaining unexercised as of the date of the amendment, which was declared effective on February 1, 2022.

Entry into 2021 ATM Agreement

On July 2, 2021, the Company entered into an equity distribution agreement (the "2021 ATM Agreement") with JMP Securities LLC ("JMP") and RBC Capital Markets, LLC ("RBCCM") under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to $75.0 million through JMP and RBCCM as its sales agents. The issuance and sale, if any, of common stock by the Company under the 2021 ATM Agreement will be made pursuant to a registration statement on Form S-3. JMP and RBCCM may sell the common stock by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act of 1933, as amended. JMP and RBCCM will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay JMP and RBCCM a commission equal to 3.0% in the aggregate of the gross sales proceeds of any common stock sold through JMP and RBCCM under the 2021 ATM Agreement. The Company filed a registration statement on Form S-3 covering the sale of the shares of its common stock up to $350.0 million, $75.0 million of which was allocated to the sales of the shares of common stock issuable under the 2021 ATM Agreement, which was declared effective on July 12, 2021. As of September 30, 2023, no shares have been issued or sold under the 2021 ATM Agreement.

Share Repurchase Program

On December 20, 2021, the Company initiated a share repurchase program (the "Share Repurchase Program") pursuant to which the Company may repurchase up to $50 million of shares of its common stock through December 31, 2023. Capital allocation to the Share Repurchase Program will be based on a variety of factors, including the Company's business results, the receipt of royalties and sales milestones under the AZSTARYS License Agreement (refer to Note B), and potentially other sources of non-dilutive capital that may become available to the Company. Repurchases will be made in compliance with Rule 10b-18 of the Securities Exchange Act of 1934, as amended, subject to a variety of factors, including the market price of the Company’s common stock, general market and economic conditions and applicable legal requirements. The exact number of shares to be repurchased by the Company is not guaranteed and the program may be suspended, modified, or discontinued at any time without prior notice. As of September 30, 2023, the Company had repurchased 1,575,692 shares of its common stock for approximately $11.0 million under the Share Repurchase Program.

Reclassifications

Certain reclassifications were made to the 2022 unaudited condensed consolidated financial statements to conform to the classifications used in 2023. These reclassifications had no impact on the consolidated net loss, changes in stockholder's equity, or cash flows previously reported.

B. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to revenue recognition, the useful lives of property and equipment, the recoverability of long-lived assets, the incremental borrowing rate for leases, and assumptions used for purposes of determining stock-based compensation, income taxes, the fair value of investments and the fair value of the derivative and warrant liability and discount and rebate liabilities, among others. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable, the results of which form the basis for making judgments about the carrying value of assets and liabilities.

Investments

The Company maintains investment securities that are classified as available-for-sale securities for which the Company has elected the fair value option under ASC 825, *Financial Instruments* ("ASC 825"). As such, these securities are carried at fair value with unrealized gains and losses included in fair value adjustment related to investments on the unaudited condensed consolidated statements of operations. The securities primarily consist of U.S. Treasury securities, U.S. government-sponsored agency securities, and corporate notes and are included in securities at fair value in the unaudited condensed consolidated balance sheets. As of September 30, 2023, and December 31, 2022, the Company held securities with an aggregate fair value of $39.7 million and $16.9 million, respectively, that contained aggregate unrealized gains (losses) of approximately $0.5 million and $(0.6) million, respectively. Applying fair value accounting to these debt securities more accurately represents the Company's investment strategy due to the fact that excess cash is currently being invested for the purpose of funding future operations. In addition, the Company held certificates of deposit totaling $20.5 million as of December 31, 2022, which are included in investments - other in the condensed consolidated balance sheet as of December 31, 2022. These certificates of deposit matured in May 2023. Interest income is recognized as earned using an effective yield method giving effect to the amortization of premium and accretion of discount and is based on the economic life of the securities. Interest income is included in interest and other income, net in the unaudited condensed consolidated statements of operations.

Variable Interest Entities

The primary beneficiary of a variable interest entity ("VIE") is required to consolidate the assets and liabilities of the VIE. When the Company obtains a variable interest in another entity, it assesses at the inception of the relationship and upon occurrence of certain significant events whether the entity is a VIE, and if so, whether the Company is the primary beneficiary of the VIE based on its power to direct the activities of the VIE that most significantly impact the VIE's economic performance and the Company's obligation to absorb losses or the rights to receive benefits from the VIE that could potentially be significant to the VIE.

To assess whether the Company has the power to direct the activities of the VIE that most significantly impact the VIE's economic performance, the Company considers all the facts and circumstances, including the Company's role in establishing the VIE and the Company's ongoing rights and responsibilities. The assessment includes identifying the activities that most significantly impact the VIE's economic performance and identifying which party, if any, has the power to direct those activities. In general, the parties that make the most significant decisions affecting the VIE (management and representation on the Board of Directors) and have the right to unilaterally remove those decision makers are deemed to have the power to direct the activities of a VIE.

To assess whether the Company has the obligation to absorb losses of the VIE or the rights to receive benefits from the VIE that could potentially be significant to the VIE, the Company considers all of its economic interests that are deemed to be variable interests in the VIE. This assessment requires judgement in determining whether these interests, in the aggregate, are considered potentially significant to the VIE.

As of September 30, 2023, the Company identified Acer Therapeutics Inc. ("Acer") to be the Company's sole interest in a VIE (Note K). The Company did not identify any interests in VIE's as of December 31, 2022.

Revenue Recognition

The Company recognizes revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers* (“ASC 606”) and, as a result, follows the five-step model when recognizing revenue: 1) identifying a contract; 2) identifying the performance obligations; 3) determining the transaction price; 4) allocating the price to performance obligations; and 5) recognizing revenue when the performance obligations have been fulfilled.

Arimoclomol Early Access Program

Net revenue includes revenue from the sale of arimoclomol for the treatment of NPC under the remunerated early access compassionate use program in France (“French nATU”). An early access compassionate use program is a program giving specific patients access to a drug, which is not yet approved for commercial sale. Only drugs targeting serious or rare indications and for which there is currently no appropriate treatment are considered for early access compassionate use programs. Further, to be considered for the early access compassionate use program, the drug must have proven efficacy and safety and must either be undergoing price negotiations or seeking marketing approval.

In accordance with ASC 606, the Company recognizes revenue when fulfilling its performance obligation under the Arimoclomol Early Access Program ("Arimoclomol EAP") by transferring control of promised goods or services to its customer, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. In determining when the customer obtains control of the product, the Company considers certain indicators, including whether the Company has a present right to payment from the customer, whether title and/or significant risks and rewards of ownership have transferred to the customer and whether the customer acceptance has been received. Revenue is recognized net of sales deductions, including discounts, rebates, applicable distributor fees, and revenue-based taxes.

The French Health Authorities and the manufacturer have agreed to a price for sales during the French nATU, but the final transaction price depends on the terms and conditions in the contracts with the French Health Authorities and is subject to price negotiations with the French Health Authorities, following market approval. Any excess in the price charged the manufacturer compared to the price agreed with the health authorities once the drug product is approved in France must be repaid. The repayment is considered in the clawback liability (rebate). An estimate of net revenue and clawback liability are recognized using the 'expected value' method. Accounting for net revenue and clawback liability requires determination of the most appropriate method for the expected final transaction price. This estimate also requires assumptions with respect to inputs into the method, including current pricing of comparable marketed products within the rare disease area in France. Management has considered the expected final sales price as well as the price of similar drug products. The Company is operating within a rare disease therapeutic area where there is unmet treatment need and hence a limited number of comparable commercialized drugs products. The limited available relevant market information for directly comparable commercialized drugs within rare disease increases the uncertainty in management's estimate.

For the three and nine months ended September 30, 2023, the Company recognized revenue related to the Arimoclomol EAP in France of $2.0 million and $6.8 million, respectively, which is net of a clawback liability of $1.1 million and $4.0 million, respectively, and other gross to net adjustments. For the three and nine months ended September 30, 2022, the Company recognized revenue related to the Arimoclomol EAP in France of $2.3 million, which is net of a clawback liability of $1.2 million during the same periods. As part of the Arimoclomol Purchase Agreement the Company assumed an estimated reserve liability of $5.2 million related to revenue generated from the Arimoclomol EAP in France. The total estimated reserve liability as of September 30, 2023, was $12.9 million. The total estimated reserve liability as of December 31, 2022, was $9.0 million. As of September 30, 2023, and December 31, 2022, this estimated reserve liability is recorded as discount and rebate liabilities in the unaudited condensed consolidated balance sheets and is separated into current and long-term based upon the timing of the expected payment to the French regulators.

Licensing Agreements

The Company enters into licensing agreements with licensees that fall under the scope of ASC 606.

The terms of the Company's licensing agreements typically include one or more of the following: (i) upfront fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; and (iii) royalties on net sales of licensed products. Each of these payments may result in licensing revenues.

As part of the accounting for these agreements, the Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. Generally, the estimation of the stand-alone selling price may include such estimates as independent evidence of market price, forecasted revenues or costs, development timelines, discount rates, and probability of regulatory success. The Company evaluates each performance obligation to determine if they can be satisfied at a point in time or over time, and it measures the services delivered to the licensee which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Up-front Fees: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time.

Milestone Payments: At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within its or the licensee's control, such as operational developmental milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative licensing revenues and earnings in the period of adjustment.

AZSTARYS License Agreement

In September 2019, the Company entered into a Collaboration and License Agreement (the "AZSTARYS License Agreement") with Commave Therapeutics SA ("Commave"), an affiliate of Gurnet Point Capital ("GPC"). Under the AZSTARYS License Agreement, the Company granted to Commave an exclusive, worldwide license to develop, manufacture and commercialize the Company's product candidates containing SDX and d-MPH, including AZSTARYS, or any other product candidates containing SDX and developed to treat ADHD or any other central nervous system ("CNS") disease. Corium, Inc. ("Corium") was tasked by Commave to lead all commercialization activities for AZSTARYS under the AZSTARYS License Agreement. Pursuant to the AZSTARYS License Agreement, Commave agreed to pay milestone payments upon the occurrence of specified regulatory milestones related to AZSTARYS, additional fixed payments upon the achievement of specified U.S. sales milestones, and quarterly, tiered royalty payments based on a range of percentages of net sales. Commave is obligated to make such royalty payments on a product-by-product basis until expiration of the royalty term for the applicable product.

In April 2021, the Company entered into Amendment No. 1 to the AZSTARYS License Agreement (the "AZSTARYS Amendment"). Pursuant to the AZSTARYS Amendment, the Company and Commave agreed to modify the compensation terms of the AZSTARYS License Agreement. The AZSTARYS Amendment increased the total remaining future regulatory and sales milestone payments related to AZSTARYS to up to an aggregate of $590.0 million in payments upon the occurrence of specified regulatory milestones related to AZSTARYS and upon the achievement of specified U.S. net sales milestones.

Commave also agreed to be responsible for and reimburse the Company for all of the development, commercialization and regulatory expenses incurred on the licensed products, subject to certain limitations as set forth in the AZSTARYS License Agreement. As part of this agreement, the Company is obligated to perform consulting services on behalf of Commave related to the licensed products. For these consulting services, Commave has agreed to pay the Company a set rate per hour on any consulting services performed on behalf of Commave for the benefit of the licensed products.

In accordance with the terms of the Company's March 20, 2012 Termination Agreement with Aquestive Therapeutics, Aquestive Therapeutics has the right to receive an amount equal to 10% of any royalty or milestone payments made to the Company related to AZSTARYS or KP1077 under the AZSTARYS License Agreement.

The AZSTARYS License Agreement is within the scope of ASC 606, as the transaction represents a contract with a customer where the participants function in a customer / vendor relationship and are not exposed equally to the risks and rewards of the activities contemplated under the AZSTARYS License Agreement. Using the concepts of ASC 606, the Company identified the grant of the exclusive, worldwide license and the performance of consulting services, which includes the reimbursement of out-of-pocket third-party research and development costs, as its only two performance obligations at inception. The Company further determined that the transaction price, at inception, under the agreement was $10.0 million upfront payment plus the fair value of the Development Costs (as defined in the AZSTARYS License Agreement) which was allocated among the performance obligations based on their respective related stand-alone selling price.

The Company is entitled to additional payments from Commave conditioned upon the achievement of specified regulatory milestones related to AZSTARYS and the achievement of certain U.S. sales milestones. Further, Commave will pay the Company quarterly, tiered royalty payments based on a range of percentage of Net Sales (as defined in the AZSTARYS License Agreement). The Company concluded that these regulatory milestones, sales milestones and royalty payments each contain a significant uncertainty associated with a future event. As such, these milestone and royalty payments are constrained at contract inception and are not included in the transaction price as the Company could not conclude that it is probable a significant reversal in the amount of cumulative revenue recognized will not occur surrounding these milestone payments. At the end of each reporting period, the Company updates its assessment of whether the milestone and royalty payments are constrained by considering both the likelihood and magnitude of the potential revenue reversal. For the three and nine months ended September 30, 2023, the Company recognized $0.9 million and $7.2 million of revenue under the AZSTARYS License Agreement, respectively, which includes recognition of a $5.0 million net sales milestone that was met in June 2023. For the three and nine months ended September 30, 2022, the Company recognized revenue under the AZSTARYS License Agreement of $0.2 million and $0.4 million, respectively, primarily related to royalties. There was no deferred revenue related to this agreement as of September 30, 2023, or December 31, 2022.

Consulting Arrangements

The Company enters into consulting arrangements with third parties that fall under the scope of ASC 606. These arrangements may require the Company to deliver various rights, services, including research and development services, regulatory services and/or commercialization support services. The underlying terms of these arrangements generally provide for consideration to the Company in the form of consulting fees and reimbursements of out-of-pocket third-party research and development, regulatory and commercial costs.

Corium Consulting Agreement

In July 2020, the Company entered into a consultation services arrangement (the "Corium Consulting Agreement") with Corium under which Corium engaged the Company to guide the product development and regulatory activities for certain current and potential future products in Corium's portfolio, as well as continue supporting preparation for the potential commercial launch of AZSTARYS (together, "Corium Consulting Services"). Corium is a portfolio company of GPC and was tasked by Commave to lead all commercialization activities for AZSTARYS under the AZSTARYS License Agreement, as discussed above.

Under the Corium Consulting Agreement, the Company was entitled to receive payments from Corium of up to $15.6 million, $13.6 million of which was paid in quarterly installments through March 31, 2022. The remaining $2.0 million was conditioned upon the approval by the FDA of the New Drug Application for Corium's product candidate, ADLARITY. This $2.0 million was earned in the first quarter of 2022. Corium also agreed to be responsible for and reimburse the Company for all development, commercialization and regulatory expenses incurred as part of the performance of the Corium Consulting Services. The Corium Consulting Agreement is within the scope of ASC 606, as the transaction represents a contract with a customer where the participants function in a customer / vendor relationship and are not exposed equally to the risks and rewards of the activities contemplated under the Corium Consulting Agreement. The Company identified the performance of consulting services, which includes the reimbursement to the Company of third-party pass-through costs, as its only performance obligation at inception. The Company further determined that the transaction price, at inception, under the agreement was $13.6 million which is the fair value of the consulting services, including the reimbursement of third-party pass-through costs. The Company concluded that the regulatory milestone contains a significant uncertainty associated with a future event. As such, this milestone is constrained at contract inception and is not included in the transaction price as the Company could not conclude that it is probable a significant reversal in the amount of cumulative revenue recognized will not occur surrounding these milestone payments.

The Company determined that the performance of consulting services, including reimbursement of third-party pass-through costs, is a performance obligation that is satisfied over time as the services are performed and the reimbursable costs are paid. As such, the revenue related to the performance obligation was recognized as the consulting services were performed and the services associated with the reimbursable third-party pass-through costs were incurred and paid by the Company, in accordance with the practical expedient allowed under ASC 606 regarding an entity's right to consideration from a customer in an amount that corresponds directly to the value to the customer of the entity's performance completed to date.

For the nine months ended September 30, 2023, the Company recognized$0.2 million of revenue under the Corium Consulting Agreement. For the nine months ended September 30, 2022, the Company recognized revenue under the Corium Consulting Agreement of $3.5 million, which included the $2.0 million milestone payment discussed above. No revenue was recognized under the Corium Consulting Agreement for the three months ended September 30, 2023, and 2022. As of September 30, 2023, and December 31, 2022, the Company had no deferred revenue related to this agreement. The Corium Consulting Agreement expired on March 31, 2023.

Foreign currency

Assets and liabilities are translated into the reporting currency using the exchange rates in effect on the unaudited consolidated condensed balance sheet dates. Equity accounts are translated at historical rates, except for the change in retained earnings during the year, which is the result of the income statement translation process. Revenue and expense accounts are translated using the weighted average exchange rate during the period. The cumulative translation adjustments associated with the net assets of foreign subsidiaries are recorded in accumulated other comprehensive income/loss in the accompanying unaudited condensed consolidated statements of stockholders' equity.

Accounts and Other Receivables

Accounts and other receivables consist of receivables under the AZSTARYS License Agreement and Arimoclomol EAP, as well as receivables related to consulting arrangements, income tax receivables and other receivables due to the Company. Receivables under the AZSTARYS License Agreement are recorded for amounts due to the Company related to reimbursable third-party costs and royalties on product sales. Receivables under the Arimoclomol EAP are recorded for product sales under the French nATU. These receivables, as well as the receivables related to consulting arrangements, are evaluated to determine if any reserve or allowance should be established at each reporting date. As of September 30, 2023, the Company had receivables related to the Arimoclomol EAP of $5.9 million, AZSTARYS License Agreement of $0.9 million, and other receivables of $3.1 million. As of December 31, 2022, the Company had receivables related to the Arimoclomol EAP of $6.3 million, Corium Consulting Agreement of $0.2 million, AZSTARYS License Agreement of $0.5 million, income tax receivables of $0.9 million and other receivables of $0.4 million. As of September 30, 2023, and December 31, 2022, no reserve or allowance for doubtful accounts had been established.

C. Debt Obligations

Secured Promissory Note

In connection with the Proposed Merger (Note K), on August 30, 2023, the Company and Nantahala, entered into a secured promissory note payable by Zevra to Nantahala in the original principal amount of $5.0 million (the "Nantahala Note"). The Nantahala Note will initially bear interest at 9.0% per annum, payable quarterly in arrears in cash. The interest rate will increase to 12.0% per annum if the Nantahala Note remains unpaid after six months from its issue date. The additional 3.0% interest will be paid in shares of Zevra's common stock based on the volume weighted average trading price ("VWAP") of Zevra's common stock during the twenty consecutive trading days ending on the date before such interest payment date. Beginning on the first interest payment date following the second anniversary of the Nantahala Note, and on each interest payment date thereafter, Zevra is required to make $0.6 million amortization payments on the Nantahala Note until it is paid in full. All principal and unpaid interest on the Nantahala Note is due on August 30, 2026, the third anniversary of the Nantahala Note. Zevra may prepay the Nantahala Note at any time without penalty. The Nantahala Note is secured by Zevra's interest in (i) the loan assets under the Loan Purchase Agreement described in Note K; (ii) the note assets under the Note Purchase Agreement described in Note K; (iii) the Bridge Loan described in Note K; and (iv) the proceeds therefrom. The Company used the proceeds from the Nantahala Note, along with $12.0 million in cash and 98,683 shares of Zevra's common stock, to acquire the SWK Loans, as more fully described in Note K.

As of September 30, 2023, the Company had a secured promissory note outstanding, in the aggregate principal amount, as follows (in thousands):

	September 30, 2023
Secured promissory note	$ 5,000
Unamortized original issue premium	163
Less: debt issuance costs	(90)
Secured promissory note, net	$ 5,073

Future minimum principal payments under the secured promissory note as of September 30, 2023, were as follows (in thousands):

Year Ending December 31,	
2023	$ —
2024	—
2025	1,200
2026	3,800
Total minimum payments	5,000
Plus: unamortized debt premium and debt issuance costs	73
Secured promissory note, net	$ 5,073

Line of Credit

On May 31, 2022, the Company and Ameris Bank, as lender, entered into a $20.0 million revolving loan agreement (the "Line of Credit"). Proceeds of the revolving facility provided by the Line of Credit are to be used for general corporate purposes. Loans under the Line of Credit bear interest at the Secured Overnight Financing Rate ("SOFR") plus 1.60%, with a SOFR floor of 0.00%.

The revolving facility under the Line of Credit is secured by a perfected security interest in deposit accounts. The revolving facility under the Line of Credit is subject to customary affirmative and negative covenants.

The latest maturity date of the loans under the Line of Credit was May 31, 2025. The Line of Credit contained customary events of default that could have led to an acceleration of the loans, including cross-default, bankruptcy and payment defaults. As of December 31, 2022, the Company had drawn $12.8 million from the Line of Credit to finance the transactions under the Arimoclomol Purchase Agreement, and this amount was supported by a $12.8 million certificate of deposit which was shown as long-term investments - other in the unaudited condensed consolidated balance sheet as of December 31, 2022. The remaining $7.2 million under the Line of Credit was in a separate interest-bearing certificate of deposit and is also recorded as long-term investments - other in the unaudited condensed consolidated balance sheet as of December 31, 2022. These certificates of deposit were pledged as collateral against the Line of Credit and could not be redeemed so long as the $20.0 million remained available under the Line of Credit. The total value of the certificates of deposit held with Ameris Bank must meet or exceed the amount available to borrow under the Line of Credit so long as the Line of Credit remains active. On January 31, 2023, the Company repaid the $12.8 million outstanding under the Line of Credit in full and subsequently closed the Line of Credit. In conjunction with closing the Line of Credit, the maturity dates of the certificates of deposit were modified to May 27, 2023.

On January 26, 2023, the Company and Wells Fargo, as lender, entered into a revolving margin account agreement. The Company's investments are used as collateral for the loan and the amount the Company is able to borrow is limited to 80-90% of its outstanding investment balance held with Wells Fargo. The margin account bears interest at the Prime rate minus 225 basis-points. As of September 30, 2023, $38.8 million was outstanding under the margin account and the remaining borrowing capacity was approximately $12.8 million.

D. Commitments and Contingencies

From time to time, the Company is involved in various legal proceedings arising in the normal course of business. For some matters, a liability is not probable, or the amount cannot be reasonably estimated and, therefore, an accrual has not been made. However, for such matters when it is probable that the Company has incurred a liability and can reasonably estimate the amount, the Company accrues and discloses such estimates.

On May 31, 2023, the Company and KVK-Tech, Inc. ("KVK") terminated the Collaboration and License Agreement (the "Agreement") that the parties entered into on October 25, 2018. In conjunction with the termination of the Agreement, the Company agreed to pay a settlement to KVK of $0.9 million, which is included in research and development in the unaudited condensed consolidated statement of operations for the nine months ended September 30, 2023, and was paid in October 2023. As of September 30, 2023, and December 31, 2022, no accruals have been made related to commitments and contingencies.

E. Stock and Warrants

Authorized, Issued, and Outstanding Common Shares

As of September 30, 2023, and December 31, 2022, the Company had authorized shares of common stock of 250,000,000 shares. Of the authorized shares, 37,787,402 and 35,450,257 shares of common stock were issued as of September 30, 2023, and December 31, 2022, respectively, and 36,211,710 and 34,540,304 shares of common stock were outstanding as of September 30, 2023, and December 31, 2022, respectively.

As of September 30, 2023 and December 31, 2022, the Company had reserved authorized shares of common stock for future issuance as follows:

	September 30, 2023	December 31, 2022
Outstanding awards under equity incentive plans	7,262,039	2,456,407
Outstanding common stock warrants	4,252,490	4,252,600
Possible future issuances under equity incentive plans	2,497,488	4,421,508
Possible future issuances under employee stock purchase plans	1,375,175	1,417,365
Total common shares reserved for future issuance	15,387,192	12,547,880

Common Stock Activity

The following table summarizes common stock activity for the nine months ended September 30, 2023:

	Shares of Common Stock
Balance as of January 1, 2023	34,540,304
Common stock issued as compensation to third parties	7,129
Common stock repurchased as a result of the Stock Repurchase Plan	(665,739)
Common stock issued as a result of stock warrants exercised	110
Balance as of March 31, 2023	33,881,804
Common stock issued as a result of the Employee Stock Purchase Plan	42,190
Common stock issued as compensation to third parties	4,011
Balance as of June 30, 2023	33,928,005
Common stock issued as compensation to third-parties	13,984
Common stock issued in connection with the Proposed Merger (Note K)	2,269,721
Balance as of September 30, 2023	36,211,710

Authorized, Issued, and Outstanding Preferred Stock

As of September 30, 2023, and December 31, 2022, the Company had 10,000,000 shares of authorized preferred stock, none of which were designated, issued, or outstanding.

Warrants to Purchase Common Stock

In prior periods, the Company issued warrants to purchase common stock to various third parties, of which 4,252,490 remain outstanding as of September 30, 2023, and 4,221,240 of these outstanding warrants are immediately exercisable.

The remaining 31,250 warrants are not initially exercisable for any shares of common stock but become exercisable upon the achievement of each of four specified milestones. The Company determined that these warrants qualify as a derivative under ASC 815 and should be recorded as a liability and stated at fair value each reporting period. The Company calculates the fair value of the warrant using a probability-weighted Black-Scholes option pricing model. Changes in fair value resulting from changes in the inputs to the Black Scholes model are accounted for as changes in the fair value of the derivative under ASC 815 and are recorded as fair value adjustment related to derivative and warrant liability in the unaudited condensed consolidated statements of operations. As of and for the three and nine months ended September 30. 2023, the fair value of the liability associated with these warrants was immaterial.

Of the outstanding and exercisable warrants, 120,192 qualify as participating securities under ASC Topic 260, *Earnings per Share*, and are treated as such in the net loss per share calculation (Note H). The Company may be required to redeem these warrants for a cash amount equal to the Black-Scholes value of the portion of the warrants to be redeemed (the “Put Option”). The Company determined that these warrants and the Put Option should be recorded as a liability and stated at fair value at each reporting period. Changes to the fair value of the warrant liability are recorded through the unaudited condensed statements of operations as a fair value adjustment. As of and for the three and nine months ended September 30. 2023, the fair value of the liability associated with these warrants and the Put Option was immaterial.

F. Stock-Based Compensation

The Company maintains a stock-based compensation plan (the “Incentive Stock Plan”) that governs stock awards made to employees and directors prior to completion of the IPO.

In November 2014, the Board of Directors of the Company ("the Board"), and in April 2015, the Company’s stockholders, approved the Company’s 2014 Equity Incentive Plan (the “2014 Plan”), which became effective in April 2015. The 2014 Plan provides for the grant of stock options, other forms of equity compensation, and performance cash awards. In June 2021, the Company's stockholders approved an Amended and Restated 2014 Equity Incentive Plan (the "A&R 2014 Plan"), following its adoption by the Board in April 2021, which among other things added 4,900,000 shares to the maximum number of shares of common stock to be issued under the plan and extended the annual automatic increases (discussed further below) until January 1, 2031 and eliminated individual grant limits that applied under the 2014 Plan to awards that were intended to comply with the exemption for "performance-based compensation" under Code Section 162(m). The maximum number of shares of common stock that may be issued under the A&R 2014 Plan is 8,271,497 as of September 30, 2023. The number of shares of common stock reserved for issuance under the A&R 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016, and ending on and including January 1, 2031, by 4% of the total number of shares of the Company’s capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Board. Pursuant to the terms of the 2014 Plan, on January 1, 2023, the common stock reserved for issuance under the 2014 Plan automatically increased by 1,381,612 shares.

During the three and nine months ended September 30, 2023, and 2022, no stock options were exercised.

In June 2021, the Company's stockholders approved an Employee Stock Purchase Plan (the "ESPP"), following its adoption by the Board in April 2021. The maximum number of shares of common stock that may be issued under the ESPP is 1,500,000. The first offering period under the ESPP began on October 1, 2021, and the first purchase date occurred on May 31, 2022. As of September 30, 2023, 124,825 shares have been issued under the ESPP.

In January 2023, the Board approved the 2023 Employment Inducement Award Plan (the "2023 Plan"). The maximum number of shares of common stock that may be issued under the 2023 Plan is 1,500,000.

In May 2023, the Board approved the Ninth Amended and Restated Non-Employee Director Compensation Policy (the “Non-Employee Director Compensation Policy”). The equity compensation made pursuant to the Non-Employee Director Compensation Policy will be granted under the A&R 2014 Plan.

Stock-based compensation expense recorded under the Incentive Stock Plan, A&R 2014 Plan, ESPP and 2023 Plan is included in the following line items in the accompanying unaudited condensed consolidated statements of operations (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Research and development	$ 720	$ 360	$ 2,023	$ 1,093
Selling, general and administrative	667	551	1,058	2,246
Total stock-based compensation expense	$ 1,387	$ 911	$ 3,081	$ 3,339

There was no stock-based compensation expense related to performance-based awards recognized during the three and nine months ended September 30, 2023. There was no stock-based compensation expense related to performance-based awards recognized during the three months ended September 30, 2022. There was $0.4 million of stock-based compensation expense related to performance-based awards recognized during the nine months ended September 30, 2022.

As a result of the Mickle Transition Agreement and the Pascoe Transition Agreement, as further discussed in Note J, certain stock options were modified, resulting in a net decrease in stock-based compensation expense of $0.2 million and $1.2 million for the three and nine months ended September 30, 2023, respectively. The effects of these modifications are reflected in the table above within selling, general and administrative expenses.

G. Fair Value of Financial Instruments

The accounting standard for fair value measurements provides a framework for measuring fair value and requires disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value. The three tiers are defined as follows:

- Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2—Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and
- Level 3—Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

The carrying amounts of certain financial instruments, including cash and cash equivalents, investments, and accounts payable and accrued expenses, approximate their respective fair values due to the short-term nature of such instruments.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period. This determination requires significant judgments to be made. The following table summarizes the conclusions reached regarding fair value measurements as of September 30, 2023, and December 31, 2022 (in thousands):

	Balance as of September 30, 2023	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Securities:				
U.S. government-sponsored agency securities	$ 7,430	$ —	$ 7,430	$ —
U.S. Treasury securities	32,242	32,242	—	—
Total assets	$ 39,672	$ 32,242	$ 7,430	$ —

	Balance as of December 31, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Securities:				
U.S. government-sponsored agency securities	$ 7,189	$ —	$ 7,189	$ —
U.S. Treasury securities	9,711	9,711	—	—
Total assets	$ 16,900	$ 9,711	$ 7,189	$ —

H. Net Loss Per Share

For all periods presented herein, the Company did not use the two-class method to compute net loss per share of common stock, even though it had issued securities, other than common stock, that contractually entitled the holders to participate in dividends and earnings, because these holders are not obligated to participate in a loss. The two-class method requires earnings for the period to be allocated between common stock and participating securities based upon their respective rights to receive distributed and undistributed earnings.

Under the two-class method, for periods with net income, basic net income per share of common stock is computed by dividing the undistributed net income by the weighted average number of shares of common stock outstanding during the period. Undistributed net income is computed by subtracting from net income the portion of current period earnings that participating securities would have been entitled to receive pursuant to their dividend rights had all of the period's earnings been distributed and subtracting the actual or deemed dividends declared. No such adjustment to earnings is made during periods with a net loss as the holders of the participating securities have no obligation to fund losses. Diluted net income per share of common stock is computed under the two-class method by using the weighted average number of shares of common stock outstanding plus the potential dilutive effects of stock options, warrants and other outstanding convertible securities. In addition to analyzing under the two-class method, the Company analyzes the potential dilutive effect of stock options and warrants, under the treasury-stock method and other outstanding convertible securities under the if-converted method when calculating diluted income (loss) per share of common stock, in which it is assumed that the stock options, warrants and other outstanding convertible securities convert into common stock at the beginning of the period or date of issuance, if the stock option, warrant or other outstanding convertible security was issued during the period. The Company reports the more dilutive of the approaches (two-class or treasury-stock/if-converted) as its diluted net income (loss) of common stock during the period.

As noted above, for all periods presented herein, the Company did not utilize the two-class approach as the Company was in a net loss position and the holders of the participating securities have no obligation to fund losses. The Company did analyze diluted net loss per share of common stock under the treasury-stock/if-converted method and noted that all outstanding stock options and warrants were anti-dilutive for the periods presented. For all periods presented, basic net loss per share of common stock was the same as diluted net loss per share of common stock.

The following securities, presented on a common stock equivalent basis, have been excluded from the calculation of weighted average number of shares of common stock outstanding because their effect is anti-dilutive:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Awards under equity incentive plans	7,262,039	2,463,509	7,262,039	2,463,509
Common stock warrants	4,252,490	4,252,600	4,252,490	4,252,600
Total securities excluded from the calculation of weighted average number of shares of common stock outstanding	11,514,529	6,716,109	11,514,529	6,716,109

A reconciliation from net loss to basic and diluted net loss per share of common stock for the three and nine months ended September 30, 2023, and 2022, is as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Basic and diluted net loss per share of common stock:				
Net loss, basic and diluted	$ (14,045)	$ (6,616)	$ (30,896)	$ (32,522)
Weighted average number of shares of common stock outstanding, basic and diluted	34,725	34,495	34,364	34,483
Basic and diluted net loss per share of common stock	$ (0.40)	$ (0.19)	$ (0.90)	$ (0.94)

I. Leases

The Company has operating and finance leases for office space, laboratory facilities and various laboratory equipment, furniture and office equipment and leasehold improvements. The Company determines if an arrangement is a lease at contract inception. Lease assets and lease liabilities are recognized based on the present value of lease payments over the lease term at the commencement date. The Company does not separate lease and non-lease components. Leases with a term of 12 months or less at commencement are not recorded on the unaudited condensed consolidated balance sheets. Lease expense for these arrangements is recognized on a straight-line bases over the lease term. The Company's leases have remaining lease terms of less than 1 year to approximately 3 years, some of which include options to extend the leases for up to 5 years, and some which include options to terminate the leases within 1 year.

Effective June 1, 2021, the Company agreed to sublease office space in Florida, comprised of one of the two contiguous suites, under a non-cancelable operating lease, which expires in February 2026.

The components of lease expense were as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
Lease Cost	**2023**	**2022**	**2023**	**2022**
Finance lease cost:				
Amortization of right-of-use assets	$ 26	$ 32	$ 90	$ 96
Interest on lease liabilities	—	—	—	1
Total finance lease cost	26	32	90	97
Operating lease cost	113	114	340	304
Short-term lease cost	55	53	165	155
Variable lease cost	13	13	39	39
Less: sublease income	(39)	(39)	(117)	(117)
Total lease costs	$ 168	$ 173	$ 517	$ 478

Supplemental cash flow information related to leases was as follows (in thousands):

	Nine months ended September 30,	
	2023	**2022**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	$ —	$ 1
Financing cash flows from finance leases	5	13
Operating cash flows from operating leases	426	381
Operating cash flows from short-term leases	165	155
Operating cash flows from variable lease costs	39	39
Right-of-use assets obtained in exchange for lease liabilities:		
Finance leases	$ —	$ —
Operating leases	—	146

Supplemental balance sheet information related to leases was as follows (in thousands, except weighted average remaining lease term and weighted average discount rate):

	September 30, 2023	December 31, 2022
Finance Leases		
Property and equipment, at cost	$ 1,031	$ 1,031
less: accumulated depreciation and amortization	(870)	(780)
Property and equipment, net	$ 161	$ 251
Other current liabilities	$ 2	$ 6
Other long-term liabilities	—	—
Total finance lease liabilities	$ 2	$ 6
Operating Leases		
Operating lease right-of-use assets	$ 698	$ 988
Total operating lease right-of-use assets	$ 698	$ 988
Current portion of operating lease liabilities	$ 433	$ 480
Operating lease liabilities, less current portion	517	843
Total operating lease liabilities	$ 950	$ 1,323
Weighted Average Remaining Lease Term		
Finance leases	0.5 year	1 year
Operating leases	2 years	3 years
Weighted Average Discount Rate		
Finance leases	14.0%	14.3%
Operating leases	7.5%	7.3%

Maturities of lease liabilities were as follows (in thousands):

Year Ending December 31,	Finance Leases	Operating Leases
2023 (excluding the nine months ended September 30, 2023)	$ 2	$ 127
2024	—	485
2025	—	389
2026	—	31
2027	—	—
Total lease payments	2	1,032
Less: future interest expense	0	(82)
Lease liabilities	$ 2	$ 950

J. Significant Events

On January 6, 2023, the Board appointed Richard W. Pascoe to serve as the Company's Chief Executive Officer, effective immediately. Concurrently with his appointment as Chief Executive Officer, Mr. Pascoe stepped down as the Company's Executive Chairman. Mr. Pascoe continued to serve as a member of the Board until the date of the Company's 2023 Annual Meeting of Stockholders (the "Annual Meeting"), which was held on April 25, 2023. Mr. Pascoe was designated as the Company's principal executive officer, succeeding Travis C. Mickle, Ph.D., the Company's President and former Chief Executive Officer, in such role. On January 6, 2023, Dr. Mickle resigned from his role (i) as Chief Executive Officer, effective immediately, and (ii) as President and as a member of the Board, in each case, effective as of the date of the Annual Meeting. Additionally, on January 6, 2023, the Board appointed Matthew R. Plooster, a member of the Board, as the Chairman of the Board.

In connection with Mr. Pascoe's appointment as the Company's Chief Executive Officer, the Company and Mr. Pascoe entered into an amendment to the employment agreement, dated November 5, 2021, by and between the Company and Mr. Pascoe (the "Amendment"). Pursuant to the Amendment, Mr. Pascoe became entitled to receive an option under the A&R 2014 Plan to purchase 700,000 shares of the Company's common stock at an exercise price equal to the closing price of the Company's common stock on January 9, 2023. The option will vest in four equal annual installments, with the first such installment occurring on January 6, 2024 (subject to Mr. Pascoe's continued service to the Company through the applicable vesting date).

In connection with the management transition, the Company entered into (i) a transition agreement with Dr. Mickle (the "Mickle Transition Agreement") and (ii) a consulting agreement with Dr. Mickle (the "Consulting Agreement"). Pursuant to the terms of the Mickle Transition Agreement, subject to his timely delivering a release of claims in the Company's favor, Dr. Mickle will receive severance payments and benefits consisting of (i) continued payment of his base salary for 18 months following the date on which Dr. Mickle's employment with the Company ends (the "Separation Date"), (ii) up to 18 months of continued medical, dental and vision coverage pursuant to COBRA and (iii) a one-time, lump sum bonus payment equal to a pro rata amount of his annual performance-based target bonus for the year in which the Separation Date occurs. In addition, immediately prior to the Separation Date, all outstanding options to purchase the Company's common stock held by Dr. Mickle will be vested in full, and such accelerated vested options may be exercised through the later of (i) the 18-month anniversary of the date of the Transition Agreement and (ii) the date of the termination of the Consulting Agreement. Pursuant to the terms of the Consulting Agreement, Dr. Mickle has agreed to provide consulting services until the first anniversary of the Company's 2023 Annual Meeting of Stockholders, which was held on April 25, 2023. In exchange for such services, Dr. Mickle will receive consulting fees of $40,000 per month. In addition, Dr. Mickle was granted, under the A&R 2014 Plan, 547,945 performance-based restricted stock units, which will vest in full upon the timely achievement of a clinical and development milestone, subject to forfeiture upon certain disqualifying events. The severance benefits consisted of personnel and other related charges of approximately $1.0 million and stock compensation expense of approximately $0.4 million related to the acceleration of vesting on unvested shares subject to certain stock options and the extension of the exercise period for certain stock options. These severance benefits are presented in selling, general and administrative expenses in the unaudited condensed consolidated statement of operations for the nine months ended September 30, 2023. No severance expense was recognized for the three months ended September 30, 2023, related to the Mickle Transition Agreement. As of September 30, 2023, the Company had accrued severance expense recorded within accounts payable and accrued expenses of approximately $0.7 million in connection with the Mickle Transition Agreement.

At the Annual Meeting, each of John B. Bode, Douglas W. Calder, and Corey Watton was elected as a director of the Company and each of Richard W. Pascoe, Christopher A. Posner, and David S. Tierney ceased serving on the Company's Board of Directors. After the Annual Meeting, the Company's Board of Directors accepted the resignation of Richard W. Pascoe from his role as Chief Executive Officer on May 5, 2023, effective June 1, 2023, and appointed Tamara A. Favorito as the Chair of the Board of Directors. In connection with Mr. Pascoe's resignation, the Company entered into a transition agreement with Mr. Pascoe (the "Pascoe Transition Agreement"). Pursuant to the terms of the Pascoe Transition Agreement, Mr. Pascoe will receive severance payments and benefits consisting of (i) continued payment of his base salary for 12 months following the date on which Mr. Pascoe's employment with the Company ends (the "Separation Date"), (ii) up to 12 months of continued medical, dental and vision coverage pursuant to COBRA, (iii) an amount equal to Mr. Pascoe's target annual bonus, pro-rated through the Separation Date and (iv) accelerated vesting of his outstanding equity awards. In addition, the exercise period of vested options to purchase the Company's common stock held by Mr. Pascoe will be extended through the nine-month anniversary of the Separation Date. The severance benefits consisted of personnel and other related charges of approximately $0.8 million and stock compensation expense of approximately $1.0 million related to the acceleration of vesting on unvested shares subject to certain stock options and the extension of the exercise period for certain stock options. These severance benefits are presented in selling, general and administrative expenses in the unaudited condensed consolidated statement of operations for the nine months ended September 30, 2023. No severance expense was recognized for the three months ended September 30, 2023, related to the Pascoe Transition Agreement. As of September 30, 2023, the Company had accrued severance expense recorded within accounts payable and accrued expenses of approximately $0.5 million in connection with the Pascoe Transition Agreement.

On May 3, 2023, Matthew R. Plooster and Joseph B. Saluri indicated to the Board of Directors that they do not intend to stand for re-election at the Company's 2024 Annual Meeting of Stockholders, and that they intend to step down from the Board of Directors as soon as replacements are found.

In May 2023, the Board of Directors appointed Christal M. M. Mickle, Co-Founder and Chief Development Officer, to serve as interim President and Chief Executive Officer effective on June 1, 2023.

On August 7, 2023, the Board of Directors appointed Thomas Anderson as a Class III director, with a term expiring at the Company's annual meeting of stockholders to be held in 2024 or until his earlier death, resignation, or removal.

On August 7, 2023, Mr. Plooster resigned from the Board of Directors effective immediately after Mr. Anderson's appointment.

On October 7, 2023, the Board of Directors appointed Neil F. McFarlane to serve as the Company’s President and Chief Executive Officer, effective October 10, 2023. Concurrently with his appointment as President and Chief Executive Officer, Mr. McFarlane was appointed to serve as a member of the Board of Directors. Mr. McFarlane was designated as the Company’s principal executive officer, succeeding Christal M.M. Mickle, the Company’s former interim President and Chief Executive Officer, in such role. Ms. Mickle will continue serving in her role as Chief Development Officer. In connection with Mr. McFarlane’s appointment as the Company’s President and Chief Executive Officer, the Company and Mr. McFarlane entered into an employment agreement, effective October 10, 2023 (the “Employment Agreement”). Pursuant to the Employment Agreement, Mr. McFarlane is entitled to (i) an annual base salary of $700,000, (ii) an annual performance-based target bonus of 60% of his annual base salary, (iii) an option to purchase 600,000 shares of the Company’s common stock at an exercise price equal to the closing price of the Company’s common stock on October 10, 2023, and (iv) restricted stock units covering 200,000 shares of the Company's common stock. The option and restricted stock units were granted to Mr. McFarlane as inducement awards under the 2023 Plan. The option and restricted stock units will vest in four equal annual installments, with the first such installment occurring on October 10, 2024 (subject to Mr. McFarlane’s continued service to the Company through the applicable vesting date). In addition, Mr. McFarlane will receive commuting and relocation assistance in connection with his move to Florida. Upon a termination of Mr. McFarlane’s termination without cause by the Company or resignation for good reason, Mr. McFarlane is entitled to receive (i) an amount of cash equal to 1.0 times annual base salary, (ii) a pro-rated target annual bonus for the year in which termination occurs, (iii) twelve months of Company paid COBRA continuation coverage, and (iv) full vesting of his outstanding and unvested equity awards. However, if any such termination occurs within one month prior to or six months after a change in control, he will instead receive (i) an amount of cash equal to 1.5 times annual base salary, (ii) a target annual bonus for the year in which termination occurs, (iii) eighteen months of Company paid COBRA continuation coverage, and (iv) full vesting of his outstanding and unvested equity awards. Upon Mr. McFarlane’s termination due to death or disability, Mr. McFarlane will receive a pro-rated target annual bonus. Mr. McFarlane is also subject to 12-month post-termination non-competition and non-solicitation restrictions.

On October 10, 2023, Joseph B. Saluri, a member of the Board of the Company, retired from such position, effective immediately after the appointment of Mr McFarlane.

K. Acer Acquisition

Proposed Acquisition of Acer

At the Effective Time, each share of common stock of Acer, par value $0.0001 per share (the “Acer Common Stock”), issued and outstanding immediately prior to the Effective Time (excluding cancelled shares and any shares held by holders who have exercised their appraisal rights) will be converted into the right to receive (i) 0.1210 fully paid and non-assessable shares of common stock of Zevra, par value $0.0001 per share (“Zevra Common Stock”), and (ii) one non-transferable contingent value right (“CVR”) to be issued by Zevra, which will represent the right to receive one or more contingent payments up to an additional $76 million upon the achievement, if any, of certain commercial and regulatory milestones for Acer’s OLPRUVA and EDSIVO products within specified time periods. Certain additional cash payments are also possible pursuant to the CVRs with respect to milestones involving Acer’s early-stage program ACER-2820 (emetine). The preliminary consideration for the Proposed Merger is $69.7 million and consists of (i) approximately 2.96 million shares of Zevra common stock valued at $15.0 million, (ii) the Bridge Loan advances of $16.5 million, (iii) $12.0 million in cash paid to Nantahala; (iv) 2,269,721 shares of Zevra Common Stock issued to Nantahala valued at $11.5 million based on the VWAP of shares of Zevra Common Stock during the 20 consecutive trading days ending on the trading date prior to August 30, 2023; (v) a secured promissory note payable by Zevra to Nantahala in the original principal amount of $5.0 million, as disclosed in Note C, and (vi) $9.7 million in the estimated fair value of contingent consideration related to the CVRs.

Bridge Loan Agreement

Immediately prior to the execution of the Merger Agreement and immediately following the execution of the Loan and Note Purchase Agreements defined below, Zevra and Acer entered into a bridge loan agreement (the “Bridge Loan Agreement”), providing for Zevra to make loans (collectively, the “Bridge Loan”) to Acer up to an aggregate principal amount of $16.5 million. At the time of entering into the Bridge Loan Agreement, Zevra made an initial advance to Acer in the principal amount of $10.0 million. The Bridge Loan is being provided to Acer to support its termination agreement with Relief Therapeutics Holding SA (“Relief”) and to provide Acer with working capital, including for payments of accounts payable to support the commercial launch of OLPRUVA and the development of EDSIVO pending the Proposed Merger’s anticipated closure. The Bridge Loan will bear interest at 12.0% per annum. The Bridge Loan is secured by a first priority lien on substantially all the assets of Acer.

Pursuant to the guidance under ASC 810, *Consolidation* ("ASC 810"), the Company concluded that Acer qualifies as a VIE. As Acer is the final decision maker for all of its research, development, and commercialization of drug candidates that it is producing, the Company lacks the power criterion under ASC 810 to direct the activities of Acer that most significantly impact its performance. Therefore, the Company is not the primary beneficiary of this VIE for accounting purposes. As a result, the Company accounts for its investment in Acer under the Bridge Loan in accordance with ASC 310, *Receivables.* The Company assessed the need to record an allowance for expected credit losses as it relates to the Bridge Loan and determined that the credit loss allowance was immaterial as of September 30, 2023, based on the fair value of Acer's net assets that are pledged as collateral. As of September 30, 2023, $13.4 million was outstanding under the Bridge Loan, which is included in secured corporate notes on the unaudited condensed consolidated balance sheet. As of September 30, 2023, the unaudited condensed consolidated balance sheet included $42.0 million of assets related to the Company's investment in Acer. No liabilities were recorded on the unaudited condensed consolidated balance sheet related to Acer as of September 30, 2023. The Company's maximum exposure to loss as of September 30, 2023, is equal to the Company's investment in the entity.

On October 31, 2023, the Company and Acer entered into an amendment to the Bridge Loan Agreement, which increased the aggregate principal amount available under the loan from $16.5 million to $18.0 million. Acer’s ability to borrow the remaining $4.6 million under the Bridge Loan Agreement is subject to certain conditions and approvals by Zevra.

Loan and Note Purchase Agreements

Immediately prior to the execution of the Bridge Loan Agreement and the Merger Agreement described above, on August 30, 2023, Zevra purchased certain indebtedness of Acer held by Nantahala pursuant to a Loan Purchase Agreement and a Note Purchase Agreement, each as described below and referred to herein collectively as the “Loan and Note Purchase Agreements.”

Under a Loan Purchase Agreement with Nantahala (the “Loan Purchase Agreement”), Zevra purchased the SWK Loans (as defined below) that Nantahala had acquired on June 16, 2023, for: (i) $12.0 million in cash; (ii) 98,683 shares of Zevra's common stock; and (iii) a secured promissory note payable by Zevra to Nantahala in the original principal amount of $5.0 million, as disclosed in Note C. The number of shares of Zevra's common stock was calculated by dividing $0.5 million by the VWAP of shares of Zevra's common stock during the twenty consecutive trading days ending on the trading date prior to the date of the Loan Purchase Agreement, which equaled $5.0667 per share. The SWK Loans purchased by Zevra from Nantahala under the Loan Purchase Agreement consist of: (i) an original senior secured term loan facility made available to Acer in an aggregate amount of $6.5 million (the “Original Term Loan”) and funded on March 14, 2022; and (ii) an additional senior secured term loan made to Acer in an aggregate amount of $7.0 million in a single borrowing which funded on January 31, 2023 (the “Second Term Loan”, and together with the Original Term Loan, the “SWK Loans”). The SWK Loans bear interest at an annual rate of the sum of (i) 3-month SOFR, subject to a 1% floor, plus (ii) a margin of 11%, with such interest payable quarterly in arrears. In the event of default, the interest rate will increase by 3% per annum over the contract rate effective at the time of default but shall not be higher than the maximum rate permitted to be charged by applicable laws. The principal amount of the SWK Loans amortizes at a monthly rate of $0.6 million. The final maturity date of the SWK Loans is March 4, 2024. Acer has the option to prepay the SWK Loans in whole or in part. Upon the repayment of the Original Term Loan (whether voluntary or at scheduled maturity), Acer must pay an exit fee so that Zevra receives an aggregate amount (inclusive of all principal, interest and origination and other fees paid on or prior to the prepayment date) equal to 1.5 times the outstanding principal amount of the Original Term Loan, plus any and all payment-in-kind interest amounts. Upon the repayment of the Second Term Loan (whether voluntary or at scheduled maturity), Acer must pay an exit fee so that Zevra receives an aggregate amount (inclusive of all principal, interest and origination and other fees paid in cash with respect to the Second Term Loan equal to the outstanding principal amount of the Second Term Loan (inclusive of payment-in-kind interest amounts) multiplied by 1.5. The SWK Loans are secured by a first priority lien on all assets of Acer and any of Acer's future subsidiaries. In connection with the sale of the SWK Loans from Nantahala to Zevra under the Loan Purchase Agreement, there were no changes to any of the contractual provisions of the SWK Loans, except that in connection with the Bridge Loan, the security interest under the SWK Loans was subordinated to the Bridge Loan.

Under a Note Purchase Agreement with Nantahala (the "Note Purchase Agreement"), Zevra purchased the Marathon Convertible Notes (described below) that Nantahala had acquired on June 16, 2023. Zevra acquired the Marathon Convertible Notes in exchange for the issuance of 2,171,038 shares of Zevra's common stock. The number of shares of Zevra's common stock was calculated by dividing $11.0 million by the VWAP of shares of Zevra's common stock during the twenty consecutive trading days ending on the trading date prior to the date of the Note Purchase Agreement, which equaled $5.0667 per share. The Marathon Convertible Notes are secured convertible notes that Acer issued and sold to MAM Aardvark, LLC ("Marathon") and Marathon Healthcare Finance Fund, L.P. ("Marathon Fund" and together with "Marathon", each a "Holder" and collectively the "Holders") pursuant to a Marathon Convertible Note Purchase Agreement which closed on March 14, 2022. On January 30, 2023, Acer entered into an Amendment Agreement (the "Marathon Amendment Agreement") with the Holders with respect to the Marathon Convertible Notes. The Marathon Convertible Notes bear interest at an annual rate of 6.5%, with such interest payable quarterly. Subject to limitations in the Bridge Loan Agreement, Zevra has the right during the 30-day periods beginning 18 months and 24 months after March 14, 2022, to require Acer to redeem the Marathon Convertible Notes at a redemption price of the outstanding principal amount plus any accrued but unpaid interest. In the event of default, interest on the Marathon Convertible Notes will increase to the lower of 11.5% per annum or the highest rate permitted by law. Zevra also has the right to convert all or any portion of the outstanding principal amount plus any accrued but unpaid interest under the Marathon Convertible Notes into shares of Acer common stock at a conversion price of $2.50 per share, subject to adjustment, for an aggregate of 2.4 million shares upon conversion of the original principal amount. The nature of the adjustment to conversion price is limited to instances such as stock splits and reverse stock splits. Any outstanding principal, together with all accrued and unpaid interest, will be payable on the earlier of the third anniversary of the date of issuance, or upon a change of control of Acer. Pursuant to the Marathon Convertible Note Purchase Agreement, the Marathon Convertible Notes are secured by a lien on collateral representing substantially all assets of Acer. In connection with the sale of the Marathon Convertible Notes from Nantahala to Zevra under the Note Purchase Agreement, there were no changes to any of the contractual provisions of the Marathon Convertible Notes, except that in connection with the Bridge Loan, the Marathon Convertible Notes were also subordinated to the Bridge Loan.

The Company's investments in the SWK Loans and the Marathon Convertible Notes are classified as available-for-sale debt securities for which the Company has elected the fair value option under ASC 825 and are included in secured corporate notes in the unaudited condensed consolidated balance sheet as of September 30, 2023. The company recorded interest income of $0.5 million for three months and nine months ended September 30, 2023, related to the Loan and Note Purchase Agreements.

Amended License Agreement and Termination Agreement

As a condition to entering into the Merger Agreement, Acer and Relief entered into an exclusive license agreement on August 30, 2023 (the "Exclusive License Agreement") and a termination agreement (the "Termination Agreement") terminating the collaboration and license agreement, dated March 19, 2021, by and between Acer and Relief (the "CLA"). Pursuant to the Exclusive License Agreement, Relief will hold exclusive development and commercialization rights for OLPRUVA in the European Union, Liechtenstein, San Marino, Vatican City, Norway, Iceland, Principality of Monaco, Andorra, Gibraltar, Switzerland, United Kingdom, Albania, Bosnia, Kosovo, Montenegro, Serbia and North Macedonia (Geographical Europe). Acer will have the right to receive a royalty of up to 10.0% of the net sales of OLPRUVA in Geographical Europe. In accordance with the terms of the Termination Agreement, Relief received an upfront payment from Acer of $10.0 million (which payment was funded with the Bridge Loan described above) with an additional payment of $1.5 million due on the first-year anniversary of the $10.0 million payment. Acer has also agreed to pay a 10.0% royalty on net sales of OLPRUVA worldwide, excluding Geographical Europe, and 20.0% of any value received by Acer from certain third parties relating to OLPRUVA licensing or divestment rights, all of the foregoing which are capped at $45.0 million, for total payments to Relief of up to $56.5 million.

Closing Conditions

The Proposed Merger is subject to certain customary closing conditions, including stockholder approval by Acer's stockholders. Both companies will continue to operate their businesses independently until the close of the Proposed Merger. The Proposed Merger is expected to close in the fourth quarter of 2023. The Company expensed approximately $1.9 million of acquisition-related costs during the three and nine months ended September 30, 2023, which is included in selling, general, and administrative expenses in the unaudited condensed consolidated statement of operations.

Following the announcement of the Proposed Merger, as of October 30, 2023, three purported stockholders of Acer filed complaints entitled *Jerry Beavee v. Acer Therapeutics, Inc., et al.*, No. 1:23-cv-08995 (S.D.N.Y. filed Oct. 12, 2023), *Kevin Turner v. Acer Therapeutics, Inc., et al.*, No. 1:23-cv-01185 (D. Del. filed Oct. 20, 2023) and *Matthew Jones v. Acer Therapeutics, Inc., et al.*, No. 1:23-cv-01186 (D. Del. filed Oct. 20, 2023) (the "Complaints") alleging that the definitive proxy statement filed on October 10, 2023, in connection with the Proposed Merger omitted material information with respect to the Proposed Merger and demanding that the Merger be enjoined unless certain supplemental disclosures are made. Certain other purported stockholders have sent demand letters to Acer making allegations and demands similar to those in the Complaints. It is possible that other complaints will be filed or demand letters received. Acer disclosed that it believes that the alleged omissions are immaterial and that no supplemental disclosure is required by applicable rule, statute, regulation or law. However, solely in order to avoid the risk that these lawsuits and demand letters may delay or otherwise adversely affect the consummation of the Proposed Merger, or further harm Acer's financial condition, on October 30, 2023, Acer disclosed that if determined to voluntarily make supplemental disclosures to the proxy statement.

L. Subsequent Events

The Company evaluated events and transactions occurring subsequent to September 30, 2023, through November 7, 2023, the date the accompanying unaudited condensed consolidated financial statements were issued. During this period, other than the appointment of Mr. McFarlane as President and Chief Executive Officer and a Class III director, and the resignation of Mr. Saluri from the Board of Directors on October 10, 2023, as disclosed in Note J, and the relevant items from Note K, there were no subsequent events that required recognition in the accompanying unaudited condensed consolidated financial statements, nor were there any additional non-recognized subsequent events that required disclosure.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part II, Item 1A. "Risk Factors" of this Quarterly Report on Form 10-Q and Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 7, 2023, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a rare disease company melding science, data and patient need to create transformational therapies for diseases with limited or no treatment options. With unique, data-driven clinical, regulatory, and commercialization strategies, we are overcoming complex drug development challenges to bring much needed therapies to patients. We have a diverse portfolio of products and product candidates, which includes a combination of both a clinical stage pipeline and commercial stage assets. The Company's pipeline includes arimoclomol, an orally-delivered, first in-class investigational product candidate being developed for Niemann-Pick disease Type C, or NPC, which has been granted orphan drug designation, Fast-Track designation, Breakthrough Therapy designation and rare pediatric disease designation for the treatment of NPC by the U.S. Food and Drug Administration, or FDA, and orphan medicinal product designation for the treatment of NPC by the European Medicines Agency, or EMA. KP1077 is our lead clinical development product candidate which is being developed as a treatment for idiopathic hypersomnia, or IH, a rare neurological sleep disorder, and narcolepsy. KP1077 is comprised solely of serdexmethylphenidate, or SDX, our proprietary prodrug of d-methylphenidate, or d-MPH. The FDA has granted KP1077 orphan drug designation for the treatment of IH, and the U.S. Drug Enforcement Agency, or DEA, has classified SDX as a Schedule IV controlled substance based on evidence suggesting SDX has a lower potential for abuse when compared to d-MPH, a Schedule II controlled substance.

We have specialized expertise and a track record of success in advancing promising therapies that face complex clinical and regulatory challenges with an approach that balances science and data with patient need. The FDA has approved AZSTARYS®, a once-daily treatment for attention deficit hyperactivity disorder, or ADHD, in patients age six years and older containing our prodrug, SDX, and d-MPH. In September 2019, we entered into a collaboration and license agreement, or the AZSTARYS License Agreement, with Commave Therapeutics S.A. (formerly known as Boston Pharmaceutical S.A.), or Commave, an affiliate of Gurnet Point Capital, L.P. Under the AZSTARYS License Agreement, we granted to Commave an exclusive, worldwide license, to develop, manufacture, and commercialize AZSTARYS and any of our product candidates containing SDX and used to treat ADHD or any other CNS disease. Commave has tasked Corium, Inc., or Corium, an affiliate of Gurnet Point Capital, L.P., to lead all commercialization activities for AZSTARYS in the U.S. under the AZSTARYS License Agreement. Corium commercially launched AZSTARYS in the U.S. during the third quarter of 2021. In December 2021, Commave sublicensed commercialization rights for AZSTARYS in greater China to Shanghai Ark Biopharmaceutical Ltd. Year-to-date net sales of AZSTARYS surpassed $25 million, triggering the first net sales milestone payment of $5 million, which was earned and recognized in revenue in the second quarter of 2023, and received after quarter-end. Net sales trend supports the potential to earn a second net sales milestone during the fourth quarter of 2023.

The FDA has also approved APADAZ®, an immediate-release combination product containing benzhydrocodone, our prodrug of hydrocodone, and acetaminophen, for the short-term (no more than 14 days) management of acute pain severe enough to require opioid analgesic and for which alternative treatments are inadequate. In October 2018, we entered into a collaboration and license agreement, or the APADAZ License Agreement, with KVK-Tech, Inc., or KVK, under which we granted to KVK the exclusive license to manufacture and commercialize APADAZ in the U.S. On May 31, 2023, the Company and KVK terminated the APADAZ License Agreement.

Our primary mission is to deliver life-changing treatments to people with rare conditions, their families, and caregivers who desperately need better options. This mission guides our efforts to expand our pipeline through both internal development and through our business development activities to collaborate, partner, and potentially acquire additional assets. We intend to target assets that will allow us to leverage the expertise and infrastructure that we have successfully built in order to mitigate risk and enhance our probability of success. In addition, we are considering external opportunities within neurology and neurodegenerative diseases, psychiatric disorders, and other rare diseases, along with adjacent or related therapeutic categories. We are seeking assets that are undergoing Phase 2 clinical trials or Phase 3 clinical trials, subject to our specific evaluation criteria, that we can in-license or acquire. If we are successful, expanding our development pipeline could be accretive to our value proposition by potentially adding new clinical data catalysts and have the potential to create incremental long-term value for stockholders. In addition, we believe that a multi-channel development program with several product candidates addressing various rare disease indications will diversify risk and potentially create an impactful portfolio of commercial-stage products in the future.

For example, in May 2022, we, through our wholly-owned subsidiary, Zevra Denmark A/S (formerly known as KemPharm Denmark A/S prior to February 21, 2023, or Zevra DK), entered into an Asset Purchase Agreement, or the Arimoclomol Purchase Agreement, with Orphazyme A/S in restructuring, a Danish public limited liability company, or Orphazyme. The transactions agreed to under the Arimoclomol Purchase Agreement closed on May 31, 2022. Under the terms of the Arimoclomol Purchase Agreement, Zevra DK purchased all of the assets and operations of Orphazyme related to arimoclomol and settled all of Orphazyme's actual outstanding liabilities to its creditors with a cash payment of $12.8 million. In addition, Zevra DK agreed to assume an estimated reserve liability of $5.2 million related to revenue generated from Orphazyme's Early Access Program in France, or the Arimoclomol EAP.

Our most advanced product candidate, arimoclomol, is being developed for the treatment of NPC, a lysosomal storage disorder, or LSD. NPC is a rare neurodegenerative disease characterized by an inability of the body to transport cholesterol and lipids inside of cells. Symptoms of NPC include a progressive impairment of mobility, cognition, speech, and swallowing, often culminating in premature death. The incidence of NPC is estimated to be one in 100,000 live births. We estimate that approximately 1,800 individuals have been diagnosed, of which approximately 300 are in the United States and approximately 1,500 are in Europe. However, diagnostic challenges may affect the number of potential patients, and we believe that the availability of treatment options could increase awareness of the disease and assist in identifying more cases. Therapies to treat NPC are desperately needed, and for this reason, arimoclomol is currently being made available to NPC patients in the United States, France, Germany, and other European Union countries under various early access programs, or EAPs.

On September 16, 2020, the previous sponsor of the arimoclomol program, Orphazyme, submitted a new drug application, or NDA, seeking approval for arimoclomol to treat NPC. In June 2021, the FDA issued a complete response letter, or CRL, which means the FDA determined that it could not approve the NDA in its present form. Our aim is to prepare and resubmit an NDA that presents meaningful evidence of safety and efficacy of arimoclomol for its intended use. To that end, we are continuing to work diligently to characterize the substantial data generated since the CRL, including the recently completed four-year open-label safety trial which was presented at the 19th World*Symposium*™ in February 2023. Results from this analysis, based on up to four years of continuous treatment, suggest that arimoclomol may reduce the long-term progression of NPC. Upon fulfilling the randomized double-blinded portion of the phase 2/3 clinical trial, both placebo- and arimoclomol-treated patients were given the option to continue into the four-year (48 month) open-label-extension, or OLE, phase of the study with arimoclomol treatment provided in addition to their current standard of care. Progression of NPC disease through the DB and OLE phases was assessed utilizing the five-domain NPC Clinical Severity Scale (5DNPCCSS) and compared with an estimated progression calculated from the combination of untreated patients from the NPC-001 observational trial and placebo patients from the NPC-002 Phase 2/3 trial. We are also investigating correlations between relevant 5DNPCCSS domains and corresponding Scale for the Assessment and Rating of Ataxia, or SARA, test items to potentially provide further supportive evidence for 5DNPCCSS validity as a tool for evaluating NPC progression. The SARA test evaluates impairment related to cerebellar ataxia, which was a secondary endpoint in the Phase 2/3 clinical trial of arimoclomol in NPC (NPC progression based on the 5DNPCCSS was the primary endpoint). Based on a comparative analysis of both measurements, it was determined that individual 5DNPCCSS domains and relevant performance-based SARA test items showed strong associations and alignment between the two instruments for all analysis methods used. These results provide further support that the evaluated 5DNPCCSS domains are appropriately standardized to allow for reliable and reproducible scoring of disease severity in NPC. In preparation of the arimoclomol NDA, we completed a productive and collaborative pre-submission meeting with the FDA in August 2023, receiving important information that will be used to finalize the NDA for resubmission. We plan to include these data as part of the updated NDA package for arimoclomol, which is anticipated to be submitted in the fourth quarter of 2023.

We also intend to advance our pipeline of prodrug product candidates for the treatment of IH and other CNS/rare diseases, and we reported top-line data from a Phase 1 proof-of-concept study of SDX in the fourth quarter of 2021 and final data for the Phase 1 proof-of-concept study of SDX in the first quarter of 2022. The proof-of-concept study was a dose-escalation study to evaluate the pharmacokinetics, pharmacodynamic stimulant effects, and safety of single oral doses of SDX in subjects with a history of high-dose stimulant use. In the trial, 240 mg and 360 mg doses of SDX were observed to be well-tolerated and produced d-MPH exposure that appeared to increase proportionally with dose. Mean d-MPH plasma concentrations showed a gradual increase after SDX administration, reaching a broad peak from eight to twelve hours post-dose, followed by a shallow decline thereafter. Increased wakefulness, alertness, hypervigilance, and insomnia effects were reported by study participants, which we believe suggests that SDX produced targeted pharmacodynamic effects that have the potential to benefit patients with IH and other sleep disorders. On November 18, 2022, we announced that the FDA has granted the Orphan Drug Designation to SDX for the treatment of IH.

In January 2022, we announced that we have selected KP1077 for the treatment of IH as our lead clinical development candidate. KP1077 utilizes SDX, our prodrug of d-MPH, as its active pharmaceutical ingredient. During the first quarter of 2022, we initiated a Phase 1 clinical trial comparing the cardiovascular safety of SDX to immediate-release and long-acting formulations of RITALIN®, a commonly prescribed CNS stimulant. In September 2022, we announced topline data from our exploratory Phase 1 clinical trial, which showed the potential for higher dose formulations of SDX to be safe and well tolerated while avoiding the potential for greater cardiovascular safety risk compared to immediate-release and long-acting formulations of Ritalin. Based on the data, we identified initial dosing strengths for the ongoing Phase 2 clinical trial of KP1077 which we believe have the potential to be well-tolerated while providing higher overall exposures to d-MPH compared to other methylphenidate products that are often used off-label as a treatment for IH. On December 21, 2022, we announced the initiation of a Phase 2 clinical trial evaluating KP1077. The Phase 2 clinical trial is actively enrolling 48 adult patients at more than 30 sites in the U.S. Part 1 of the trial consists of a five-week open-label titration phase during which patients are optimized to one of four doses of SDX (80, 160, 240, or 320 mg/day). Part 2 of the trial entails a two-week randomized, double-blind, withdrawal phase, during which two-thirds of the trial participants will continue to receive their optimized dose while the remaining one-third will receive placebo. Participants are further assigned into two evenly divided cohorts. The first cohort will receive a single daily dose just before bedtime, and the second cohort will receive half the daily dose shortly after awakening and half the daily dose prior to bedtime. In June 2023, we presented the Phase 2 clinical trial design evaluating KP1077 as a treatment for IH at a medical conference. Interim Phase 2 data for the open-label titration phase of the trial were announced in October of 2023. The Interim Phase 2 data provided valuable information on the primary endpoint of the trial, which is the safety and tolerability of KP1077 in patients with IH, as well as insights related to the effective dose range and regimen. Topline Phase 2 data in IH is expected to be reported in the first half of 2024 after all patients have completed the double-blind withdrawal phase. The combined interim and upcoming topline data are expected to also provide information related to a number of secondary and exploratory endpoints, including excessive daytime sleepiness, sleep inertia, and brain fog. In the second quarter of 2023, we initiated a Phase 1 clinical trial in narcolepsy, which since has been completed and will be analyzed alongside the IH data to support both the narcolepsy and IH programs. By leveraging the data from the IH and narcolepsy programs and the existing data set generated as part of the AZSTARYS development program for serdexmethylphenidate (SDX), the sole active pharmaceutical ingredient in KP1077, Zevra can potentially initiate a pivotal Phase 3 trial in IH sometime next year.

In May 2021, we announced that SDX, our proprietary prodrug of d-MPH and the primary active pharmaceutical ingredient, or API, in AZSTARYS, was classified as a Schedule IV controlled substance by the DEA. AZSTARYS is classified as a Schedule II controlled substance as its formulation includes a 70:30 mixture of SDX (Schedule IV) and d-MPH (Schedule II), respectively.

Merger Agreement

On August 30, 2023, Zevra and Aspen Z Merger Sub, Inc., a wholly-owned subsidiary of Zevra (“Merger Sub”), entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Acer Therapeutics Inc. (the “Proposed Merger”). At the time the Proposed Merger becomes effective (the "Effective Time"), Merger Sub will merge with and into Acer, with Acer continuing as the surviving entity and as a wholly owned subsidiary of Zevra. The Proposed Merger is subject to certain customary closing conditions, including stockholder approval by Acer’s stockholders. Both companies will continue to operate their businesses independently until the close of the Merger. The Proposed Merger is expected to close in the fourth quarter of 2023. For additional information regarding the Merger, see Note K to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Our Product Candidates and Approved Products

We have employed our proprietary LAT platform technology to create a portfolio of approved products that we believe will offer, and product candidates that we believe have the potential to offer, significant improvements over currently available FDA-approved drugs.

A selection of our product candidates and approved products are summarized in the table below:

Selected Zevra Partnered and Other Development Assets

Parent Drug (Effect Profile) - Indication	Product Candidate	Development Status	Next Milestone(s)
Arimoclomol (ER) - NPC	Arimoclomol	NDA Preparation	NDA resubmission expected in Q4 2023
Methylphenidate (ER) - IH	KP1077IH*	Clinical - Phase 2	Top-line Phase 2 data - expected HI 2024
Methylphenidate (ER) - Narcolepsy Types I and II	KP1077N*	Clinical - Phase 1/2	Evaluation of potential Phase 3 Trial
Methylphenidate (ER) - ADHD	AZSTARYS	FDA Approved/Partnered	Tracking TRx's

* This product candidate is subject to a right of first negotiation upon completion of a Phase 1 proof-of-concept study in favor of Commave under the terms of the AZSTARYS License Agreement, but is not currently licensed to Commave, thereunder.

These anticipated milestones are based on information currently available to us. Our current plans and expectations are subject to a number of uncertainties, risks, and other important factors that could materially impact our plans, including risks which are not solely within our control. See Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 7, 2023, as updated by Part II, Item 1A. “Risk Factors” of this Quarterly Report on Form 10-Q.

Other Third-Party Agreements

Under our March 2012 termination agreement with Aquestive, Aquestive has the right to receive a royalty amount equal to 10% of any value generated by AZSTARYS and any product candidates containing SDX.

In July 2020, we entered into the Corium Consulting Agreement under which Corium and Commave, respectively, engaged us to guide the product development and regulatory activities for certain current and potential future products in their portfolio, as well as continue supporting preparation for the potential commercial launch of AZSTARYS. Under the Corium Consulting Agreement, we were entitled to receive payments from Corium of up to $15.6 million, $13.6 million of which was paid in quarterly installments through March 31, 2022. The remaining $2.0 million was conditioned upon the approval by the FDA of the NDA for Corium's product candidate, ADLARITY. This $2.0 million was earned in the first quarter of 2022. Corium also agreed to be responsible for and reimburse us for all development, commercialization and regulatory expenses incurred as part of the performance of the consulting services. The Corium Consulting Agreement expired on March 31, 2023.

Results of Operations

Comparison of the three months ended** September 30, 2023 and 2022**(in thousands):

	Three months ended September 30,		Period-to-Period Change
	2023	2022	
Revenue, net	$ 2,895	$ 2,874	$ 21
Operating expenses:			
Cost of revenue	144	141	3
Research and development	12,297	5,385	6,912
Selling, general and administrative	5,818	3,974	1,844
Total operating expenses	18,259	9,500	8,759
Loss from operations	(15,364)	(6,626)	(8,738)
Other income (expense):			
Interest expense	(366)	(124)	(242)
Fair value adjustment related to derivative and warrant liability	—	22	(22)
Fair value adjustment related to investments	124	(139)	263
Interest and other income, net	1,738	218	1,520
Total other income (expense)	1,496	(23)	1,519
Loss before income taxes	(13,868)	(6,649)	(7,219)
Income tax (expense) benefit	(177)	33	(210)
Net loss	$ (14,045)	$ (6,616)	$ (7,429)

Net Loss

Net loss for the three months ended September 30, 2023, was $14.0 million, compared to net loss of $6.6 million for the three months ended September 30, 2022, an increase in net loss of $7.4 million. The change was primarily attributable to an increase in loss from operations of $8.7 million and an increase in other income of $1.5 million.

Revenue

Revenue for the three months ended September 30, 2023, was $2.9 million, which was consistent when compared to revenue of $2.9 million for the three months ended September 30, 2022. Royalties from AZSTARYS of $0.9 million, and French EAP reimbursements of $2.0 million drove net revenue for the three months ended September 30, 2023.

Cost of Revenue

Cost of revenue for the three months ended September 30, 2023, remained consistent with the cost of revenue for the three months ended September 30, 2022.

Research and Development

Research and development expenses increased by$6.9 million, from $5.4 million for the three months ended September 30, 2022, to $12.3 million for the three months ended September 30, 2023. This increase was primarily driven by the ongoing Phase 2 clinical trial in KP1077, along with the ongoing work to prepare the arimoclomol NDA for resubmission.

Selling, General and Administrative

Selling, general and administrative expenses increased by $1.8 million, from $4.0 million for the three months ended September 30, 2022, to $5.8 million for the three months ended September 30, 2023. The period-over-period increase was primarily related to an increase in personnel costs and professional fees.

Other Income (Expense)

Other income (expense) changed by $1.5 million, from $23,000 of expense for the three months ended September 30, 2022, to $1.5 million of income for the three months ended September 30, 2023. This increase was primarily attributable to a change in net interest expense and other items of $1.5 million.

Comparison of the nine months ended September 30, 2023, and 2022 (in thousands):

	Nine months ended September 30,		Period-to-Period Change
	2023	2022	
Revenue, net	$ 14,244	$ 8,139	$ 6,105
Operating expenses:			
Cost of revenue	946	200	746
Research and development	28,574	13,262	15,312
Selling, general and administrative	19,657	10,266	9,391
Acquired in-process research and development	—	17,663	(17,663)
Total operating expenses	49,177	41,391	7,786
Loss from operations	(34,933)	(33,252)	(1,681)
Other (expense) income:			
Interest expense	(745)	(165)	(580)
Fair value adjustment related to derivative and warrant liability	—	295	(295)
Fair value adjustment related to investments	451	(634)	1,085
Interest and other income, net	4,331	482	3,849
Total other income (expense)	4,037	(22)	4,059
Loss before income taxes	(30,896)	(33,274)	2,378
Income tax benefit	—	752	(752)
Net loss	$ (30,896)	$ (32,522)	$ 1,626

Net Loss

Net loss for the nine months ended September 30, 2023, was $30.9 million compared to net loss of $32.5 million for the nine months ended September 30, 2022, a decrease in net loss of $1.6 million. The change was primarily attributable to an increase in other income of $4.0 million, partially offset by an increase in loss from operations of $1.7 million. The net loss during the nine months ended September 30, 2022, included recognition of $17.7 million of expense related to acquired in-process research and development from the arimoclomol asset acquisition which was immediately expensed.

Revenue

Revenue for the nine months ended September 30, 2023, was $14.2 million, an increase of $6.1 million compared to revenue of $8.1 million for the nine months ended September 30, 2022. AZSTARYS net sales milestone revenues of $5.0 million, royalties from AZSTARYS of $2 .0 million, and French EAP reimbursements of $ 6.8 million primarily drove net revenue for the nine months ended September 30, 2023.

Cost of Revenue

Cost of revenue for the nine months ended September 30, 2023, w as $0.9 million, an increase of $0.7 million compared to $0.2 million cost of revenue for the nine months ended September 30, 2022. The increase was primarily attributable to cost of goods sold under the AZSTARYS License Agreement.

Research and Development

Research and development expenses increased by $15.3 million, from $13.3 million for the nine months ended September 30, 2022, to $28.6 million for the nine months ended September 30, 2023. This increase was primarily driven by the ongoing Phase 2 clincial trial in KP1077, along with the ongoing work to prepare the arimoclomol NDA for resubmission .

Selling, General and Administrative

Selling, general and administrative expenses increased b y $9.4 million, from $10.3 million for the nine months ended September 30, 2022, to $19.7 million for the nine months ended September 30, 2023. The period-over-period increase was primarily related to an increase in personnel costs and professional fees.

Acquired In-Process Research and Development

Acquired in-process research and development expense decreased by $17.7 million, from $17.7 million for the nine months ended September 30, 2022, to none for the nine months ended September 30, 2023. This decrease was due to one-time acquired in-process research and development expense in 2022 as a result of the transactions under Arimoclomol Purchase Agreement.

Other Income (Expense)

Other income (expense) changed by $4.0 million, from $22,000 of expense for the nine months ended September 30, 2022 , to $4.0 million of income for the nine months ended September 30, 2023 . This increase was primarily attributable to a change in interest and other income, net of $3.8 million, a change in fair value adjustment related to investments of $1.1 million; partially offset by a change in net interest expense of $0.6 million and a change in fair value adjustment related to derivative and warrant liability of $0.3 million.

Liquidity and Capital Resources

Sources of Liquidity

Through September 30, 2023, we have funded our research and development and operating activities primarily through the issuance of debt, private placements of redeemable convertible preferred stock and the sale of common stock in our initial public offering, at-the-market offering, underwritten public offerings, through our purchase agreements with Lincoln Park Capital LLC, or Lincoln Park, and from revenue received under the Arimoclomol EAP, AZSTARYS License Agreement, the Corium Consulting Agreement and other consulting arrangements. As of September 30, 2023, we had cash, cash equivalents and investments of $83.4 million.

To date, we have generated revenue from the Arimoclomol EAP, AZSTARYS License Agreement, reimbursement of out-of-pocket third-party costs, and the performance of consulting services.

In July 2020, we entered into the Corium Consulting Agreement under which Corium and Commave, respectively, engaged us to guide the product development and regulatory activities for certain current and potential future products in their portfolio, as well as continue supporting preparation for the potential commercial launch of AZSTARYS. Under the Corium Consulting Agreement, we were entitled to receive payments from Corium of up to $15.6 million, $13.6 million of which was paid in quarterly installments through March 31, 2022. The remaining $2.0 million was conditioned upon the approval by the FDA of the NDA for Corium's product candidate, ADLARITY. This $2.0 million was earned in the first quarter of 2022. Corium also agreed to be responsible for and reimburse us for all development, commercialization and regulatory expenses incurred as part of the performance of the consulting services. The Corium Consulting Agreement expired on March 31, 2023.

We have had recurring negative net operating cash flows and we anticipate that we may continue to incur negative net cash flows or minimal positive net cash flows from operations for at least the next several years. We expect that our sources of revenue will be through payments arising from our license agreements with Corium, through the Arimoclomol EAP or through potential consulting arrangements and any other future arrangements related to one of our product candidates.

We filed a registration statement on Form S-3 covering the sale of the shares of our common stock up to $350.0 million, $75.0 million of which was allocated to the sales of the shares of common stock issuable under the Equity Distribution Agreement. The Form S-3 was declared effective on July 12, 2021. As of September 30, 2023, no shares have been issued or sold under the Equity Distribution Agreement.

Share Repurchase Program

On December 20, 2021, we initiated the Share Repurchase Program, pursuant to which we may repurchase up to $50 million of shares of our common stock through December 31, 2023. Capital allocation to the Share Repurchase Program will be based on a variety of factors, including our business results, the receipt of royalties and sales milestones under the AZSTARYS License Agreement, and potentially other sources of non-dilutive capital that may become available to us. Repurchases will be made in compliance with Rule 10b-18 of the Securities Exchange Act of 1934, as amended, subject to a variety of factors, including the market price of our common stock, general market and economic conditions and applicable legal requirements. The exact number of shares to be repurchased by us is not guaranteed and the program may be suspended, modified, or discontinued at any time without prior notice. We did not repurchase any shares of our common stock during the three months ended September 30, 2023. As of September 30, 2023, we had repurchased an aggregate of 1,575,692 shares of our common stock for approximately $11.0 million under the Share Repurchase Program.

Line of Credit

On May 31, 2022, we and Ameris Bank, as lender, entered into a $20.0 million revolving loan agreement, or the Line of Credit. Proceeds of the revolving facility provided by the Line of Credit are to be used for general corporate purposes. Loans under the Line of Credit bear interest at the Secured Overnight Financing Rate, or SOFR, plus 1.60%, with a SOFR floor of 0.00%

The revolving facility under the Line of Credit is secured by a perfected security interest in deposit accounts. The revolving facility under the Line of Credit is subject to customary affirmative and negative covenants.

The latest maturity date of the loans under the Line of Credit is May 31, 2025. The Line of Credit contains customary events of default that could lead to an acceleration of the loans, including cross-default, bankruptcy and payment defaults. As of December 31, 2022, we had drawn $12.8 million from the Line of Credit to finance the transactions under the Arimoclomol Purchase Agreement, and this amount was supported by a $12.8 million certificate of deposit which was shown as long-term investments - other in the condensed consolidated balance sheet as of December 31, 2022. The remaining $7.2 million available under the Line of Credit was secured by a separate interest-bearing certificate of deposit and was also recorded as long-term investments - other in the condensed consolidated balance sheet as of December 31, 2022. These certificates of deposit were pledged as collateral against the Line of Credit and could not be redeemed so long as the $20.0 million remained available under the Line of Credit. The total value of the certificates of deposit held with Ameris Bank must meet or exceed the amount available to borrow under the Line of Credit so long as the Line of Credit remains active. On January 31, 2023, we repaid the $12.8 million outstanding under the Line of Credit in full, and subsequently closed the Line of Credit during the first quarter of 2023. In conjunction with closing the Line of Credit, the maturity dates of the certificates of deposit were modified to May 2023.

On January 26, 2023, we and Wells Fargo, as lender, entered into a margin account agreement. Our investments are used as collateral for the loan and the amount we are able to borrow is limited to 80-90% of our outstanding investment balance held with Wells Fargo. The margin account bears interest at the Prime Rate minus 225 basis-points. As of September 30, 2023, $38.8 million was outstanding under the margin account.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine months ended September 30,	
	2023	2022
Net cash used in operating activities	$ (17,377)	$ (14,255)
Net cash used in investing activities	(27,975)	(36,656)
Net cash provided by financing activities	23,460	8,609
Effect of exchange rates on cash and cash equivalents	(305)	15
Net decrease in cash and cash equivalents	$ (22,197)	$ (42,287)

Operating Activities

For the nine months ended September 30, 2023, net cash used in operating activities of $17.4 million consisted of a net loss of $30.9 million; partially offset by $4.5 million in adjustments for non-cash items and $9.0 million in changes in working capital. Net loss was primarily attributable to our spending on research and development programs and operating costs; partially offset by revenue received under the AZSTARYS License Agreement, Arimoclomol EAP and the Corium Consulting Agreement. The changes in working capital consisted of $3.9 million related to a change in discount and rebate liabilities, $5.8 million related to a change in accounts payable and accrued expenses, $0.2 million related to a change in operating lease right-of-use assets,$0.2 million related to a change in inventories, and $0.1 million related to a change in prepaid expenses and other assets, $0.7 million related to a change in other liabilities; partially offset by $1.6 million related to a change in accounts and other receivables and $0.3 million related to a change in operating lease liabilities. The adjustments for non-cash items primarily consisted of stock-based compensation expense of $3.1 million, non-cash severance expense of $1.4 million, and $0.5 million related to depreciation, amortization and other items; partially offset by a change in the fair value adjustment related to investments of $0.5 million.

For the nine months ended September 30, 2022, net cash used in operating activities of $14.3 million consisted of a net loss of $32.5 million and $3.9 million in changes in working capital; partially offset by $22.2 million in adjustments for non-cash items. Net loss was primarily attributable to our spending on research and development programs and operating costs, partially offset by revenue received under the AZSTARYS License Agreement, Arimoclomol EAP and the Corium Consulting Agreement. The changes in working capital consisted of $1.2 million related to a change in prepaid expenses and other assets, $4.6 million related to a change in accounts and other receivables, $0.2 million related to a change in operating lease liabilities and $0.4 million related to a change in other liabilities, partially offset by $1.3 million related to a change in accounts payable and accrued expenses, $0.3 million related to a change in inventories, $0.1 million related to a change in operating lease right-of-use assets and $0.9 million related to a change in discount and rebate liabilities. The adjustments for non-cash items primarily consisted of stock-based compensation expense of $3.3 million, a change in the fair value adjustment related to investments of $0.6 million, $17.7 million related to acquired in-process research and development which was expensed as part of the transactions under the Arimoclomol Purchase Agreement and $0.8 million related to depreciation, amortization and other items, partially offset by a change in the fair value adjustment related to derivative and warrant liabilities of $0.3 million.

Investing Activities

For the nine months ended September 30, 2023, net cash used in investing activities was $28.0 million, which was primarily attributable to purchases of investments of $45.8 million, purchases of secured corporate notes of $25.4 million, and purchases of property and equipment of $0.2 million; partially offset by maturities of investments of $43.4 million.

For the nine months ended September 30, 2022, net cash used in investing activities was $36.7 million, which was attributable to net acquisition costs of the transactions under the Arimoclomol Purchase Agreement of $14.1 million and purchases of investments of $23.8 million; partially offset by maturities of investments of $1.3 million.

Financing Activities

For the nine months ended September 30, 2023, net cash provided by financing activities was $23.5 million, which was primarily attributable to proceeds from the issuance of debt of $38.8 million, proceeds from insurance financing programs of $1.3 million and proceeds from the Employee Stock Purchase Plan of $0.1 million; partially offset by repayment of debt of $12.8 million, payments to repurchase shares as part of the Share Repurchase Program of $3.4 million, and payments of principal on insurance financing arrangements of $0.5 million.

For the nine months ended September 30, 2022, net cash provided by financing activities was $8.6 million, which was primarily attributable to proceeds from the issuance of debt of $12.8 million, proceeds from insurance financing arrangements of $1.3 million and proceeds from sales of common stock under the Employee Stock Purchase Plan of $0.2 million; partially offset by payments to repurchase shares as part of the Share Repurchase Program of $4.7 million, payments of principal on insurance financing arrangements of $0.9 million and payment of offering costs of $0.1 million.

Future Funding Requirements

Based on our current operating forecast, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our operations into 2026. This estimate includes the ongoing reimbursements from the French early access program for arimoclomol, completion of the arimoclomol NDA resubmission, commercial activities to support the launch of arimoclomol, if approved, and completion of the KP1077 development program for IH up to NDA submission This estimate does not include revenue from arimoclomol after potential FDA approval, or the potential sale of the priority review voucher of arimoclomol, which would be received at that time, as well, or the costs of a Phase 3 trial for KP1077 in narcolepsy. Certain of the milestones are associated with regulatory matters that are outside our control. In addition, we maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of a failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Potential near-term sources of additional funding include:

- any consulting revenue or short-term milestone payments generated under the AZSTARYS License Agreement;
- any product sales under the Arimoclomol EAP; and
- any consulting services revenue generated under other potential consulting arrangements.

We cannot guarantee that we will be able to generate sufficient proceeds from any of these potential sources to fund our operating expenses. We anticipate that our expenses will fluctuate substantially as we:

- continue our ongoing preclinical studies, clinical trials and our product development activities for our pipeline of product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue research and preclinical development and initiate clinical trials of our product candidates;
- seek to discover and develop additional product candidates either internally or in partnership with other pharmaceutical companies;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio; and
- incur additional legal, accounting and other expenses in operating as a public company.

In addition, if the Proposed Merger is consummated, we will assume certain of Acer’s contractual obligations, which include $1.5 million owed by Zevra to Relief Therapeutics, Inc. Additionally, in connection with and immediately prior to the execution of the Merger Agreement, we entered into the Bridge Loan Agreement and the Loan and Note Purchase Agreements. For additional information, see Note K to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. To date, we have generated revenue from the AZSTARYS License Agreement, reimbursements of out-of-pocket third-party costs, the performance of consulting services and product sales under the Arimoclomol EAP. We expect that, for the foreseeable future, our only sources of revenues will be through payments arising from the AZSTARYS License Agreement, through potential consulting arrangements and any other future arrangements related to one of our product candidates and product sales under the Arimoclomol EAP. While we have entered into the AZSTARYS License Agreement to develop, manufacture and commercialize AZSTARYS, we cannot guarantee that this, or any strategy we adopt in the future, will be successful. For instance, we received milestone payments under the AZSTARYS License Agreement, but we cannot guarantee that we will earn any additional milestone or royalty payments under this agreement in the future. We also cannot guarantee that we will continue to generate revenue under the Arimoclomol EAP. We also expect to continue to incur additional costs associated with operating as a public company.

We have based our estimates of our cash needs and cash runway on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect and we cannot guarantee that we will be able to generate sufficient proceeds from the AZSTARYS License Agreement, product reimbursements under the Arimoclomol EAP and potential consulting arrangements or other funding transactions to fund our operating expenses. To meet any additional cash requirements, we may seek to sell additional equity or convertible securities that may result in dilution to our stockholders, issue additional debt or seek other third-party funding, including potential strategic transactions, such as licensing or collaboration arrangements. Because of the numerous risks and uncertainties associated with the development and commercialization of product candidates and products, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the commercialization and development of our partnered product or product candidates, should they obtain regulatory approval.

Critical Accounting Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of our unaudited condensed consolidated financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our unaudited condensed consolidated financial statements, as well as the reported revenues and expenses during the reported periods. We evaluate these estimates on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies have not changed materially from those described in *Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations* of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 7, 2023.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023. Based on the evaluation of our disclosure controls and procedures as of September 30, 2023, our chief executive officer and our chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during our fiscal quarter ended September 30, 2023, that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be involved in routine legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business. We believe there is no litigation pending that would reasonably be expected to, individually or in the aggregate, have a material adverse effect on our results of operations or financial condition.

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider all the risk factors and uncertainties described in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 7, 2023, before investing in our common stock. Except as discussed below, there have been no material changes to the risk factors described in that report. If any of those risks materialize, our business, financial condition and results of operations could be seriously harmed. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements because of those risk factors and the other factors described in in this Quarterly Report on Form 10-Q.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our senior leadership team, as well as the other members of our scientific and clinical teams. Although we have employment agreements with each of our executive officers, these agreements do not obligate them to continue working for our company and they may terminate their employment with us at any time. Among other recent changes in our senior management team, our new Chief Executive Officer was appointed effective October 10, 2023. Our future performance will depend, in part, on a successful transition period with our new Chief Executive Officer, the successful integration of any other new senior level executives into their roles, and the continuity of leadership among the larger workforce. If we do not successfully manage these transitions, it could be viewed negatively by our customers, employees, investors, and other third-party partners, and could have an adverse impact on our business and results of operations.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product candidate pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our prodrug product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We could be negatively affected as a result of the actions of activist stockholders, which could be disruptive and costly and may conflict with or disrupt the strategic direction of our business.

In January 2023, our board of directors received notice from a stockholder of his intention to nominate three nominees to stand for election to our board of directors at our 2023 annual meeting of stockholders and to submit a proposal at the annual meeting, which resulted in a contested election at the annual meeting at which such nominees were elected by our stockholders. Similar to the activist stockholder activities initiated in January 2023, activist stockholders may from time to time attempt to effect changes in our strategic direction and seek changes regarding our corporate governance or structure. Our board of directors and management team strive to maintain constructive, ongoing communications with all stockholders who wish to speak with us, including activist stockholders, and welcome their views and opinions with the goal of working together constructively to enhance value for all stockholders. Any future proxy contest with respect to election of our directors, or other activist stockholder activities, could adversely affect our business because: (1) responding to a proxy contest and other actions by activist stockholders can be costly and time-consuming, disruptive to our operations and divert the attention of management and our employees; (2) actual or perceived uncertainties as to our future direction caused by activist activities may cause or appear to cause instability or lack of continuity, resulting in the loss of potential business opportunities, and potentially making it more difficult to attract and retain qualified personnel and business partners; and (3) if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plans. Activist stockholder activities may also cause significant fluctuations in our stock price based on temporary or speculative market perceptions, or other factors that do not necessarily reflect the fundamental underlying value of our business.

Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults, or non-performance by financia institutions, could adversely affect our business, financial condition or results of operations.

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash, cash equivalents, and investments. The Company invests in money market funds, U.S. treasury securities, and U.S. government agency securities. The Company maintains bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash and cash equivalents to the extent recorded on the unaudited condensed consolidated balance sheets. Should events, including limited liquidity, defaults, non-performance or other adverse developments occur with respect to the banks or other financial institutions that hold our funds, or that affect financial institutions or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, our liquidity may be adversely affected. For example, on March 10, 2023, the Federal Deposit Insurance Corporation (FDIC) announced that Silicon Valley Bank had been closed by the California Department of Financial Protection and Innovation. Although we did not have any funds in Silicon Valley Bank or other institutions that have been closed, we cannot guarantee that the banks or other financial institutions that hold our funds will not experience similar issues.

Risks Related to the Proposed Merger

The consummation of the Proposed Merger is subject to a number of conditions, many of which are largely outside of the parties' control, and, if these conditions are not satisfied or waived on a timely basis, the Proposed Merger Agreement may be terminated and the Proposed Merger may not be completed.

The Proposed Merger is subject to certain customary closing conditions, including: (i) obtaining the required stockholder approval; (ii) the waiting period, if any, applicable to the consummation of the Proposed Merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"), will have expired or been terminated; and (iii) the absence of any law or order of any governmental authority of competent jurisdiction that enjoins, prohibits or makes illegal the consummation of the Proposed Merger. In addition, each of Zevra's and Acer's obligations to complete the Proposed Merger is subject to certain other conditions, such as (a) the accuracy of the representations and warranties of the other party, subject to the standards set forth in the Merger Agreement; (b) compliance by the other party with its covenants in all material respects; and (c) the absence of a material adverse effect on Acer. The failure to satisfy all of the required conditions could delay the completion of the Proposed Merger by a significant period of time or prevent it from occurring. Any delay in completing the Proposed Merger could cause the parties to not realize some or all of the benefits that are expected to be achieved if the Proposed Merger is successfully completed within the expected timeframe. There can be no assurance that the conditions to closing of the Proposed Merger will be satisfied or waived or that the Proposed Merger will be completed.

While the Proposed Merger is pending, Zevra and Acer will be subject to business uncertainties and certain contractual restrictions that could adversely affect the business and operations of Zevra and Acer.

In connection with the Proposed Merger, some tenants, operators, borrowers, managers, vendors or other third parties of each of Zevra and Acer may react unfavorably, delay or defer decisions concerning their business relationships or transactions with Zevra or Acer, which could adversely affect the revenues, earnings, funds from operations, cash flows and expenses of Zevra and Acer, regardless of whether the Proposed Merger is completed.

Zevra and Acer will incur substantial transaction fees and Merger-related costs in connection with the Proposed Merger.

Zevra and Acer expect to incur non-recurring transaction fees, which include legal and advisory fees and substantial Merger-related costs associated with completing the Proposed Merger, combining the operations of the two companies and achieving desired synergies. Additional unanticipated costs may be incurred in the course of the integration of the businesses of Zevra and Acer. The companies cannot be certain that the realization of other benefits related to the integration of the two businesses will offset the transaction and Merger-related costs in the near term, or at all.

Litigation against Acer, Zevra or the members of their respective boards, could prevent or delay the completion of the Proposed Merger or result in the payment of damages following completion of the Proposed Merger.

It is a condition to the Proposed Merger that no temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Merger Agreement or the transactions contemplated thereby shall have been issued by any court of competent jurisdiction or other governmental authority of competent jurisdiction and remain in effect. Zevra or Acer stockholders may file lawsuits challenging the Proposed Merger or the other transactions contemplated by the Merger Agreement, which may name Zevra, members of the Zevra Board, Acer and/or members of the Acer Board as defendants. Following the announcement of the Proposed Merger, three purported stockholders of Acer filed complaints alleging that the definitive proxy statement filed on October 10, 2023, in connection with the Merger omitted material information with respect to the Merger and demanding that the Merger be enjoined unless certain supplemental disclosures are made. For additional information, see Note K to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. The outcome of such lawsuits cannot be assured, including the amount of costs associated with defending these claims or any other liabilities that may be incurred in connection with the litigation of these claims. If plaintiffs are successful in obtaining an injunction prohibiting the parties from completing the Proposed Merger on the agreed-upon terms, such an injunction may delay the consummation of the Proposed Merger in the expected timeframe, or may prevent the Proposed Merger from being consummated at all. Whether or not any plaintiff's claim is successful, this type of litigation can result in significant costs and divert management's attention and resources from the Closing and ongoing business activities, which could adversely affect the operation of Zevra's and Acer's businesses.

Zevra is required to use "diligent efforts" to achieve the milestones, which allows for consideration of a variety of factors to determine the efforts Zevra is required to take; accordingly, under certain circumstances, Zevra may not be required to take certain actions to achieve the milestones, which would have an adverse effect on the value, if any, of the CVRs.

Zevra has agreed to use "diligent efforts," as defined in the CVR Agreement, to achieve the milestones. Under the CVR Agreement, the definition of "diligent efforts" requires Zevra to use such efforts and resources normally used by a company in the pharmaceutical business similar in size and resources to Zevra, in the exercise of their reasonable business discretion, relating to development of, seeking regulatory approval of or commercializing, as applicable, a similar product, that is of similar market potential and at a similar development stage, regulatory stage or commercialization stage. The CVR Agreement allows for the consideration of a variety of factors in determining such effort, including without limitation:

- market exclusivity (including patent coverage, regulatory and other exclusivity);
- product profile, including efficacy, safety, tolerability, methods of administration, product labeling (including anticipated product labeling);
- other product candidates;
- the competitiveness of alternative products in the marketplace or under development;
- the regulatory environment and the expected profitability of the applicable product (including direct regulatory required support and medical affairs costs, direct intellectual property defense costs, and direct distribution and logistics costs); and • other relevant commercial, financial, technical, legal, scientific and/or medical factors. As a result, factors and events may come to pass that result in Zevra permissibly devoting less effort to the achievement of the milestone than Acer would have devoted had Acer remained a stand-alone company.

If the Proposed Merger is not consummated by February 29, 2024 (or, under certain circumstances, May 29, 2024), either Acer or Zevra may terminate the Merger Agreement.

Either Acer or Zevra may terminate the Merger Agreement if the Proposed Merger has not been consummated by February 29, 2024, subject to automatic extension to May 29, 2024, if, as of February 29, 2024, all of the closing conditions have been satisfied other than the expiration or earlier termination of any applicable waiting period under the HSR Act. However, this termination right will not be available to a party if that party failed to fulfill its obligations under the Merger Agreement and that failure was the principal cause of, or directly resulted in, the failure to consummate the Proposed Merger on time. In the event the Merger Agreement is terminated by either party due to the failure of the Proposed Merger to close by February 29, 2024 (or, under certain circumstances, May 29, 2024), Acer will have incurred significant costs and will have diverted significant management focus and resources from other strategic opportunities and ongoing business activities without realizing the anticipated benefits of the Proposed Merger.

Risks Related to the Combined Company Following the Proposed Merger

The financial analyses and forecasts considered by Acer and its financial advisor may not be realized, which may adversely affect the market price of Zevra's Common Stock following the completion of the Proposed Merger.

In performing its financial analyses and rendering its opinions related to the Proposed Merger, William Blair & Company, LLC ("William Blair"), who was retained to act as exclusive financial advisor to Acer in connection with a possible business combination, relied on, among other things, internal standalone financial analyses and forecasts as separately provided by Acer. These analyses and forecasts were prepared by, or as directed by, the management of Acer and provided to William Blair on August 24, 2023 and approved by Acer for William Blair's use. None of these analyses or forecasts were prepared with a view towards public disclosure or compliance with the published guidelines of the SEC, the U.S. generally accepted accounting principles ("GAAP"), or the guidelines established by the American Institute of Certified Public Accountants for preparation and presentation of financial forecasts. These projections are inherently based on various estimates and assumptions that are subject to the judgment of those preparing them. These projections are also subject to significant economic, competitive, industry and other uncertainties and contingencies, all of which are difficult or impossible to predict and many of which are beyond the control of Zevra and Acer. There can be no assurance that Acer's or the combined company's financial condition or results of operations will be consistent with those set forth in such analyses and forecasts, which could have an adverse impact on the market price of Zevra's common stock or the financial position of the combined company following the Proposed Merger. William Blair expressed no opinion in the opinion as to the price at which Zevra's common stock will trade at any future time or as to the effect of the Proposed Merger on the trading prices of Zevra's common stock.

Following the Proposed Merger, Zevra may be unable to integrate the Acer business successfully or realize the anticipated synergies and related benefits of the Proposed Merger.

Zevra and Acer entered into the Merger Agreement with the expectation that the Proposed Merger will result in various benefits and synergies. However, the Proposed Merger involves the combination of two companies that currently operate as independent public companies. In particular, as discussed above in "—Acer may need additional capital to meet its current obligations and continue to operate its business if the Proposed Merger is not completed in a timely fashion" and "The Merger—Acer Reasons for the Merger," prior to the signing of the Merger Agreement and the extension of the Bridge Loan, Acer's assets consisted primarily of approximately $0.6 million in cash or cash equivalents and certain product rights. Moreover, prior to the Merger Agreement, Acer had historically been unable to fund its operations on a standalone basis without substantial additional investment. Even after the Closing, Zevra may be unable to successfully operate Acer's business or integrate it into its own operations as a combined company.

After the Closing, Zevra will be required to devote significant management attention and resources to integrating the portfolio and operations of Acer. Potential difficulties that Zevra may encounter in the integration process include the following:

- the inability to combine the businesses of Zevra and Acer in a manner that permits Zevra to achieve the cost savings or other synergies anticipated as a result of the Proposed Merger or to achieve such cost savings or other anticipated synergies in a timely manner, which could result in Zevra not realizing some anticipated benefits of the Proposed Merger in the time frame currently anticipated, or at all;

- the inability to realize the anticipated value from various Acer assets;

- the inability to coordinate and integrate research and development teams across technologies and products to enhance product development;

- the inability to integrate and manage personnel from the companies and minimizing the loss of key employees;

- the inability to consolidate the companies' administrative and information technology infrastructure and financial systems and identify and eliminate redundant and underperforming functions and assets;

- the inability to harmonize the companies' operating practices, employee development and compensation programs, internal controls and other policies, procedures and processes;

- the inability to coordinate distribution and marketing efforts;

- potential unknown liabilities and unforeseen increased expenses, delays or unfavorable conditions in connection with the Closing and the subsequent integration; and

- performance shortfalls at one or both of the companies as a result of the diversion of management's attention from ongoing business activities as a result of completing the Proposed Merger and integrating the companies' operations.

It is possible that the integration process could result in the distraction of Zevra's management, the loss of key employees, the disruption of Zevra's ongoing business or inconsistencies in Zevra's operations, services, standards, controls, procedures and policies, any of which could adversely affect the ability of Zevra to maintain relationships with third parties and employees or to achieve the anticipated benefits of the Proposed Merger, or could otherwise adversely affect the business and financial results of Zevra.

Zevra's future results will suffer if it does not effectively manage its expanded operations following the Proposed Merger.

Following the Proposed Merger, the size and scope of operations of the business of the combined company will increase beyond the current size and scope of operations of either Zevra's or Acer's current businesses. In addition, Zevra may continue to expand its size and operations through additional acquisitions or other strategic transactions. Zevra's future success depends, in part, upon its ability to manage its expanded business, which may pose substantial challenges for its management, including challenges related to the management and monitoring of new operations and locations and associated increased costs and complexity. There can be no assurances that Zevra will be successful in managing such expanded business or that it will realize the expected economies of scale, synergies and other benefits currently anticipated from the Proposed Merger or anticipated from any additional acquisitions or strategic transactions.

The market price of Zevra Common Stock may decline as a result of the completion of the Proposed Merger.

The market price of Zevra Common Stock may decline as a result of the completion of the Proposed Merger for a number of reasons, including if Zevra does not achieve the perceived benefits of the Proposed Merger as rapidly or to the degree anticipated by financial and industry analysts, or if the effect of the Proposed Merger on Zevra's financial results is not consistent with the expectations of financial and industry analysts. In addition, if the Proposed Merger is consummated, Zevra stockholders, including the former Acer Stockholders, will own interests in a company operating an expanded business with a different mix of assets, risks and liabilities. Current stockholders of Zevra and former Acer Stockholders may not wish to continue to invest in Zevra, or for other reasons may wish to dispose of some or all of their shares of Zevra Common Stock. If, following the consummation of the Proposed Merger, there is selling pressure on Zevra Common Stock that exceeds demand at the market price, the price of Zevra Common Stock could decline.

The combined company may not be able to retain suppliers or distributors, or suppliers or distributors may seek to modify contractual relationships with the combined company, which could have an adverse effect on the combined company's business and operations. Third parties may terminate or alter existing contracts or relationships with Zevra or Acer.

As a result of the Proposed Merger, the combined company may experience impacts on relationships with customers, suppliers and distributors that may harm the combined company's business and results of operations. Certain suppliers or distributors may seek to terminate or modify contractual obligations following the Proposed Merger whether or not contractual rights are triggered as a result of the Proposed Merger. There can be no guarantee that customers, suppliers and distributors will remain with or continue to have a relationship with the combined company or do so on contractual terms amenable to Zevra following the Proposed Merger. If any suppliers or distributors seek to terminate or modify contractual obligations or discontinue their relationship with the combined company, then the combined company's business and results of operations may be harmed.

Acer (or certain of its subsidiaries) also has contracts with vendors, landlords and other business partners which may require Acer (or certain of its subsidiaries) to obtain consent from or provide notice to these other parties in connection with the Proposed Merger, or which may otherwise contain limitations applicable to such contracts following the Proposed Merger. If these consents cannot be obtained, the combined company may suffer a loss of potential future revenue, incur costs and lose rights that may be material to the combined company's business. In addition, third parties with whom Zevra and Acer currently have relationships may terminate or otherwise reduce the scope of their relationship with either party in anticipation of the Proposed Merger. Any such disruptions could limit the combined company's ability to achieve the anticipated benefits of the Proposed Merger. The adverse effect of any such disruptions could also be exacerbated by a delay in the completion of the Proposed Merger or by a termination of the Merger Agreement

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities By the Issuer and Affiliated Purchasers

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

(a) None.

(b) None.

(c) Not applicable.

ITEM 6. EXHIBITS

The following is a list of exhibits filed as part of this Form 10-Q (the SEC file number for all items incorporated by reference herein from reports on Forms 10-K, 10-Q, and 8-K is 001-36913):

Exhibit No.	Description
2.1***	Agreement and Plan of Merger dated as of August 30, 2023, by and among Zevra Therapeutics, Inc., Aspen Z. Merger Sub. Inc., and Acer Therapeutics Inc. (incorporated herein by reference to the Registrants' Current Report on 8-K as filed with the SEC on August 31, 2023).
3.1	Amended and Restated Certificate of Incorporation of Zevra Therapeutics, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on April 21, 2015).
3.1.1	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant, effective as of December 23, 2020 (incorporated herein by reference to Registrant's Current Report on Form 8-K as filed with the SEC on December 23, 2020).
3.1.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Zevra Therapeutics, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 24, 2023).
3.2	Amended and Restated Bylaws, as currently in effect, of Zevra Therapeutics, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 24, 2023).
4.1	Specimen stock certificate evidencing shares of Common Stock (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 12, 2021).
10.1	Employment Agreement, effective as of October 10, 2023, between the Registrant and Neil F. McFarlane (incorporated herein by reference to the Registrant's Current Report on 8-K as filed with the SEC on October 10, 2023).
10.2	Bridge Loan Agreement dated as of August 30, 2023, by and between Zevra Therapeutics, Inc. and Acer Therapeutics Inc. (incorporated herein by reference to the Registrants' Current Report on 8-K as filed with the SEC on August 31, 2023).
10.3***	Loan Purchase Agreement dated as of August 30, 2023, by and among Zevra Therapeutics, Inc. and Nantahala Capital Management, LLC and the other sellers party thereto (incorporated herein by reference to the Registrants' Current Report on 8-K as filed with the SEC on August 31, 2023).
10.4***	Note Purchase Agreement dated as of August 30, 2023, by and among Zevra Therapeutics, Inc. and Nantahala Capital Management, LLC and the other sellers party thereto (incorporated herein by reference to the Registrants' Current Report on 8-K as filed with the SEC on August 31, 2023).
10.5	Registration Rights Agreement dated as of August 30, 2023, by and among Zevra Therapeutics, Inc. and each of the sellers party thereto (incorporated herein by reference to the Registrants' Current Report on 8-K as filed with the SEC on August 31, 2023).
10.6***	Voting and Support Agreement dated as of August 30, 2023, by and among Zevra Therapeutics, Inc. Aspen Z Merger Sub., Inc. and certain stockholders of Acer Therapeutics Inc. (incorporated herein by reference to the Registrants' Current Report on 8-K as filed with the SEC on August 31, 2023).
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1**	Certification of the Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18. U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18. U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104**	Cover page Interactive Data File (embedded within the Inline XBRL and combined in Exhibit 101)

* Filed herewith

** Furnished herewith

*** Pursuant to Item 601(a)(5) of Regulation S-K, schedules and similar attachments have been omitted. The registrant hereby agrees to furnish a copy of any omitted schedule or similar attachment to the SEC upon request.

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 thereunto duly authorized.

Zevra Therapeutics, Inc.

Date: November 7, 2023

By: /s/ Neil F. McFarlane
Neil F. McFarlane
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2023

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, MBA, CPA
Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

EXHIBIT 31.1

CERTIFICATION

I, Neil F. McFarlane, certify that:

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

November [ ], 2023

/s/ Neil F. McFarlane

Name: Neil F. McFarlane

Title: President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, R. LaDuane Clifton, certify that:

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

November [ ], 2023

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton, MBA, CPA

Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Zevra Therapeutics, Inc., (the "Company") for the quarterly period ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Neil F. McFarlane, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

November [ ], 2023

/s/ Neil F. McFarlane
Name: Neil F. McFarlane
Title: President and Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Zevra Therapeutics, Inc., (the "Company") for the quarterly period ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, R. LaDuane Clifton, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

November [ ], 2023

/s/ R. LaDuane Clifton
Name: R. LaDuane Clifton, MBA, CPA
Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.