UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2024

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: 001-38542

Kezar Life Sciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-3366145**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

4000 Shoreline Court, Suite 300
South San Francisco, CA, 94080
(650) 822-5600
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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, $0.001 par value	KZR	The Nasdaq Stock Market LLC
Preferred Share Purchase Rights		The Nasdaq Stock Market LLC

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 8, 2024, the registrant had 7,296,222 shares of common stock, $0.001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve substantial risks and uncertainties. In some cases, you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "should," "would," "potential," "project," "plan," "expect," "seek," "target" or similar expressions, or the negative or plural of these words or expressions. These forward-looking statements include statements concerning the following:

- our plans to develop and commercialize our product candidates;
- the initiation, timing, progress and expected results of our current and future clinical trials and our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to maintain and establish collaborations or strategic relationships or obtain additional funding;
- the timing and likelihood of obtaining regulatory approval of our current and future product candidates;
- the potential milestone and royalty payments under certain of our license agreements;
- our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources;
- the implementation of our business model and strategic plans for our business and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights and the duration of our patent rights covering our product candidates;
- developments or disputes concerning our intellectual property or other proprietary rights;
- the scalability and commercial viability of our manufacturing methods and processes;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets for our product candidates;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad, including as a result of bank failures, public health crisis or geopolitical tensions;
- the impact of government laws and regulations;
- developments relating to our competitors and our industry; and
- other factors that may impact our financial results.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" and elsewhere in this report. You should not rely upon forward-looking statements as predictions of future events.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements in this report, whether as a result of new information, future events or otherwise, after the date of this report.

Unless the context otherwise requires, the terms "Kezar," "Kezar Life Sciences," "the Company," "we," "us," "our" and similar references in this Quarterly Report on Form 10-Q refer to Kezar Life Sciences, Inc. and our wholly owned Australian subsidiary, Kezar Life Sciences Australia Pty Ltd.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

KEZAR LIFE SCIENCES, INC.

Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	September 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 34,858	$ 35,493
Marketable securities	113,530	165,879
Prepaid expenses and other current assets	7,991	5,578
Total current assets	156,379	206,950
Property and equipment, net	3,149	3,912
Operating lease right-of-use asset	2,143	4,778
Other assets	2,415	5,595
Total assets	$ 164,086	$ 221,235
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,461	$ 8,251
Accrued and other current liabilities	9,664	6,481
Operating lease liabilities, current	3,391	3,012
Debt, current	3,913	—
Total current liabilities	20,429	17,744
Operating lease liabilities, noncurrent	3,259	5,852
Debt, noncurrent	6,349	10,069
Total liabilities	30,037	33,665
Stockholders' equity:		
Common stock, $0.001 par value, 250,000,000 and 250,000,000 shares authorized as of September 30, 2024 (unaudited) and December 31, 2023, respectively; 7,296,222 and 7,277,908 shares issued and outstanding as of September 30, 2024 (unaudited) and December 31, 2023, respectively	7	7
Preferred stock, $0.001 par value, 10,000,000 shares authorized; zero shares issued and outstanding as of September 30, 2024 (unaudited) and December 31, 2023	—	—
Additional paid-in capital	548,216	538,456
Accumulated other comprehensive income (loss)	107	(130)
Accumulated deficit	(414,281)	(350,763)
Total stockholders' equity	134,049	187,570
Total liabilities and stockholders' equity	$ 164,086	$ 221,235

See accompanying notes to the unaudited condensed consolidated financial statements

KEZAR LIFE SCIENCES, INC.

Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration revenue	$ —	$ 7,000	$ —	$ 7,000
Operating expenses:				
Research and development	16,242	23,738	49,712	63,055
General and administrative	5,706	8,789	17,848	20,780
Restructuring and impairment charges	—	—	1,482	—
Total operating expenses	21,948	32,527	69,042	83,835
Loss from operations	(21,948)	(25,527)	(69,042)	(76,835)
Interest income	2,038	2,820	6,728	8,376
Interest expense	(403)	(396)	(1,204)	(1,151)
Net loss	$ (20,313)	$ (23,103)	$ (63,518)	$ (69,610)
Net loss per common share, basic and diluted	$ (2.78)	$ (3.18)	$ (8.72)	$ (9.60)
Weighted-average shares used to compute net loss per common share, basic and diluted	7,296,222	7,268,165	7,286,967	7,249,188

See accompanying notes to the unaudited condensed consolidated financial statements

KEZAR LIFE SCIENCES, INC.

Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	$ (20,313)	$ (23,103)	$ (63,518)	$ (69,610)
Other comprehensive income:				
Foreign currency translation adjustments	27	(23)	12	(40)
Unrealized gain on marketable securities	465	166	225	276
Total other comprehensive income, net of tax	492	143	237	236
Comprehensive loss	$ (19,821)	$ (22,960)	$ (63,281)	$ (69,374)

See accompanying notes to the unaudited condensed consolidated financial statements

KEZAR LIFE SCIENCES, INC.

Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands, except share amounts)

	COMMON STOCK SHARES	COMMON STOCK AMOUNTS	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE (LOSS) INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
Balance at December 31, 2023	7,277,908	$ 7	$ 538,456	$ (130)	$ (350,763)	$ 187,570
Issuance of common stock under employee stock incentive plans	2,228	—	—	—	—	—
Stock-based compensation expense	—	—	3,434	—	—	3,434
Other comprehensive loss	—	—	—	(225)	—	(225)
Net loss	—	—	—	—	(21,658)	(21,658)
Balance as of March 31, 2024	7,280,136	$ 7	$ 541,890	$ (355)	$ (372,421)	$ 169,121
Issuance of common stock under employee stock incentive plans	8,618	—	56	—	—	56
Stock-based compensation expense	—	—	3,085	—	—	3,085
Other comprehensive loss	—	—	—	(30)	—	(30)
Net loss	—	—	—	—	(21,547)	(21,547)
Balance as of June 30, 2024	7,288,754	$ 7	$ 545,031	$ (385)	$ (393,968)	$ 150,685
Issuance of common stock under employee stock incentive plans	7,468	—	—	—	—	—
Stock-based compensation expense	—	—	3,185		—	3,185
Other comprehensive income	—	—	—	492	—	492
Net loss	—	—	—	—	(20,313)	(20,313)
Balance as of September 30, 2024	7,296,222	$ 7	$ 548,216	$ 107	$ (414,281)	$ 134,049

	COMMON STOCK SHARES	COMMON STOCK AMOUNTS	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE (LOSS) INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
Balance at December 31, 2022	6,849,343	$ 7	$ 519,681	$ (923)	$ (248,893)	$ 269,872
Cashless exercise of pre-funded warrants	223,624	—	—	—	—	—
Issuance of common stock under employee stock incentive plans	8,633	—	154	—	—	154
Stock-based compensation expense	—	—	4,263	—	—	4,263
Other comprehensive income	—	—	—	400	—	400
Net loss	—	—	—	—	(22,199)	(22,199)
Balance as of March 31, 2023	7,081,600	$ 7	$ 524,098	$ (523)	$ (271,092)	$ 252,490
Cashless exercise of pre-funded warrants	155,665	—	—	—	—	—
Issuance of common stock under employee stock incentive plans	16,017	—	382	—	—	382
Stock-based compensation expense	—	—	4,020	—	—	4,020
Other comprehensive loss	—	—	—	(307)	—	(307)
Net loss	—	—	—	—	(24,308)	(24,308)
Balance as of June 30, 2023	7,253,282	$ 7	$ 528,500	$ (830)	$ (295,400)	$ 232,277
Issuance of common stock under employee stock incentive plans	16,015	—	43	—	—	43
Stock-based compensation expense	—	—	6,634	—	—	6,634
Other comprehensive income	—	—	—	143	—	143
Net loss	—	—	—	—	(23,103)	(23,103)
Balance as of September 30, 2023	7,269,297	$ 7	$ 535,177	$ (687)	$ (318,503)	$ 215,994

See accompanying notes to the unaudited condensed consolidated financial statements

KEZAR LIFE SCIENCES, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (63,518)	$ (69,610)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	781	786
Stock-based compensation	9,704	14,917
Amortization of premiums and discounts on marketable securities	(4,128)	(5,298)
Amortization of debt discount and issuance costs and other non-cash interest	193	176
Impairment loss of right-of-use asset	1,549	—
Loss on disposition of fixed assets	—	3
Changes in operating assets and liabilities		
Accounts receivable	—	(7,000)
Prepaid expenses and other current assets	(2,413)	3,850
Other assets	3,180	(5,661)
Accounts payable, accrued and other current liabilities	(1,607)	5,388
Operating lease assets and liabilities	(1,128)	(216)
Net cash used in operating activities	(57,387)	(62,665)
Cash flows from investing activities:		
Purchases of property and equipment	(18)	(1,809)
Proceeds from sale of equipment	—	5
Purchases of marketable securities	(72,102)	(130,528)
Maturities of marketable securities	128,804	180,500
Net cash provided by investing activities	56,684	48,168
Cash flows from financing activities:		
Proceeds from issuance of common stock under employee stock incentive plans	56	579
Net cash provided by financing activities	56	579
Effect of exchange rate changes on cash and cash equivalents	12	(40)
Net decrease in cash and cash equivalents	(635)	(13,958)
Cash and cash equivalents at the beginning of period	35,493	40,456
Cash and cash equivalents at the end of period	$ 34,858	$ 26,498
Supplemental disclosures of noncash investing and financing information:		
Purchases of property and equipment in accounts payable	$ —	$ 4
Par value of common stock upon cashless exercise of prefunded warrants	$ —	$ 4
Supplemental disclosures		
Cash paid for interest	$ 1,011	$ 975

See accompanying notes to the unaudited condensed consolidated financial statements

Kezar Life Sciences, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

1. Organization and Description of the Business

Description of Business

Kezar Life Sciences, Inc. (the "Company," "we," "us," or "our") was incorporated in the state of Delaware in February 2015 and commenced operations in June 2015. The Company is a clinical-stage biotechnology company developing novel small molecule therapeutics to treat unmet needs in immune-mediated diseases. The Company's principal operations are in South San Francisco, California, and it operates in one segment.

Reverse Stock Split

On October 29, 2024, the Company effected a reverse stock split of its common stock at a ratio of one-for-ten (the "Reverse Stock Split"), as authorized at the Company's 2024 annual meeting of stockholders held on June 18, 2024 and approved by the Company's board of directors on September 23, 2024. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders of record who otherwise were entitled to a fractional share of common stock as a result of the Reverse Stock Split were entitled to receive one full share of common stock in lieu of such fractional share.

The number of shares of common stock subject to outstanding options, restricted stock unit awards and other equity awards issued by the Company, and the number of shares reserved for future issuance and all other share limits were reduced by the same ratio as the reduction in the outstanding shares, in each case rounded down to the nearest whole share. As a result of the Reverse Stock Split, proportionate adjustments were made to the number of shares issuable under the Company's equity incentive plans and other existing agreements, as well as to the exercise or conversion prices, as applicable. There were no changes to the total number of authorized shares or the par value per share.

The Company has retroactively restated the shares and per share amounts in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q. The impact due to the issuance of full shares in lieu of fractional shares of common stock as a result of the Reverse Stock Split will be reflected in the period of issuance, which will be our fourth quarter. Proportionate adjustments were made to the per share exercise price and number of shares of common stock issuable under all outstanding stock options. In addition, proportionate adjustments have been made to the number of shares of common stock reserved for the Company's equity incentive plans. The condensed consolidated statements of stockholders' equity and balance sheets reflect the impact of the Reverse Stock Split by reclassifying from "common stock" to "additional paid-in capital" an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split.

Liquidity

Since commencing operations in mid-2015, substantially all of the Company's efforts have been focused on research, development, and the advancement of the Company's product candidates. The Company's ultimate success depends on the outcome of these ongoing research and development activities. The Company has not yet generated product sales and as a result has experienced operating losses since inception and had an accumulated deficit of $414.3 million as of September 30, 2024. The Company expects to incur additional losses in the future to conduct research and development and will need to raise additional capital to fully implement management's business plan. The Company intends to raise such capital through the issuance of additional equity, including through at-the-market ("ATM") offerings, and potentially through borrowings, strategic alliances with partner companies and other licensing transactions, such as our collaboration with Everest Medicines II (HK) Limited ("Everest"). However, if financing is not available at adequate levels, the Company may need to reevaluate its operating plans. Management believes that its existing cash, cash equivalents and marketable securities will be sufficient to fund the Company's cash requirements for at least 12 months following the issuance of these financial statements.

In December 2021, the Company entered into a Sales Agreement (the "ATM Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which the Company can offer and sell, from time to time at its sole discretion through Cowen, as its sales agent, shares of its common stock having an aggregate offering price of up to $200.0 million. Any shares of its common stock sold will be issued pursuant to the Company's shelf registration statement on Form S-3ASR (File No. 333-261774). The Company will pay Cowen a commission up to 3.0% of the gross sales proceeds of any shares of its common stock sold through Cowen under the ATM Agreement and also has provided Cowen with indemnification and contribution rights. As of December 31, 2023, the Company had sold an aggregate of 1,198,601 shares of its common stock for gross proceeds of approximately $131.7 million at a weighted average purchase price of $109.84 per share pursuant to the ATM Agreement. No shares were sold under the ATM Agreement during the nine months ended September 30, 2024. As of September 30, 2024, approximately $68.3 million remains available under the ATM Agreement.

2. Summary of Significant Accounting Policies

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2023 and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the U.S. Securities and Exchange Commission ("SEC") on March 14, 2024 (the "Annual Report"), and there have been no material changes to such policies during the nine months ended September 30, 2024.

Basis of Presentation and Consolidation

The condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and include the Company's accounts and those of its wholly owned Australian subsidiary, Kezar Life Sciences Australia Pty Ltd., which is a proprietary company limited by shares. All intercompany balances and transactions have been eliminated upon consolidation.

The condensed consolidated balance sheet as of December 31, 2023 has been derived from the audited consolidated financial statements at that date but does not include all information and footnotes required by GAAP for complete financial statements. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements included in the Annual Report.

Unaudited Condensed Consolidated Financial Statements

The accompanying financial information as of September 30, 2024 is unaudited. The condensed consolidated financial statements included in this report reflect all adjustments (consisting only of normal recurring adjustments) that our management considers necessary for the fair statement of the results of operations for the interim periods covered and of our financial condition at the date of the interim balance sheet. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with GAAP for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The results for interim periods are not necessarily indicative of the results for the entire year or any other interim period. The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto included in our Annual Report.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant items subject to such judgments, estimates and assumptions include the valuation of marketable securities, impairment of long-lived assets, determining the fair-value of stock-based compensation, and evaluating the progress to completion of external research and development costs. Management bases its estimates on historical experience and on various other market-specific relevant assumptions that management believes to be reasonable under the circumstances. Actual results may differ from those estimates.

Estimates and assumptions about future events and their effects cannot be determined with certainty and therefore require the exercise of judgment. As of the date of issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update its judgments, estimates and assumptions or revise the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information is obtained and are recognized in the consolidated financial statements as soon as they become known. Actual results could differ from those estimates and any such differences may be material to the Company's condensed consolidated financial statements.

Recently Issued Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2023-09 *Income Taxes (Topic 740) – Improvements to Income Tax Disclosures* ("ASU 2023-09"), which requires entities to disclose specific categories in the income tax rate reconciliation annually and provide additional information for reconciling items that meet a qualitative threshold. ASU 2023-09 also requires that entities disclose annually additional information about income taxes paid and disaggregated information for certain items. ASU 2023-09 is effective for the Company beginning on January 1, 2025. The Company is currently evaluating the impact of the adoption of ASU 2023-09 on its financial position, results of operations and cash flows.

In November 2023, the FASB issued Accounting Standards Update No. 2023-07 *Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which requires entities to disclose incremental segment information on an annual and interim basis. ASU 2023-07 requires entities with a single reportable segment to provide all the disclosures required by the

amendments in ASU 2023-07 and all existing segment disclosures in *Segment Reporting (Topic 280)*. ASU 2023-07 is effective for the Company beginning with the Annual Report on Form 10-K for the year ending December 31, 2024. The Company is currently evaluating the effect of adopting the update on its related disclosures.

There have been no other recent accounting pronouncements, changes in accounting pronouncements or recently adopted accounting guidance that are expected to have a material impact on the Company's condensed consolidated financial statements upon adoption.

3. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The carrying amount of certain financial instruments, including cash equivalents, other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. Assets and liabilities recorded at fair value on a recurring basis in the condensed consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The Company applies fair value accounting for all financial assets and liabilities and nonfinancial assets and liabilities that are required to be recognized or disclosed at fair value in the financial statements. The Company determines the fair value of Level 1 assets using quoted prices in active markets for identical assets. The Company reviews trading activity and pricing for Level 2 investments as of each measurement date. Level 2 inputs, which are obtained from various third-party data providers, represent quoted prices for similar assets in active markets and were derived from observable market data, or, if not directly observable, were derived from or corroborated by other observable market data.

In certain cases, where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3 within the valuation hierarchy. The Company did not have any financial assets or liabilities measured using Level 3 inputs as of September 30, 2024 or December 31, 2023.

The following table summarizes the Company's financial assets measured at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above (in thousands):

	September 30, 2024			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Cash equivalents:				
U.S. Treasury money market funds	$ 34,180	$ 34,180	$ —	$ —
Certificate of deposit	555	—	555	—
Marketable securities:				
U.S. Treasury securities	47,903	47,903	—	—
Commercial paper	42,514	—	42,514	—
Corporate debt securities	11,119	—	11,119	—
U.S. government agency bonds	11,994	—	11,994	—
Total	$ 148,265	$ 82,083	$ 66,182	$ —

	December 31, 2023			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Cash equivalents:				
U.S. Treasury money market funds	$ 35,349	$ 35,349	$ —	$ —
Marketable securities:				
Certificate of deposit	544	—	544	—
U.S. Treasury securities	54,175	54,175	—	—
Commercial paper	65,070	—	65,070	—
U.S. government agency bonds	46,090	—	46,090	—
Total	$ 201,228	$ 89,524	$ 111,704	$ —

Nonrecurring Fair Value Measurements

The right-of-use ("ROU") asset associated with Suite 400 of the Company's headquarters in South San Francisco, California, is a separate asset group measured at fair value on a nonrecurring basis as of December 31, 2023 due to an impairment recognized on the ROU asset at that date (see Note 6). The fair value of this asset group calculated as the present value of the estimated future cash flows of sublease income attributable to the ROU asset associated with Suite 400, was classified in Level 3 of the fair value hierarchy. When calculating the present value of the estimated future cash flows, sublease income was estimated to increase at a rate of 3.5% per year, and the cash flows were discounted using a rate of 13.3%. In June 2024, the Company recognized an additional $1.5 million impairment charge in relation to Suite 400 to write off the net book value of the ROU asset as the estimated future cash flow from sublease income is zero due to current market conditions.

4. Available-for-Sale Securities

The following table is a summary of available-for-sale securities recorded in cash and cash equivalents or marketable securities in the Company's condensed consolidated balance sheets (in thousands):

	September 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:				
U.S. Treasury money market funds	$ 34,180	$ —	$ —	$ 34,180
Certificate of deposit	555	—	—	555
Marketable securities:				
U.S. Treasury securities	47,780	123	—	47,903
Commercial paper	42,380	137	(3)	42,514
Corporate debt securities	11,065	54	—	11,119
U.S. government agency bonds	11,964	30	—	11,994
Total	$ 147,924	$ 344	$ (3)	$ 148,265
Cash				123
Total cash, cash equivalent and marketable securities				$ 148,388

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:				
U.S. Treasury money market funds	$ 35,349	$ —	$ —	$ 35,349
Marketable securities:				
Certificate of deposit	544	—	—	544
U.S. Treasury securities	54,066	151	(42)	54,175
Commercial paper	65,038	41	(9)	65,070
U.S. government agency bonds	46,115	27	(52)	46,090
Total	$ 201,112	$ 219	$ (103)	$ 201,228
Cash				144
Total cash, cash equivalent and marketable securities				$ 201,372

The Company has not recognized an allowance for credit losses on any securities in an unrealized loss position as of September 30, 2024 and December 31, 2023.

The following tables display additional information regarding gross unrealized losses and fair value by major security type for available-for-sale securities in an unrealized loss position as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024 Less than 12 consecutive months	
	Fair Value	Unrealized Losses
Commercial paper	$ 959	$ (3)
Total	$ 959	$ (3)

	December 31, 2023 Less than 12 consecutive months	
	Fair Value	Unrealized Losses
U.S. Treasury securities	$ 16,261	$ (42)
Commercial paper	20,789	(9)
U.S. government agency bonds	39,052	(52)
Total	$ 76,102	$ (103)

The Company believes that the individual unrealized losses represent temporary declines primarily resulting from interest rate changes and intends to hold these marketable securities to their maturities.

The Company currently does not intend to sell these securities prior to maturity, and it is not more likely than not that the Company will be required to sell these securities before recovery of their amortized cost basis, which may be at maturity. The Company evaluated securities with unrealized losses to determine whether such losses, if any, were due to credit-related factors and determined that there were no credit-related losses to be recognized as of September 30, 2024. There were no sales of available-for-sale securities in any of the periods presented.

As of September 30, 2024, the amortized cost and estimated fair value of the Company's available-for-sale securities by contractual maturity are shown below (in thousands):

Available-for-sale securities maturing in:	Amortized Cost	Estimated Fair Value
One year or less	$ 147,924	$ 148,265
Total available-for-sale securities	$ 147,924	$ 148,265

5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Receivable from Everest, current (Note 10)	$ 500	$ 1,596
Advance for clinical-related costs, current	5,268	1,818
Licenses, dues and subscriptions	597	506
Insurance	847	712
Interest receivable	589	695
Other	190	251
Total prepaid expenses and other current assets	$ 7,991	$ 5,578

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Leasehold improvements	$ 3,488	$ 3,488
Furniture, laboratory and office equipment	5,577	5,559
Computer equipment	285	285
Total property and equipment	9,350	9,332
Less: accumulated depreciation and amortization	(6,201)	(5,420)
Property and equipment, net	$ 3,149	$ 3,912

Depreciation expense was $0.3 million and $0.8 million for each of the three and nine months ended September 30, 2024, respectively, compared to $0.3 million and $0.8 million for the three and nine months ended September 30, 2023, respectively.

Other Assets

Other assets consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Advance for clinical related costs, noncurrent	$ —	$ 4,787
Unbilled receivable from Everest, noncurrent (Note 10)	1,741	—
Deposits for operating lease	674	674
Other	—	134
Total other assets	$ 2,415	$ 5,595

Accrued and Other Current Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued clinical costs	$ 6,070	$ 1,801
Accrued employee-related costs	2,120	3,708
Accrued preclinical and research costs	1,311	756
Accrued professional services	121	110
Other	42	106
Total accrued liabilities	$ 9,664	$ 6,481

6. Lease

In November 2022, the Company entered into an amendment to the lease agreement for its corporate headquarters in South San Francisco, California, which expanded the leased premises in the same building as its corporate headquarters and extended the lease term of the original premises to be coterminous with the expansion premises to July 31, 2026. The transaction was treated as a lease modification as of the effective date and resulted in the recognition of approximately $8.0 million in new lease liabilities and ROU assets.

In December 2023, the Company committed to a plan to sublease Suite 400 of its corporate headquarters in connection with a workforce reduction (see Note 14) and evaluated the recoverability of ROU asset by comparing the carrying amount of the asset to future net undiscounted cash flows associated with the asset. The ROU asset is considered to be impaired if the carrying amount of the assets exceeds the fair value of the assets. Consequently, the Company recognized a $2.7 million impairment charge in 2023. In June 2024, the Company recognized an additional $1.5 million impairment charge in relation to Suite 400 to write off the net book value of the ROU asset as the estimated future cash flow from sublease income is zero due to current market conditions.

Information related to the Company's lease liabilities were as follows (in thousands):

	Three months ended September 30, 2024	Nine months ended September 30, 2024
Cash paid for operating lease liabilities	$ 762	$ 2,215
Operating lease costs	457	1,778
Variable lease costs	466	1,382
Maturities of lease liabilities as of September 30, 2024 were as follows:		
Less than 12 months		$ 3,991
13 - 24 months		3,437
Total undiscounted lease payments		7,428
Less: imputed interest		(778)
Total lease liabilities		$ 6,650
Operating lease liabilities, current		$ 3,391
Operating lease liabilities, noncurrent		3,259
Total operating lease liabilities		$ 6,650

7. Debt

In November 2021, the Company entered into a loan agreement (the "Loan Agreement") with Oxford Finance, LLC ("Oxford Finance"), which provided the Company up to $50.0 million in borrowing capacity across five potential tranches (each a "Term Loan," and collectively "Term Loans"). The initial tranche of $10.0 million was funded at the closing of the Loan Agreement. The remaining tranches were dependent on achieving certain clinical trial milestones, and the Company declined these remaining tranches in borrowing capacity available to it under the Loan Agreement. The loan facility is secured by all assets except intellectual property, which is subject to a negative pledge, and will mature on November 1, 2026 (the "Maturity Date"). There are no warrants or financial covenants associated with the Loan Agreement.

Until June 30, 2023, the Term Loans bore interest at a floating per annum rate (based on the actual number of days elapsed divided by a year of 360 days) equal to the sum of (a) the greater of (i) 30-day U.S. LIBOR rate reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue and (ii) 0.08%, plus (b) 7.87%. A LIBOR transition event occurred effective July 1, 2023 and Oxford Finance subsequently replaced the LIBOR rate with the 1-month CME term SOFR plus 0.1%. The rate change did not require contract remeasurement at the effective date of the change or a reassessment of any previous accounting determinations pertaining to the facility. The rate change did not have a material impact on the Company's financial statements. The Company is required to make monthly interest-only payments prior to the amortization date of January 1, 2025, subject to a potential one-year extension upon satisfaction of certain conditions.

All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. The Company has the option to prepay the outstanding balance prior to maturity, subject to a prepayment fee of 1.0% to 2.0% depending upon when the prepayment occurs. Upon repayment of the Term Loans, the Company is required to make a final payment fee to the lenders equal to 6.5% of the original principal amount of the Term Loans funded which will be accrued by charges to interest expense over the term of the loans using the effective interest method.

The Loan Agreement also includes subjective acceleration clauses that permit the lenders to accelerate the Maturity Date under certain circumstances, including, but not limited to, material adverse effects on a Company's financial status or otherwise. As of September 30, 2024, the Company is in compliance with all covenants in the Loan Agreement.

Interest expense was $0.4 million and $1.2 million for the three and nine months ended September 30, 2024, respectively, compared to $0.4 million and $1.2 million for the three and nine months ended September 30, 2023, respectively. The initial effective interest rate

on the Term Loans, including the amortization of the debt discount and issuance costs, and accretion of the final payment, was 11%. The components of the long-term debt balance are as follows:

	September 30, 2024	December 31, 2023
Principal loan balance	$ 10,000	$ 10,000
Unamortized debt discount and issuance costs	(163)	(243)
Cumulative accretion of final fee	425	312
	$ 10,262	$ 10,069
Debt, current	$ 3,913	$ —
Debt, noncurrent	6,349	10,069
Debt, net	$ 10,262	$ 10,069

As of September 30, 2024, the estimated future principal payments due were as follows:

Years Ending December 31,	
2024	$ —
2025	5,217
2026	4,783
Total	$ 10,000

8. Pre-Funded Warrants

In connection with the Company's previous underwritten public offerings, the Company issued pre-funded warrants to purchase an aggregate of 379,371 shares of the Company's common stock. Each pre-funded warrant entitled the holder to purchase shares of common stock at an exercise price of $0.01 per share and expired 20 years from the date of issuance. These warrants were recorded as a component of stockholders' equity within additional paid-in capital. The warrant holders exercised all the shares of outstanding pre-funded warrants in 2023 at an exercise price of $0.01 per share. As of September 30, 2024, there were no pre-funded warrants outstanding.

9. Stock-Based Compensation

Stock Incentive Plans

2022 Inducement Plan

In April 2022, the Company adopted the Kezar Life Sciences, Inc. 2022 Inducement Plan (the "Inducement Plan"), which is a non-stockholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq Listing Rule 5635(c)(4), for the award of nonstatutory stock options ("NSOs"), restricted stock units ("RSUs") and other equity awards as permitted by the Inducement Plan (collectively, "Inducement Awards") to persons not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to such persons entering into employment with the Company ("Eligible Recipients"). Under the Inducement Plan, the Company may grant up to 300,000 shares of Common Stock in the form of Inducement Awards to Eligible Recipients in compliance with the requirements of Nasdaq Listing Rule 5635(c)(4). Awards must be approved by either a majority of the Company's independent directors or the Company's independent compensation committee. Consultants and directors are not eligible to received grants under the Inducement Plan.

As of September 30, 2024, options to purchase 119,637 shares of common stock were outstanding and 180,363 shares were available for future issuance under the Inducement Plan.

2018 Equity Incentive Plan

In June 2018, the Company's board of directors adopted and the stockholders approved the 2018 Equity Incentive Plan (the "2018 Plan"), which became effective as of June 20, 2018, at which point no further grants could be made under the 2015 Equity Incentive Plan (the "2015 Plan") described below. Under the 2018 Plan, the Company may grant incentive stock options ("ISOs"), NSOs, stock appreciation rights, restricted stock awards, RSUs and other stock-based awards. As of September 30, 2024, options to purchase 1,459,665 shares of common stock and 11,054 RSUs were outstanding, and 89,315 shares were available for future issuance under the 2018 Plan.

Initially, subject to adjustment as provided in the 2018 Plan, the aggregate number of shares of the Company's common stock authorized for issuance pursuant to stock awards under the 2018 Plan was 400,000 shares, which is the sum of (i) 160,069 shares plus (ii) the number of shares reserved and available for issuance under the 2015 Plan at the time the 2018 Plan became effective and (iii) the number of shares subject to stock options or other stock awards granted under the 2015 Plan that expire, terminate are forfeited or otherwise not issued, or are withheld to satisfy a tax withholding obligation in connection with an award or to satisfy a purchase or exercise price of an award (such as upon the expiration or termination of a stock award prior to vesting). The number of shares of the Company's common stock reserved for issuance under the 2018 Plan automatically increases on January 1 of each year, beginning on January 1, 2019 and continuing through and including January 1, 2028, by 5% of the total number of shares of capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors prior to such increase.

The maximum number of shares that may be issued upon the exercise of ISOs under the 2018 Plan is 1,250,000 shares.

2015 Equity Incentive Plan

The 2015 Plan provided for the granting of ISOs and NSOs to employees, directors and consultants at the discretion of the Company's board of directors. The 2015 Plan was terminated as to future awards in June 2018, although it continues to govern the terms of options that remain outstanding under the 2015 Plan.

No additional stock awards will be granted under the 2015 Plan, and all outstanding stock awards granted under the 2015 Plan that are repurchased, forfeited, expire or are cancelled will become available for grant under the 2018 Plan in accordance with its terms.

Options granted under the 2015 Plan expire no later than 10 years from the date of grant. Options granted under the 2015 Plan vest over periods determined by the Company's board of directors, generally over four years. The 2015 Plan allows for early exercise of certain options prior to vesting. Upon termination of employment, the unvested shares are subject to repurchase at the original exercise price. As of September 30, 2024, options to purchase 136,325 shares of common stock were outstanding under the 2015 Plan.

2018 Employee Stock Purchase Plan

In June 2018, the Company's board of directors adopted and the stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"), which became effective as of June 20, 2018. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the U.S. Internal Revenue Code of 1986, as amended. The number of shares of common stock initially reserved for issuance under the ESPP was 20,000 shares. The ESPP provides for an annual increase on January 1 of each year, beginning on January 1, 2019 and continuing through and including January 1, 2028, equal to the lesser of (i) 1% of the shares of common stock outstanding on the last day of the prior fiscal year or (ii) 37,500 shares, or a lesser number of shares determined by the Company's board of directors prior to such increase. In December 2023, the Company's board of directors acted such that there was no increase of the number of shares of common stock reserved for issuance under the ESPP as of January 1, 2024. As of September 30, 2024, 67,501 shares of common stock had been issued under the ESPP and 65,709 shares remained available for future issuance under the ESPP.

The price per share of common stock to be paid by an ESPP participant on the applicable purchase date of an offering period shall be equal to 85% of the lesser of the fair market value of a share of common stock on (i) the applicable offering date or (ii) the applicable purchase date. The Company's board of directors authorized an initial six-month offering period beginning on November 16, 2018 and ending on May 15, 2019. The Company's board of directors has subsequently authorized additional six-month offering periods, with the most recent offering period beginning on May 16, 2024.

Option Repricing

In July 2023, the Compensation Committee of the Company's board of directors approved a stock option repricing (the "Option Repricing") in which the exercise price of certain outstanding options to purchase shares of the Company's common stock under the 2018 Plan was reduced to $22.80 per share, the closing price of the Common Stock on July 24, 2023. Outstanding options that were granted under the 2015 Plan and the Inducement Plan were not included in the Option Repricing. The Option Repricing included options granted pursuant to the 2018 Plan that were held by, among others, members of the Company's board of the directors (other than options granted in June 2023) and the Company's named executive officers and principal financial officer.

As a result of the Option Repricing, 990,367 shares of vested and unvested stock options outstanding as of July 24, 2023, with original exercise prices ranging from $24.40 to $228.50 per share, were repriced to $22.80 per share. The total incremental fair value to be recognized as a result of the repricing was approximately $4.7 million on the date of Option Repricing, of which $3.2 million related to the vested option shares had been recognized as stock-based compensation expense and $0.6 million related to the unvested option shares subsequently cancelled due to termination as of September 30, 2024. As of September 30, 2024, there was $0.9 million remaining related to the unvested option shares which will be amortized over the remaining requisite service periods through the end of 2026.

Stock Option Activity

The following table summarizes activity under the Company's stock option plans and related information (in thousands, except share and per share amounts):

	Number of Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	1,310,651	$ 25.95	7.1	$ 118
Options granted	578,797	$ 7.93		
Options cancelled/forfeited	(173,821)	$ 31.43		
Outstanding as of September 30, 2024	1,715,627	$ 19.32	7.4	$ 367
Vested and exercisable as of September 30, 2024	884,010	$ 24.62	5.9	$ 3

The weighted average grant date fair value of options granted during the three and nine months ended September 30, 2024 was $4.61 and $5.92 per share, respectively. There were no options exercised during the nine months ended September 30, 2024. The aggregate intrinsic value is calculated as the difference between the exercise price and the estimated fair value of the Company's common stock at the date of exercise.

Performance Option Grants Activities

On July 11, 2024, the Compensation Committee of the Company's board of directors approved performance-based stock option grants to all employees, except the Chief Executive Officer, under the 2018 Plan. Performance-based stock options will vest upon the achievements of specified clinical trial milestones. The grant-date fair value of these performance-based stock options is calculated using the Black-Scholes option-pricing model. Performance-based stock options are included in the outstanding stock options table above. Stock-based compensation cost related to performance-based stock options is recognized over the period from the date the performance condition is determined to be probable of occurring through the date the applicable condition is expected to be met. If the performance condition is not considered probable of being achieved, no stock-based compensation is recognized until such time as the performance condition is considered probable of being achieved and related compensation cost would be recognized through a cumulative catch-up adjustment in the period of change. Stock-based compensation expenses of $0.1 million related to performance-based stock options were recognized for the three and nine months ended September 30, 2024.

Restricted Stock Units Activity

There were no RSUs granted during the nine months ended September 30, 2024. One-third of each RSU granted vests annually following the vesting commencement dates, over a vesting period of three years. RSUs are awards that entitle the holder to receive freely tradable shares of the Company's common stock upon vesting and are not forfeitable once fully vested. The valuations for these

RSUs were based on the closing prices of the Company's common stock on the grant dates and recognized as stock-based compensation expenses over the respective vesting terms.

	Number of RSUs Outstanding	Weighted Average Grant-Date Fair Price
Outstanding as of December 31, 2023	21,945	$ 92.00
RSUs vested	(9,702)	$ 93.64
RSUs forfeited	(1,189)	$ 92.57
Outstanding as of September 30, 2024	11,054	$ 90.48

Stock-Based Compensation Expense

Total stock-based compensation expense recognized by function was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 991	$ 3,140	$ 2,962	$ 7,421
General and administrative	2,194	3,494	6,742	7,496
Total stock-based compensation expense	$ 3,185	$ 6,634	$ 9,704	$ 14,917

As of September 30, 2024, the unrecognized stock-based compensation cost related to outstanding unvested stock options and RSUs that are expected to vest was $17.7 million with an estimated weighted average amortization period of 2.3 years.

The fair value of the stock options granted is calculated using the Black-Scholes option-pricing model with the following range of assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Expected term (years)	5.5 - 6.1	6.1	5.5 - 6.1	5.5 - 6.1
Expected volatility	86.2 - 87.3%	87.6 - 88.0%	86.2 - 87.9%	87.6 - 88.3%
Risk-free interest rate	3.6 - 4.2%	4.1 - 4.2%	3.6 - 4.6%	3.5 - 4.3%
Expected dividend yield	—	—	—	—

The expected term of options granted represents the period of time that options granted are expected to be outstanding and was determined by calculating the midpoint between the date of vesting and the contractual life of each option. The expected term of the ESPP rights is equal to the six-month look-back period. Since inception until March 2024, the volatility of the Company's stock price was based on the weighted average of the historical volatility of the Company's stock price and that of a peer group of public companies over the expected term due to the Company's limited public trading history of its common stock. The peer group was selected on the basis of operational and economic similarity with the Company's principal business operations. Effective as of the quarter-ended June 30, 2024, the expected volatility is based on the daily historical volatility of the Company's common stock covering the estimated expected term. The risk-free interest rate for the expected term of the options is based on the U.S. Treasury yield curve with a maturity equal to the expected term in effect at the time of grant. The Company has not paid, and does not anticipate paying, cash dividends on its shares of common stock; therefore, the expected dividend yield is zero.

10. Everest Collaboration

In September 2023, the Company entered into a Collaboration and License Agreement (the "Everest License Agreement") with Everest pursuant to which, among other things, the Company granted to Everest an exclusive license to develop and commercialize one or more products containing the Company's proprietary compound, zetomipzomib (the "Products"), in the licensed field in the Greater China region (Mainland China, Taiwan, Hong Kong and Macau), South Korea, Singapore, Malaysia, Thailand, Indonesia, Vietnam and the Philippines (the "Territory"). The licensed field includes all uses other than the diagnosis or treatment in humans of cancerous or pre-cancerous diseases or conditions. During the PALIZADE trial, Everest contributed their local regulatory and clinical trial expertise and were responsible for study costs in the Territory. Everest Medicines Limited is also a party to the Everest License Agreement solely for limited purposes, including to guarantee the performance by Everest of its obligations under the Everest License Agreement.

Under the terms of the Everest License Agreement, the Company received a one-time, irrecoverable, non-refundable and non-creditable upfront payment of $7.0 million in October 2023 and is entitled to receive certain variable payments for manufacturing

supply services and milestone payments upon achievement of certain development, regulatory and commercial milestone events, for total potential milestone payments of up to $125.5 million. In addition, Everest will pay to the Company tiered royalties on the net sales of the Products in the Territory during the term of the Everest License Agreement ranging from the single digit to the low-teens, subject to certain reductions for patent expiration, generic competition and payments for licenses to third-party patents.

The term of the Everest License Agreement will continue on a market-by-market basis until expiration of the relevant royalty term of the Products, unless terminated earlier. Everest has the right to terminate the Everest License Agreement for convenience at any time following the October 2024 termination of the PALIZADE clinical trial. The Company may terminate the Everest License Agreement if Everest challenges the Company's patents or fails to perform any development or commercialization activities for a continuous period of more than twelve (12) months, subject to certain exceptions. In addition, either party may terminate the Everest License Agreement for the other party's uncured breach or insolvency, and the Everest License Agreement will automatically terminate in the event of termination of the Company's exclusive license agreement with Onyx Therapeutics, Inc.

Under the terms of the Everest License Agreement, at the election of Everest, the Company may manufacture and provide clinical supply to Everest to use in development and commercialization in the Territory at the fully burdened manufacturing cost plus specified margins, as defined within the Everest License Agreement. Certain of these provisions were determined to be options to acquire additional goods or services at a price that approximates the stand-alone selling price for that good or service and therefore do not represent material rights, or separate performance obligations, within the context of the Everest License Agreement. The Company evaluated the Everest License Agreement and determined it was within the scope of ASC 606. The transaction price was determined to consist of the upfront payment of $7.0 million.

License of Intellectual Property. The license to the Company's intellectual property and associated know-how represents a distinct performance obligation. The license and associated know-how was transferred to Everest in the third quarter of 2023 to satisfy this performance obligation. The Company allocated the full transaction price to the license of the Company's intellectual property and accordingly recognized collaboration revenue of $7.0 million in 2023.

Milestone Payments. The potential development, regulatory and commercial milestone payments are paid upon achievement of certain milestones as defined in the Everest License Agreement. It was determined that their achievement is highly dependent on factors outside of the Company's control. These payments have been fully constrained until the Company concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods and, as such, have been excluded from the transaction price. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of each milestone and any related constraint and, if necessary, adjust its estimate of the overall transaction price. As of September 30, 2024, the Company has not recognized any revenue associated with development, regulatory and commercial milestones.

Royalties. Any consideration related to royalties will be recognized if and when the related sales occur, as they were determined to relate predominantly to the license granted to Everest and, therefore, have also been excluded from the transaction price. No royalty revenue was recognized as of September 30, 2024.

In July 2024, the Company amended the Everest License Agreement to modify a development milestone and adjust certain payment terms relating to Everest's responsibility for PALIZADE study costs in the Territory. As of September 30, 2024, the Company had a receivable of $0.5 million, representing the billed amounts related to Everest's share of the Territory-specific direct costs and pro rata portion of indirect costs incurred to conduct the PALIZADE study under the Everest License Agreement, and a noncurrent unbilled receivable of $1.7 million representing reimbursement for payments made by the Company that is yet to be billed or due. The receivable amount was included in prepaid expenses and other current assets and the unbilled receivable was included in other assets in the Company's condensed consolidated balance sheet. In connection with the cost-sharing arrangement with Everest, $1.1 million and $3.6 million was recognized as contra research and development expense for each of the three and nine months ended September 30, 2024, respectively.

In October 2024, the Company made the strategic decision to terminate the PALIZADE study and focus clinical development efforts of zetomipzomib in autoimmune hepatitis, or AIH. The termination does not change Everest's payment obligation under the Everest License Agreement.

11. Income Taxes

No provision for income taxes was recorded for the three and nine months ended September 30, 2024 and 2023, respectively. Deferred tax assets generated from the Company's net operating losses have been fully reserved, as the Company believes it is not more likely than not that the benefit will be realized.

Effective January 1, 2022, under the Tax Cuts and Jobs Act, for tax purposes the Company is required to capitalize and subsequently amortize all R&D expenditures over five years for research activities conducted in the U.S. and over fifteen years for research activities conducted outside of the U.S. Given the significant loss and credit carryforwards in the U.S., the Company does not anticipate having a change in valuation allowance assertion.

In March 2020, the Coronavirus Aid, Relief and Economic Security ("CARES") Act was signed into law. The CARES Act included several tax changes as part of its economic package. These changes principally related to expanded net operating loss carryback periods, increases to interest deductibility limitations, and accelerated alternative minimum tax refunds. The CARES Act enacted the Employee Retention Credit ("ERC") to incentivize companies to retain employees, which was subsequently modified by extension of the CARES Act. Under the provisions of the CARES Act and its subsequent extension, the Company was eligible for ERCs, subject to certain criteria. During the nine months ended September 30, 2023, the Company received refunds of approximately $1.4 million related to ERCs that offset the related payroll expenses in the respective operating costs and expenses line item in the condensed consolidated statements of operations. During the nine months ended September 30, 2024, no refund related to ERCs was received by the Company.

12. Net Loss Per Share

Net Loss Per Share

The following table sets forth the calculation of basic and diluted net loss per share during the periods presented (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	$ (20,313)	$ (23,103)	$ (63,518)	$ (69,610)
Denominator:				
Weighted-average shares of common stock outstanding	7,296,222	7,268,165	7,286,967	7,249,188
Net loss per share, basic and diluted	$ (2.78)	$ (3.18)	$ (8.72)	$ (9.60)

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of shares of common stock and pre-funded warrants outstanding during the period, without consideration of common share equivalents. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of shares of common stock, pre-funded warrants and common share equivalents outstanding for the period. The pre-funded warrants were included in the computation of basic and diluted net loss per common share as the exercise price was negligible and the pre-funded warrants were fully vested and exercisable. Common share equivalents are only included in the calculation of diluted net loss per common share when their effect is dilutive.

Potential dilutive securities, which include, vested and unvested options to purchase common stock and RSUs subject to future vesting have been excluded from the computation of diluted net loss per share as the effect is antidilutive. Therefore, the denominator used to calculate both basic and diluted net loss per common share is the same in all periods presented.

The following outstanding shares of common stock equivalents were excluded from the computation of the diluted net loss per share for the periods presented because their effect would have been anti-dilutive:

	Three and Nine Months Ended September 30,	
	2024	2023
Stock options to purchase common stock	1,715,627	1,333,045
Restricted stock units subject to future vesting	11,054	30,423
Total	1,726,681	1,363,468

13. Related Party Transactions

In connection with the resignation of John Fowler from his role as Chief Executive Officer, the Company and Mr. Fowler entered into a Separation and Consulting Agreement, effective as of November 7, 2023 (the "Fowler Agreement"), pursuant to which Mr. Fowler provides consulting services to the Company at a rate of $5,000 per month for one year ending November 7, 2024. Pursuant to the Fowler Agreement, the Company recognized $15,000 and $45,000 of compensation expense within general and administrative

expenses in the Condensed Consolidated Statement of Operations during the three and nine months ended September 30, 2024, respectively.

14. 2023 Restructuring and Impairment Charges

In October 2023, the Company announced a strategic restructuring and workforce reduction to prioritize its clinical-stage assets, extend its cash runway and reduce its total workforce. All employees affected by the workforce reduction separated from the company by December 31, 2023. In connection with the workforce reduction, the Company committed to a plan to sublease Suite 400 of its corporate headquarters which resulted in an impairment to the ROU asset and certain property and equipment was no longer utilized under then-current or expected future operations.

The Company recognized cumulative restructuring charges of $6.2 million, comprised primarily of one-time employee termination benefits and long-lived assets impairment costs during the year ended December 31, 2023. In June 2024, the Company recognized an additional $1.5 million impairment charge in relation to Suite 400 to write off the net book value of the ROU asset. The unpaid severance and related benefit costs included in accrued liabilities in the condensed consolidated balance sheets were $30 thousand and $1.4 million as of September 30, 2024 and December 31, 2023, respectively. The Company expects that substantially all of the remaining accrued restructuring liabilities will be paid in cash over next three months.

The following table illustrates the accrual activities and payments relating to restructuring and impairment charges (in thousands):

	Severance and related benefit costs	Asset impairments	Total
Balance as of January 1, 2023	$ —	$ —	$ —
Restructuring charges	3,279	2,908	6,187
Cash payments made	(1,858)	—	(1,858)
Non-cash charges	—	(2,908)	(2,908)
Balance as of December 31, 2023	$ 1,421	$ —	$ 1,421
Cash payments made	(775)	—	(775)
Balance as of March 31, 2024	$ 646	$ —	$ 646
Restructuring charges	(67)	1,549	1,482
Cash payments made	(344)	—	(344)
Non-cash charges	—	(1,549)	(1,549)
Balance as of June 30, 2024	$ 235	$ —	$ 235
Cash payments made	(205)	—	(205)
Balance as of September 30, 2024	$ 30	$ —	$ 30

15. Subsequent Events

Adoption of a Stockholder Rights Plan

On October 17, 2024, the Company's board of directors adopted a limited duration stockholder rights plan (the "Rights Plan"), effective immediately, and declared a dividend of one preferred share purchase right (a "Right") for each outstanding share of the Company's common stock as of the close of business on October 28, 2024, the record date. The Rights are exercisable only if a person or group (an "Acquiring Person") acquires or launches a tender or exchange offer to acquire beneficial ownership (which includes certain synthetic equity interests) of 10% or more of the Company's outstanding common stock (15% in the case of a passive institutional investor as described in the Rights Plan). Once the Rights become exercisable, each Right will entitle its holder (other than any Acquiring Person, whose Rights will become void) to purchase, for $71.60, one one-hundredth of a share of the Company's newly designated Series A Junior Participating Preferred Stock, par value $0.001 per share (each, a "Preferred Share" and collectively, the "Preferred Shares") (with such exercise price and Preferred Share amounts adjusted to account for the Reverse Stock Split). The description and terms of the Rights Plan are set forth in the Rights Agreement, dated as of October 17, 2024 (the "Rights Agreement"), between the Company and Computershare Trust Company, N.A. The terms of the Preferred Shares are set forth in a Certificate of Designation filed with the Secretary of State of Delaware on October 17, 2024. The Rights will expire on October 17, 2025, unless the Rights are earlier redeemed or exchanged by the Company.

One-for-Ten Reverse Stock Split

On October 29, 2024, the Company completed the Reverse Stock Split of the Company's common stock at a ratio of one-for-ten. There were no changes in the total number of shares of common stock authorized for issuance by the Company, nor a change in par value per share. No fractional shares were issued as a result of the Reverse Stock Split. Instead, stockholders of record who would

otherwise have been entitled to receive a fractional share were entitled to have the fractional share rounded up to the nearest whole share. All share and share-related information presented in these condensed consolidated financial statements has been retroactively adjusted for all periods presented to reflect the decreased number of shares resulting from the Reverse Stock Split.

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

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and related notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, and with our audited consolidated financial statements and related notes thereto for the year ended December 31, 2023 included in our Annual Report on Form 10-K, as filed with the U.S. Securities and Exchange Commission, or the SEC, on March 14, 2024, or the Annual Report.

Overview

We are a clinical-stage biotechnology company developing novel small molecule therapeutics to treat unmet needs in immune-mediated diseases. We believe therapies that inhibit multiple drivers of disease by targeting fundamental upstream control processes within the cell have the potential for profound therapeutic benefit in a number of difficult-to-treat diseases. To that end, we are advancing a drug development program that harnesses a key regulator of cellular function by targeting the immunoproteasome, which is responsible for protein degradation in cells of the immune system and drives many key aspects of immune cell function. We believe targeting this fundamental regulator of cellular function offers an attractive approach to treating autoimmune diseases.

Our lead product candidate, zetomipzomib, is a first-in-class selective immunoproteasome inhibitor that we are evaluating for the treatment of severe autoimmune diseases of high unmet medical need. Zetomipzomib has completed testing in healthy volunteers in a Phase 1a clinical study and in patients with systemic lupus erythematosus, or SLE, with or without lupus nephritis, or LN, in the MISSION Phase 1b/2 clinical study.

In October 2024, we announced the termination of our PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN. This decision was made after the PALIZADE Phase 2b clinical trial was placed on clinical hold by the U.S. Food and Drug Administration, or FDA, following four Grade 5 (fatal) serious adverse events (SAEs) that occurred in patients enrolled in the Philippines and Argentina, including one patient on placebo. A total of 84 patients were enrolled in PALIZADE as of the date of termination, and we plan to report available data on those patients at a later date.

We are currently conducting PORTOLA, a placebo-controlled, randomized, double-blind Phase 2a clinical trial of zetomipzomib in patients with autoimmune hepatitis, or AIH, that are insufficiently responding to standard of care or have relapsed. We have completed enrollment of the PORTOLA trial and plan to report topline data from this trial in the first half of 2025.

In October 2024, the Independent Data Monitoring Committee, or IDMC, recommended that the PORTOLA trial may proceed without modification. The IDMC examined safety data from all patients enrolled in the trial, including data from patients who completed the 24-week double-blinded treatment period, or DBTP, and continued to the open-label extension, or OLE, portion of the trial which includes an additional 24 weeks of treatment. Following the recommendation made by the IDMC, the FDA notified us that it is allowing enrolled patients to complete the DBTP of PORTOLA without modification. However, the FDA has placed a partial clinical hold on PORTOLA requiring that the four patients currently in the DBTP should not continue to the OLE portion of the trial. The patients who are currently participating in the OLE may continue treatment on zetomipzomib, but their prednisone dosage may not be tapered below 5mg/day, and any patients who tapered below this amount will raise their prednisone back to 5 mg/day.

Based on clinical data generated to date with zetomipzomib, we believe that zetomipzomib has the potential to address multiple chronic immune-mediated diseases. We believe that the immunoproteasome is a validated target for the treatment of a wide variety of immune-mediated diseases given its ability to regulate multiple drivers of the inflammatory disease process. Many inflammatory disorders are currently treated one cytokine or cell type at a time, but the immunoproteasome affects a broad spectrum of immune regulators. We observed encouraging clinical activity and biomarker data in the SLE and LN patients who received zetomipzomib in our MISSION Phase 1b/2 clinical study. The safety and tolerability profile of zetomipzomib observed in the MISSION Phase 1b/2 clinical study was also favorable and consistent with the needs for a long-term therapy.

Our other product candidate, KZR-261, is a small molecule agent we have studied in an open-label Phase 1 clinical study designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, as well to explore preliminary anti-tumor activity. KZR-261 was discovered from our novel research platform targeting the Sec61 translocon and the protein secretion pathway. KZR-261 demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies by targeting multiple pathways driving tumor growth and survival. In August 2024, we announced that we had stopped enrollment in the KZR-261 Phase 1 clinical study, and we reallocated clinical resources toward development of zetomipzomib. No objective responses have been observed to date in the KZR-261 study. We plan to report data from the trial at a medical conference following completion of the study.

Since the commencement of our operations, we have devoted substantially all of our resources to performing research and development activities in support of our product development efforts, hiring personnel, raising capital to support and expand such activities and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily from the issuance and sale of

convertible preferred stock, public offerings of common stock and pre-funded warrants to purchase common stock, and debt. We acquired exclusive worldwide rights to zetomipzomib pursuant to a license agreement, or the Onyx License Agreement, with Onyx Therapeutics, Inc., or Onyx, a wholly owned subsidiary of Amgen, Inc.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates and programs. Our net losses were $101.9 million and $63.5 million for the year ended December 31, 2023 and the nine months ended September 30, 2024, respectively, and we expect to continue to incur significant losses for the foreseeable future. As of September 30, 2024, we had an accumulated deficit of $414.3 million. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the necessary development, obtaining regulatory approval and preparing for potential commercialization of our product candidates.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures on other research and development activities. We expect our expenses will increase substantially over time as we:

- continue the ongoing and planned development of zetomipzomib;
- seek to develop additional product candidates, including preclinical studies and clinical trials for such product candidates;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- seek marketing approvals for zetomipzomib and any future product candidates that successfully complete clinical trials;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- continue to build a portfolio of product candidates through the acquisition or in-license of drugs, product candidates or technologies;
- implement operational, financial, management and compliance systems; and
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel.

Financial Operations Overview

Collaboration Revenue

We have no products approved for commercial sales and, to date, have not generated any revenue from the sale of products, and we do not expect to generate any revenue from the sale of products in the near future.

Our revenue to date has been generated from the upfront payment pursuant to our collaboration with Everest Medicines II (HK) Limited, or Everest, under our license agreement with them, or the Everest License Agreement. Collaboration revenue consists of revenue received from upfront, milestone and contingent payments received from the strategic partner. We recognize collaboration revenue when the performance obligation is satisfied.

In addition to receiving an upfront payment, we may also be entitled to milestones and other contingent payments upon achieving predefined objectives. If a milestone is considered probable of being reached, and if it is probable that a significant revenue reversal would not occur, the associated milestone amount would also be included in the transaction price.

We expect that any collaboration revenue we generate from our current collaboration and license agreement, and from any future collaboration partners, will fluctuate as a result of the timing and amount of upfront, milestones and other collaboration agreement payments and other factors.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- fees paid to consultants for services directly related to our product development and regulatory effort;
- expenses incurred under agreements with third-party contract organizations, investigative clinical trial sites and consultants that conduct research and development activities on our behalf;
- costs associated with preclinical studies and clinical trials;
- costs associated with technology and intellectual property licenses;

- the costs related to production of clinical supplies; and
- facilities and other allocated expenses, which include expenses for rent and facility-related costs and supplies.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, collaborators and third-party service providers.

The following table summarizes our research and development expenses incurred during the respective periods (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(unaudited)		(unaudited)	
Research and development expenses by program:				
Zetomipzomib	$ 13.3	$ 15.2	$ 40.0	$ 39.3
KZR-261	2.9	4.2	9.4	11.9
Protein Secretion	—	4.3	0.3	11.9
Total research and development expenses	$ 16.2	$ 23.7	$ 49.7	$ 63.1

In October 2024, the Company made the strategic decision to terminate the PALIZADE Phase 2b clinical trial in patients with active LN and focus clinical development efforts of zetomipzomib in AIH. We expect our research and development expenses to increase for the foreseeable future as our product candidates advance into later stages of development. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, allocated facilities costs and expenses for outside professional services, including legal, human resource, information technology and audit services. Personnel costs consist of salaries, benefits and stock-based compensation. We may incur additional expenses to support the growth of our business.

Restructuring and Impairment Charges

In October 2023, we announced a strategic restructuring and workforce reduction (the “Workforce Reduction”) to prioritize our clinical-stage assets and extend our cash runway, reducing our workforce by approximately 40%. All employees affected by the Workforce Reduction separated from the Company by December 31, 2023. In connection with the Workforce Reduction, we committed to a plan to sublease the vacated floor in our leased office facility, which resulted in an impairment to the right-of-use (“ROU”) asset, and certain property and equipment no longer being utilized under then-current or expected future operations. We recognize an impairment loss when the total estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. See Note 14 to our condensed consolidated financial statements for additional information on the restructuring and impairment charges.

Interest Income

Our interest income consists of interest income earned on our cash, cash equivalents and marketable securities.

Interest Expense

Our interest expense is related to our debt facility. A portion of the interest expense is non-cash expense relating to the accretion of the final payment fees and amortization of debt discount and debt issuance costs associated with our loan agreement, or the Loan Agreement, that we entered into in November 2021 with Oxford Finance, LLC, or Oxford Finance.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

(dollars in millions)	Three Months Ended September 30, 2024	2023	$ Change
Collaboration revenue	$ —	$ 7.0	$ (7.0)
Operating expenses:			
Research and development	16.2	23.7	(7.5)
General and administrative	5.7	8.8	(3.1)
Total operating expenses	21.9	32.5	(10.6)
Loss from operations	(21.9)	(25.5)	3.6
Interest income	2.0	2.8	(0.8)
Interest expense	(0.4)	(0.4)	—
Net loss	$ (20.3)	$ (23.1)	$ 2.8

Collaboration Revenue

Collaboration revenue decreased by $7.0 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023 due to the upfront payment under the Everest License Agreement realized in September 2023.

Research and Development Expenses

Research and development expenses decreased by $7.5 million for the three months ended September 30, 2024, compared to the three months ended September 30, 2023. The decrease was primarily due to our October 2023 strategic restructuring to prioritize clinical-stage programs, reduce our headcount and pause early-stage research and discovery activities that resulted in a decrease of $4.9 million in stock-based compensation and personnel-related expenses, a decrease of $1.5 million in research and pre-clinical expenses, a decrease of $0.6 million in facility-related expenses, a decrease of $0.5 million in consulting expenses, and a decrease in $0.3 million in manufacturing expenses related to the timing of drug manufacturing runs, offset by an increase of $0.3 million in clinical expenses primarily related to increased activities for the PALIZADE and PORTOLA trials.

General and Administrative Expenses

General and administrative expenses decreased by $3.1 million for the three months ended September 30, 2024, compared to the three months ended September 30, 2023. The decrease was mainly due to a decrease of $1.7 million in legal and professional services in connection with the negotiation and implementation of the Everest License Agreement in the third quarter of 2023, a decrease of $1.3 million in stock-based compensation and a decrease of $0.1 million in D&O insurance.

Interest Income

Interest income decreased by $0.8 million for the three months ended September 30, 2024, compared to the three months ended September 30, 2023. The decrease was primarily due to the decrease in the balance of cash equivalents and marketable securities.

Interest Expense

Interest expense was $0.4 million for the three months ended September 30, 2024, compared to $0.4 million for the three months ended September 30, 2023. The interest expense was composed of the contractual coupon interest expense, the amortization of the debt discount and issuance costs and the accretion of the final payment fee associated with the Loan Agreement with Oxford Finance.

Comparison of the Nine Months Ended September 30, 2024 and 2023

(dollars in millions)	Nine Months Ended September 30, 2024	2023	$ Change
Collaboration revenue	$ —	$ 7.0	$ (7.0)
Operating expenses:			
Research and development	49.7	63.1	(13.4)
General and administrative	17.8	20.8	(3.0)
Restructuring and impairment charges	1.5	—	1.5
Total operating expenses	69.0	83.9	(14.9)
Loss from operations	(69.0)	(76.9)	7.9
Interest income	6.7	8.4	(1.7)
Interest expense	(1.2)	(1.1)	(0.1)
Net loss	$ (63.5)	$ (69.6)	$ 6.1

Collaboration Revenue

Collaboration revenue decreased by $7.0 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 due to the upfront payment under the Everest License Agreement realized in September 2023.

Research and Development Expenses

Research and development expenses decreased by $13.4 million for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023. The decrease was primarily due to our October 2023 strategic restructuring to prioritize clinical-stage programs, reduce our headcount and pause early-stage research and discovery activities. As the result of the restructuring, a decrease of $10.8 million in stock-based compensation and personnel-related expenses, a decrease of $5.0 million in research and pre-clinical expenses, a decrease of $1.4 million in facility-related expenses, a decrease of $0.6 million in consulting expense and a decrease of $0.4 million in manufacturing offset by an increase of $4.8 million in clinical expenses primarily related to increased activities for the PALIZADE and PORTOLA trials.

General and Administrative Expenses

General and administrative expenses decreased by $3.0 million for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023. The decrease was mainly due to a decrease of $2.1 million in legal and professional services in connection with the negotiation and implementation of the Everest License Agreement in the third quarter of 2023, a decrease of $0.4 million in stock-based compensation and personnel-related expenses, a decrease of $0.3 million in consulting expenses and a decrease of $0.2 million in D&O insurance.

Restructuring and Impairment Charges

Restructuring and impairment charges increased by $1.5 million for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023. The increase was primarily related to the ROU asset impairment charge related to the vacated floor in our leased office facility as the estimated future cash flow from sublease income is zero due to current market conditions.

Interest Income

Interest income decreased by $1.7 million for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023. The decrease was primarily due to the decrease in the balance of cash equivalents and marketable securities.

Interest Expense

Interest expense increased by $0.1 million for the nine months ended September 30, 2024, compared to $1.1 million for the nine months ended September 30, 2023. The increase was due to an increase in interest rates.

Liquidity and Capital Resources

Overview

As of September 30, 2024, we had $148.4 million in cash, cash equivalents and marketable securities. As of September 30, 2024, our cash equivalents and marketable securities had an average maturity of approximately five months and the longest maturity was 12 months.

We have incurred operating losses and experienced negative operating cash flows since our inception and anticipate that we will continue to incur losses for at least the foreseeable future. Our net loss was $63.5 million for the nine months ended September 30, 2024, and we had an accumulated deficit of $414.3 million as of September 30, 2024.

We believe that our cash, cash equivalents and marketable securities as of September 30, 2024 will be sufficient to meet our projected operating requirements through at least the next 12 months from the date these financial statements were issued. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

At-the-Market Offering Program

In December 2021, we entered into a Sales Agreement, or the ATM Agreement, with Cowen and Company, LLC, or Cowen, pursuant to which we can offer and sell, from time to time at our sole discretion, through Cowen, as our sales agent, shares of common stock having an aggregate offering price of up to $200.0 million. Any shares of common stock sold will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-261774). We will pay Cowen a commission up to 3.0% of the gross sales proceeds of any shares of common stock sold through Cowen under the ATM Agreement and also have provided Cowen with indemnification and contribution rights. As of December 31, 2023, we have sold an aggregate of 1,198,601 shares of our common stock for gross proceeds of approximately $131.7 million at a weighted average purchase price of $109.84 per share pursuant to the ATM Agreement. No shares were sold under the ATM Agreement during the nine months ended September 30, 2024. As of September 30, 2024, approximately $68.3 million remains available under the ATM Agreement.

Debt Facility

In November 2021, we entered into the Loan Agreement with Oxford Finance, which provides up to $50.0 million in borrowing capacity across five potential tranches. The initial tranche of $10.0 million was funded at the closing of the Loan Agreement. The remaining tranches were dependent on achieving certain clinical trial milestones. As of September 30, 2024, we declined these tranches in borrowing capacity available to us under the Loan Agreement.

Until June 30, 2023, the Loan Agreement bore interest at a floating per annum rate (based on the actual number of days elapsed divided by a year of 360 days) equal to the sum of (a) the greater of (i) the 30-day U.S. LIBOR rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue and (ii) 0.08%, plus (b) 7.87%. We are required to make monthly interest-only payments prior to the amortization date of January 1, 2025, subject to a potential one-year extension upon satisfaction of certain conditions. The loan facility is secured by all assets except intellectual property, which is subject to a negative pledge, and will mature on November 1, 2026. There are no warrants or financial covenants associated with the Loan Agreement. A LIBOR transition event occurred effective July 1, 2023 and Oxford Finance revised the Loan Agreement to replace the LIBOR rate with the 1-month CME term SOFR plus 0.1%. The rate change did not require contract remeasurement at the effective date of the change or a reassessment of any previous accounting determinations pertaining to the facility. The rate change did not have a material impact on the Company's financial statements.

Funding Requirements

We believe that our available cash, cash equivalents and short-term investments are sufficient to fund existing and planned cash requirements for the next 12 months. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, clinical costs, legal and other regulatory expenses and general overhead costs. We have based our estimates on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we currently expect.

Our future funding requirements will depend on many factors, including the following:

- the progress, timing, scope, results and costs of our clinical trials and preclinical studies for our product candidates, including the ability to enroll patients in a timely manner for our clinical trials;
- the costs of obtaining clinical and commercial supplies for zetomipzomib and any other product candidates we may identify and develop;
- the cost, timing and outcomes of regulatory approvals;
- the extent to which we may acquire or in-license other product candidates and technologies;
- the cost of attracting, hiring and retaining qualified personnel;
- our ability to successfully commercialize any product candidates for which we obtain regulatory approval; and
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

Our material cash requirements as of September 30, 2024 primarily relate to the maturities of principal obligations under our Term Loan and operating leases for office space and equipment. As of September 30, 2024, we have $8.5 million payable within 12 months, inclusive of interest payments on Term Loan. Refer to Notes 6 and 7 to our condensed consolidated financial statements for additional information.

Our expected material cash requirements do not include any potential contingent payments upon the achievement by us of clinical, regulatory and commercial events, as applicable, or royalty payments that we may be required to make under license agreements we have entered into or may enter into with various entities pursuant to which we have in-licensed certain intellectual property, including our Onyx License Agreement. Under the Onyx License Agreement, we are obligated to pay Onyx milestone payments of up to $167.5 million in the aggregate upon the achievement of certain development, regulatory and sales milestones. We excluded the contingent payments given that the timing and amount (if any) of any such payments cannot be reasonably estimated at this time. We also have no material non-cancellable purchase commitments with service providers, as we have generally contracted on a cancellable, purchase order basis.

We will require additional financing to fund working capital and pay our obligations. We may pursue financing opportunities through a combination of equity offerings, debt financings and additional funding from license and collaboration agreements. Except for any obligations of Everest to reimburse us for research and development expenses or to make milestone or royalty payments under the Everest License Agreement, we have no committed external sources of funding. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us or at all. Funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations and other licensing arrangements. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Cash Flows

The following summarizes our cash flows for the periods indicated:

	Nine Months Ended September 30,	
	2024	2023
(dollars in millions)	**(unaudited)**	
Net cash used in operating activities	$ (57.4)	$ (62.7)
Net cash provided by investing activities	$ 56.7	$ 48.2
Net cash provided by financing activities	$ 0.1	$ 0.6

Cash Flows from Operating Activities

During the nine months ended September 30, 2024, cash used in operating activities was $57.4 million, which consisted of a net loss of $63.5 million and a net change of $2.0 million in our net operating assets and liabilities, adjusted by non-cash charges of $8.1 million. The non-cash charges consisted of $9.7 million for stock-based compensation expense, $1.5 million for the impairment loss of ROU asset, $0.8 million for depreciation and amortization, and $0.2 million of non-cash interest expense, offset by $4.1 million of amortization of premium and discounts on marketable securities. The change in our net operating assets and liabilities was primarily due to a decrease of $0.7 million in prepaid expenses, other current assets and other assets, a decrease of $1.1 million in operating lease asset and liabilities, and a decrease of $1.6 million in accounts payable and accrued liabilities due to increased clinical expenditures.

During the nine months ended September 30, 2023, cash used in operating activities was $62.7 million, which consisted of a net loss of $69.6 million and a net change of $3.6 million in our net operating assets and liabilities, adjusted by non-cash charges of $10.6 million. The non-cash charges consisted of $14.9 million for stock-based compensation expense, $0.8 million for depreciation and amortization, and $0.2 million of non-cash interest expense, offset by $5.3 million of amortization of premium and discounts on marketable securities. The change in our net operating assets and liabilities was primarily due to an increase of $7.0 million in accounts receivable, an increase of $1.8 million in prepaid expenses, other current assets and other assets driven by the start-up clinical activities related to the PALIZADE trial, and a decrease of $0.2 million in operating lease asset and liabilities, offset by an increase of $5.4 million in accounts payable and accrued liabilities due to increased clinical expenditures.

Cash Flows from Investing Activities

Net cash provided by investing activities was $56.7 million for the nine months ended September 30, 2024, primarily relating to the maturities of marketable securities exceeding purchases of such marketable securities.

Net cash provided by investing activities was $48.2 million for the nine months ended September 30, 2023, primarily relating to the maturities of marketable securities exceeding purchases of such marketable securities. Payments for the purchases of property and equipment were $1.8 million during the nine months ended September 30, 2023.

Cash Flows from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 was $0.1 million, primarily from the issuance of common stock pursuant to our employee equity plans.

Net cash provided by financing activities for the nine months ended September 30, 2023 was $0.6 million, primarily from the issuance of common stock pursuant to our employee equity plans.

Critical Accounting Estimates

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

There have been no other material changes to our critical accounting judgments and estimates from those described under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report.

Status as a Smaller Reporting Company

We are a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. As a result, we may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by nonaffiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. The market risk inherent in our financial instruments and in our financial position reflects the potential losses arising from adverse changes in interest rates and concentration of credit risk. We had cash, cash equivalents and marketable securities of $148.4 million as of September 30, 2024, which consisted of bank deposits, highly liquid U.S. Treasury money market funds, U.S. Treasury securities, commercial paper, corporate debt securities and U.S. agency bonds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of September 30, 2024, our cash equivalents and marketable securities had an average maturity of approximately 5 months and the longest maturity was 12 months. Due to the short-term duration and the lower risk profile of our cash equivalents and marketable securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities. We have the ability to hold our cash equivalents and marketable securities until maturity, and we therefore do not expect a change in market interest rates to affect our operating results or cash flows to any significant degree.

Our investment portfolio consists of investment grade securities diversified amongst security types, industries, and issuers. We maintain cash, cash equivalents, and investments with multiple financial institutions that we believe are financially sound and have minimal credit risk exposure, although at times our balances may exceed the applicable insurance coverage limits. We monitor and manage the overall counterparty credit risk exposure of our cash balances to individual financial institutions on an ongoing basis. All our securities are held in custody by a recognized financial institution. Our policy limits the amount of credit exposure to a maximum of 10% to any one issuer, except for the U.S. Treasury, Federal Agencies, or Government Money Market Funds, and we believe no significant concentration risk exists with respect to these investments.

Approximately $0.7 million of our cash, cash equivalents and marketable securities balance was located in Australia as of September 30, 2024. Our expenses, except those related to our Australian operations, are generally denominated in U.S. dollars. For our operations in Australia, the majority of the expenses are denominated in Australian dollars. To date, we have not had a formal hedging program with respect to foreign currency. A 10% increase or decrease in current exchange rates would not have a material effect on our consolidated financial results.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. Based upon the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting.

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that materially affected or are 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 become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q, including our financial statements and related notes hereto, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. We cannot assure you that any of the events discussed below will not occur.

Summary of Selected Risks Associated with our Business

Our business is subject to numerous risks and uncertainties, including those discussed at length in the section titled “Risk Factors.” These risks include, among others, the following:

- We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- We have a limited operating history and have never generated revenue from product sales, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We will require substantial additional capital to finance our operations, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, reduce or terminate certain of our product development programs or other operations.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.
- Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of zetomipzomib, as well as any future product candidates.
- We may explore strategic collaborations, which would require us to relinquish important rights to and control over the development and commercialization of our product candidates to any future collaborators.
- Success in preclinical studies or earlier clinical trials may not be indicative of future clinical trial results, and we cannot assure you that any clinical trials will lead to results sufficient for the necessary regulatory approvals.
- Clinical trials are very expensive, time consuming and difficult to design and implement.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.
- We may encounter substantial delays or difficulties in enrolling and retaining patients in our clinical trials.
- The manufacture of our product candidates is complex and uncertain, and until we develop a validated manufacturing process, we may encounter difficulties in supplying our planned and future clinical trials. If we encounter such difficulties, or fail to meet quality standards, our ability to meet clinical timelines and expand our development strategy could be impacted.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.
- We may not be able to obtain or maintain orphan drug designations or exclusivity for our product candidates, which could limit the potential profitability of our product candidates.

•Even if our product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

•We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.

•We are dependent upon Everest for the further development and commercialization of zetomipzomib in the greater China region, South Korea and certain Southeast Asian countries.

•Our relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

•We rely on third parties to manufacture clinical supplies of our product candidates and to conduct, supervise and monitor our clinical trials and preclinical studies. If those third parties perform in an unsatisfactory manner, it may harm our business.

•Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach our exclusive license agreement with Onyx Therapeutics, Inc., we could lose the ability to continue the development and commercialization of zetomipzomib.

•If we are unable to obtain and maintain patent protection for zetomipzomib or any future product candidate, if the scope of patent protection is not sufficiently broad, or if our patents are insufficient to protect our product candidates for an adequate amount of time, we may not be able to compete effectively in our markets.

•Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

•We are highly dependent on the services of our executive officers, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

•If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports, about our business or our market, our stock price and trading volume could decline.

•Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

Since inception in February 2015, we have incurred significant operating losses. Our net loss was $101.9 million for the year ended December 31, 2023 and $63.5 million for the nine months ended September 30, 2024. As of September 30, 2024, we had an accumulated deficit of $414.3 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Since inception, we have devoted substantially all of our efforts to research and preclinical and clinical development of our product candidates, as well as to expanding our management team and infrastructure. It could be several years, if ever, before we have a commercialized drug. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

•continue the ongoing and planned development of zetomipzomib and future product candidates from our protein secretion program;

•seek to discover and develop additional product candidates, including preclinical studies and clinical trials for such product candidates;

•maintain, protect and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;

•seek marketing approvals for zetomipzomib and any future product candidates that successfully complete clinical trials;

•establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;

•continue to build a portfolio of product candidates through the acquisition or in-license of drugs, product candidates or technologies;

•implement operational, financial, management and compliance systems; and

•attract, hire and retain additional administrative, clinical, regulatory and scientific personnel.

In addition, because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to accurately predict the timing or amount of increased expenses and when, or if, we will be able to achieve profitability. Our expenses could increase, and profitability could be further delayed if we decide to or are required by regulatory authorities to perform studies or trials in addition to those currently expected or if there are any delays in the initiation, enrollment or completion of any planned or future preclinical studies or clinical trials of our current and future product candidates. Even if we complete the development and regulatory processes necessary to obtain marketing approval, we anticipate incurring significant costs associated with launching and commercializing zetomipzomib and any future product candidates.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

We have a limited operating history and have never generated revenue from product sales, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage company and our operations to date have been largely focused on raising capital and conducting preclinical and clinical development of zetomipzomib. As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization of our product candidates. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with any future collaborative partners, to successfully complete the development of and obtain the regulatory approvals necessary to commercialize zetomipzomib and any future product candidates. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate revenue from product sales depends heavily on our, or any future collaborators', success in:

•timely and successfully completing preclinical and clinical development of zetomipzomib and any future product candidates;

•obtaining regulatory approvals for zetomipzomib and any future product candidates for which we successfully complete clinical trials;

•launching and commercializing any product candidates for which we obtain regulatory approval by establishing a sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;

•qualifying for and obtaining coverage and adequate reimbursement by government and third-party payors for any product candidates for which we obtain regulatory approval, both in the United States and internationally;

•developing, validating and maintaining commercially viable, sustainable, scalable, reproducible and transferable manufacturing processes for zetomipzomib, a self-administered dual-chamber system for administering zetomipzomib and any future product candidates that are compliant with current good manufacturing practices, or cGMP;

•establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate amount and quality of starting materials, drug substance, drug product and drug delivery devices and services to support clinical development, as well as the market demand for zetomipzomib and any future product candidates, if approved;

•obtaining market acceptance, if and when approved, of zetomipzomib or any future product candidate as a viable treatment option by physicians, patients, third-party payors and others in the medical community;

•effectively addressing any competing technological and market developments;

•implementing additional internal systems and infrastructure, as needed;

•negotiating favorable terms in any collaboration, licensing, spin-off or other arrangements into which we may enter and performing our obligations pursuant to such arrangements;

•maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and

- securing appropriate pricing in the United States and internationally.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We may need to eventually transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

We will require substantial additional capital to finance our operations, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, reduce or terminate certain of our product development programs or other operations.

Our operations have consumed substantial amounts of cash since our inception. We expect our expenses to increase in connection with our ongoing and planned activities, particularly as we continue to develop and potentially commercialize our product candidates, in addition to costs associated with the acquisition or in-licensing of any additional product candidates we may pursue. Our expenses could increase beyond expectations if the FDA or comparable foreign regulatory authorities require us to perform clinical and other studies in addition to those that we currently anticipate. In addition, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to sales, marketing, manufacturing and distribution.

As of September 30, 2024, we had cash, cash equivalents and marketable securities of $148.4 million. We believe that our cash, cash equivalents and marketable securities as of September 30, 2024 will fund our current operating plans through at least the next 12 months from the date the financial statements were issued. However, our operating plan may change as a result of many factors currently unknown to us, including as a result of the macroeconomic uncertainties and geopolitical tensions, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. If the adverse global economic conditions, including higher inflation rates and changes in interest rates, persist or worsen, we could experience an inability to access additional capital or engage in strategic transactions on terms reasonable to us, or at all.

We do not currently have any commitments for future funding other than reimbursement, milestone and royalty payments we may receive under our Everest License Agreement, and we may not receive any further funds under that agreement. In any event, we will require substantial additional capital to develop a delivery system for zetomipzomib, conduct additional clinical trials, seek regulatory approval and commence commercialization of zetomipzomib or any future product candidates. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize zetomipzomib and any future product candidates.

If we do not raise additional capital in sufficient amounts, or on terms acceptable to us, we may be prevented from pursuing discovery, development and commercialization efforts, which will harm our business, operating results and prospects.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. In December 2021, we entered into Sales Agreement, or the ATM Agreement, with Cowen and Company, LLC, for an at-the-market offering program that allows us to sell up to an aggregate of $200 million of our common stock. As of September 30, 2024, approximately $68.3 million remains available under the at-the-market offering program. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. In addition, we may issue equity or debt securities as consideration for obtaining rights to additional compounds.

Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could negatively impact our ability to conduct our business. For example, our obligations under the Loan Agreement are secured by a security interest in all of our assets, other than our intellectual property which is subject to a negative pledge. In addition, the Loan Agreement contains customary covenants that, subject to specific exceptions, restrict our ability to, among other things, declare dividends or redeem or repurchase equity interests, incur additional liens, make loans and investments, incur additional indebtedness, engage in mergers, acquisitions and asset sales, transact with affiliates, undergo a change in control, add or change business locations, or engage in businesses that are not related to its existing business.

In addition, if we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. For example, in September 2023, we entered into a collaboration and license agreement with Everest granting it an exclusive license to develop and commercialize zetomipzomib in the greater China region, South Korea and certain Southeast Asian countries in exchange for an upfront payment and potential milestone and royalty payments.

If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

The terms of the Loan Agreement with Oxford Finance place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In November 2021, we entered into a Loan Agreement with Oxford Finance that provided us with up to $50.0 million of borrowing capacity across five potential tranches. The initial tranche of $10.0 million was funded at the closing of the Loan Agreement, and we declined the remaining tranches in borrowing capacity available to us. Our overall leverage and certain obligations and affirmative and negative covenants contained in the related documentation could adversely affect our financial health and business and future operations by limiting our ability to, among other things, satisfy our obligations under the Loan Agreement, refinance our debt on terms acceptable to us or at all, plan for and adjust to changing business, industry and market conditions, use our available cash flow to fund future acquisitions and make dividend payments, and obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity.

If we default under the Loan Agreement, Oxford Finance may accelerate all of our repayment obligations and exercise all of their rights and remedies under the Loan Agreement and applicable law, potentially requiring us to renegotiate our agreement on terms less favorable to us. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Oxford Finance could declare a default upon the occurrence of an event of default, including events that they interpret as a material adverse change as defined in the Loan Agreement, payment defaults or breaches of certain affirmative and negative covenants, thereby requiring us to repay the loan immediately. Any declaration by Oxford Finance of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. Additionally, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We are required and expect to make significant payments in connection with our license agreement with Onyx Therapeutics, Inc., or Onyx, for zetomipzomib.

We acquired rights to zetomipzomib, pursuant to an exclusive license agreement with Onyx, or the Onyx License Agreement. Under the Onyx License Agreement, we are subject to significant obligations, including payment obligations triggered upon achievement of specified milestones and royalties on licensed product sales. We have paid $5.0 million in milestone payments to date under the Onyx License Agreement, and we are obligated to pay Onyx additional milestone payments of up to $167.5 million in the aggregate upon the achievement of certain development, regulatory and sales milestones. In addition, we are obligated to pay Onyx tiered royalties based on net sales of zetomipzomib. If these payments become due, we may not have sufficient funds available to meet our obligations and our development efforts may be harmed.

Our ability to use net operating losses and certain other tax attributes to offset future taxable income may be subject to limitation.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Our NOLs generated in tax years beginning on or prior to December 31, 2017 are permitted to be carried forward for only 20 years under applicable U.S. tax law. Our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to federal law with respect to the limitations on the use of NOLs.

In addition, under Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” its ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points (by value) over their lowest ownership percentage over a rolling three-year period. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of

accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our NOL carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

Changes in tax laws or regulations could materially adversely affect our company.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, our suppliers, manufacturers, or our customers, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

Risks Related to the Development and Commercialization of Our Product Candidates

Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of our product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be adversely affected.

The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that neither our current product candidates, nor any product candidates we may seek to develop in the future, will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market zetomipzomib in the United States or abroad until we receive regulatory approval from the FDA or the applicable foreign regulatory authority.

Prior to obtaining approval to commercialize our product candidates in the United States or abroad, we must demonstrate with substantial evidence from well controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from clinical trials and preclinical studies can be interpreted in different ways. Even if we believe the clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA may also require us to conduct additional clinical trials or nonclinical studies for our product candidates either prior to or post-approval, or it may object to the design of our clinical trials and other elements of our clinical development programs. In addition, the FDA typically refers applications for novel drugs to an advisory committee comprising outside experts. The FDA is not bound by the recommendation of the advisory committee, but it considers such recommendation when making its decision.

Of the large number of product candidates in development, only a small percentage are successfully approved by the FDA or a comparable foreign regulatory authority and are commercialized. The lengthy approval or marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval or marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We have invested a significant portion of our time and limited financial and management resources in the development of zetomipzomib and KZR-261. Our business is dependent on our ability to successfully complete development of, obtain regulatory approval for, and, if approved, successfully commercialize zetomipzomib or any future product candidates in a timely manner. In August 2024, we stopped enrollment in the KZR-261 Phase 1 clinical study to reallocate resources toward development of

zetomipzomib. This and other resource allocation decisions may cause us to fail to capitalize on profitable market opportunities for our product candidates.

Even if we eventually complete clinical testing and receive approval of a new drug application, or NDA, or foreign marketing application for zetomipzomib or any future product candidates, the FDA or the comparable foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA and comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. In addition, we could also experience delays in the timing of our interactions with regulatory authorities due to absenteeism by governmental employees, inability to conduct planned physical inspections related to regulatory approval, which could delay anticipated approval decisions and otherwise delay or limit our ability to make planned regulatory submissions or obtain new product approvals.

Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Furthermore, even if we obtain regulatory approval for any of our product candidates, we will still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for adequate reimbursement from third-party and government payors. If we are unable to successfully commercialize zetomipzomib and any future product candidates, we may not be able to generate sufficient revenue to continue our business.

Clinical trials are very expensive, time consuming and difficult to design and implement.

Our product candidates will require clinical testing before we are prepared to submit an NDA for regulatory approval. The clinical trial process is expensive, time consuming, difficult to design and implement, and subject to uncertainty. We estimate that the successful completion of clinical trials of our product candidates will take several years to complete. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval for any of our product candidates or whether any such NDA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any future clinical trial of our product candidates, which may delay the commencement of our clinical trials. We may design the inclusion and exclusion criteria for trial participation too narrowly, which would make it difficult to find and enroll patients for our clinical trials. In addition, we may not succeed in developing and validating disease-relevant clinical endpoints based on insights regarding biological pathways for the disorders we are studying.

Delays in or failure to complete any preclinical studies or clinical trials of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. For example, in October 2024, we terminated our global PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN after the trial was placed on clinical hold by the FDA following four deaths in patients enrolled in the trial in the Philippines and Argentina. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Failure can occur at any stage, and we could encounter problems that cause us to suspend, abandon or repeat clinical trials.

Any delays to our preclinical studies or clinical trials, that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

If the market opportunities for zetomipzomib or any future product candidates are smaller than we believe they are, our business may suffer.

We currently focus our drug development of zetomipzomib on treatments of immune-mediated diseases, including autoimmune hepatitis. Our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidates. Our projections of both the number of people who have these disorders, as well as the subset of people with these

disorders who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these disorders. The number of eligible patients for either product candidate may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates. If the market opportunities for our product candidates are smaller than we estimate, our business and results of operations could be adversely affected.

Due to the significant resources required for clinical development, we are required to make strategic decisions for the development of our product candidates. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on other opportunities that may be more profitable or for which there may be a greater likelihood of success.

The development of a product candidate like zetomipzomib requires significant capital investment. Due to the significant resources required for clinical development, we must focus our research and development efforts on specific indications and decide which development opportunities to pursue and advance for each program. For example, in October 2024, we terminated our global PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN, after the trial was placed on clinical hold by the FDA, to focus clinical development efforts of zetomipzomib in AIH. Our decisions concerning the allocation of development, management and financial resources may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we do not accurately evaluate the viability, development costs and commercial potential of our product candidates, we may fail to capitalize on profitable market opportunities, forego or delay opportunities to pursue other product candidates or other indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to product candidates through strategic transactions, including collaboration, licensing or other royalty arrangements, asset sales, and spin-offs, in cases in which it would have been more advantageous for us to retain ownership and sole development and commercialization rights to such product candidates.

We may explore strategic collaborations, which would require us to relinquish important rights to and control over the development and commercialization of our product candidates to any future collaborators.

Over time, our business strategy may include entering into product development collaborations, including strategic collaborations with major biotechnology or pharmaceutical companies. For example, in September 2023, we entered into a collaboration and license agreement with Everest granting it exclusive license to develop and commercialize zetomipzomib in the greater China region, South Korea and certain Southeast Asian countries in exchange for an upfront payment and potential milestone and royalty payments. We cannot predict what form any other strategic collaboration might take. We face significant competition in seeking appropriate strategic collaborators, and the negotiation process can be complicated and time consuming. Even if we are successful in our efforts to establish new development collaborations, the terms of such collaborations may not be favorable to us. Entering into future collaborations could subject us to a number of risks, including:

- we may be required to relinquish important rights to and control over the development and commercialization of our product candidates;
- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our stockholders' percentage ownership of our company;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- strategic collaborators may select indications or design clinical trials in a way that may be less successful or slower than if we were doing so;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;

•strategic collaborators may experience financial difficulties;

•strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

•business combinations or significant changes in a strategic collaborator's business strategy may adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;

•strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and

•strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Success in preclinical studies or earlier clinical trials may not be indicative of future clinical trial results, and we cannot assure you that any clinical trials will lead to results sufficient for the necessary regulatory approvals.

Success in preclinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and early clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical studies and earlier clinical trials does not ensure that later trials designed to test efficacy will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through earlier clinical trials. For example, in October 2024, we terminated our global PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN after the trial was placed on clinical hold by the FDA following four deaths in patients enrolled in the trial in the Philippines and Argentina.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. We are developing zetomipzomib to address several autoimmune diseases with high degrees of unmet medical need, including autoimmune hepatitis. If the actual number of patients with these disorders is smaller than we anticipate, or if these patients are unwilling to participate in a clinical trial, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our product candidates. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of patients to clinical sites, our ability to provide zetomipzomib for at-home administration, and the eligibility criteria for the trial. Because our focus includes rare disorders, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. For example, political instability or disruption in a geographic region where we are conducting trials, regardless of cause, including public health crises, war, terrorism, social unrest and political changes, could delay or prevent patients from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay our clinical trials, or prevent us from completing our clinical trials at all. Any inability to timely and successfully complete clinical development will increase our costs, slow our development plans and impair our ability to generate revenue from our product candidates. In addition, we may be reliant on CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

We may encounter substantial delays or difficulties in our clinical trials.

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA or a comparable foreign regulatory authority, and we may never receive such approvals. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. For example, in October 2024, we terminated our global PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN after the trial was placed on clinical hold by the FDA. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, circumstances may arise that could result in suspending or terminating our ongoing clinical trials. The closure of sites, the inability to screen and enroll new patients or any premature discontinuation of treatment by patients already enrolled in our trial could result in the need to enroll additional patients, which would be costly and could delay our anticipated timeline for the completion of the trial. Any inability to timely and successfully complete clinical development will increase our costs, slow our development plans and impair our ability to generate revenue from our product candidates.

We have experienced and may in the future experience numerous unforeseen events that may prevent the timely and successful completion of our clinical trials, or result in the termination of such clinical trials prior to their completion, including:

- failure to recruit suitable patients to participate in a clinical trial, enrollment in these clinical trials may be slower than we anticipate, and participants may drop out during the course of these trials at a higher rate than we anticipate;
- delays in manufacturing, testing, releasing, validating and shipping stable quantities of our product candidates and placebo for our clinical trial sites;
- delays in reaching a consensus with the FDA and foreign regulatory authorities on the design of our clinical trials;
- the number of patients required for clinical trials to produce statistically meaningful data may be larger than we anticipate;
- the costs of clinical trials of our product candidates may be greater than we anticipate, which may be more likely as a result of increased price inflation worldwide;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, such as the clinical hold imposed by the FDA on our PALIZADE Phase 2b clinical trial of zetomipzomib in patients with LN following four patient deaths in the Philippines and Argentina;
- concerns with a class of product candidates or after an inspection of our clinical trial operations, trial sites or manufacturing facilities;
- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site, or may otherwise suspend our clinical trials at any time if it appears we are or our collaborators are failing to conduct a trial in accordance with regulatory requirements;
- delays in identifying and recruiting suitable clinical investigators or reaching agreement on acceptable terms with prospective clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, such as the topline data from our PRESIDIO Phase 2 clinical trial of zetomipzomib in patients with dermatomyositis and polymyositis, in which zetomipzomib did not demonstrate significant differentiation from placebo;
- failure to perform our clinical trials in accordance with current Good Clinical Practice, or cGCP, or regulations required by the FDA or foreign regulatory authorities;
- changes in regulatory requirements and guidance or other unforeseen regulatory developments that require amending or submitting new clinical protocols;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; or
- business interruptions resulting from geo-political actions, war, terrorism, natural disasters or public health crises.

Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring competing drugs to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued or held liable for harm causes to patients; or
- experience damage to our reputation.

For example, in October 2024, we terminated our PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN. This decision was made after the trial was placed on clinical hold by the FDA following four deaths in patients enrolled in the trial in the Philippines and Argentina.

Further, we, the FDA, comparable foreign regulatory authorities, or an IRB may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including cGCP, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our INDs, or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed.

The manufacture of our product candidates is complex and uncertain, and until we develop a validated manufacturing process, we may encounter difficulties in supplying our planned and future clinical trials. If we encounter such difficulties, or fail to meet quality standards, our ability to meet clinical timelines and expand our development strategy could be impacted.

The processes involved in manufacturing the active drug substance and finished drug product of zetomipzomib are complex, expensive, highly regulated and subject to multiple risks and uncertainties. As product candidates are developed through early to late-stage clinical trials and then to approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are modified along the way to optimize the scale, process and results. Any changes to the manufacturing processes carry the risk that they will not achieve these intended objectives, or that the product candidates may not meet the rigorous quality standards necessary for use in our clinical trials.

We are continuing to manufacture zetomipzomib and placebo in support of our PORTOLA trial. However, if planned or future manufacturing of zetomipzomib fails to meet the quality standards for use in our clinical trials, or the active drug substance does not meet our quality specifications, it could impact our timelines and limit our development strategy.

In addition, our contract manufacturing organizations, or CMOs, may be unable to successfully increase the manufacturing scale for our product candidates in a timely or cost-effective manner and may experience delays due to limited manufacturing capacity. In addition, quality issues may arise during manufacturing activities. If our CMOs are unable to successfully manufacture our product candidates in sufficient quantity in a timely manner, our planned clinical trials may be delayed or modified and we may also be unable to fulfill our obligations under the Everest License Agreement, allowing Everest to terminate its collaboration or other potential adverse consequences as provided in the Everest License Agreement.

Our product candidates have been involved, and may be involved in the future, in investigator-initiated clinical trials, and we have limited or no control over the conduct of such trials.

Zetomipzomib has been involved in an investigator-initiated clinical trial, and our product candidates may be involved in investigator-initiated clinical trials in the future. Investigator-initiated clinical trials pose similar risks as those set forth elsewhere in this "Risk Factor" section relating to our own internal clinical trials. However, while investigator-initiated clinical trials may provide us with clinical data that can inform our development strategy, we are not the sponsors of such trials, and therefore, we do not control the protocols, administration, quality or conduct of these trials, including follow-up with patients and ongoing data collection. Despite this lack of control, negative results in investigator-initiated clinical trials could have a material adverse effect on our business and prospects and the perception of our product candidates.

Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available, particularly from our open-label studies. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Preliminary or topline data may include, for example, data regarding a small percentage of the patients enrolled in a clinical trial, and such preliminary data should not be viewed as an indication, belief or guarantee that other patients enrolled in such clinical trial will achieve similar results or that the preliminary results from such patients will be maintained. As a result, interim and preliminary data may not be statistically significant and should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data may cause the trading price of our common stock to fluctuate significantly and could significantly harm our business prospects.

Zetomipzomib is being developed as a lyophilized formulation which could adversely affect market acceptance if patients are required to reconstitute zetomipzomib themselves prior to injection.

We are developing zetomipzomib as a lyophilized product candidate, meaning that it will be freeze-dried and must be reconstituted with water prior to patient administration. While lyophilized products are common in the drug industry, this method for administering zetomipzomib could adversely affect market acceptance and make it more difficult to conduct clinical trials of zetomipzomib. In our current trials, zetomipzomib is reconstituted in the hospital pharmacy prior to patient administration or reconstituted and self-administered by the patient at home.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, discomforts and other adverse events, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur. In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects or patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale pivotal trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that zetomipzomib or any future product candidates has side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition.

Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed and our ability to generate revenue through their sale may be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly. For example, in October 2024, we terminated our PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN. This decision was made after the trial was placed on clinical hold by the FDA following four deaths in patients enrolled in the trial in the Philippines and Argentina, including one patient on placebo. Review of the data by the IDMC revealed that three of the fatalities showed a common pattern of symptoms and proximity to dosing, and additional non-fatal SAEs showed a similar proximity to dosing.

Additionally, if any of our product candidates receive marketing approval, the FDA could require us to include a black box warning in our label or adopt a REMS to ensure that the benefits outweigh the risks, which may include, among other things, a Medication Guide outlining the risks of the drug for distribution to patients and a communication plan to healthcare practitioners. Furthermore, if we or

others identify undesirable side effects caused by our product candidates during development or after obtaining U.S. regulatory approval, several potentially significant negative consequences could result, including:

- regulatory authorities may not permit us to initiate our studies or could put them on hold;
- regulatory authorities may not approve, or may withdraw, their approval of the product;
- regulatory authorities may require us to recall the product;
- regulatory authorities may add new limitations for distribution and marketing of the product;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered or modify the product in some other way;
- we may be required to implement a REMS program;
- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved. In addition, these events could substantially increase the costs of commercializing our product candidates and could significantly harm our business, prospects, financial condition and results of operations.

We may not be able to obtain or maintain orphan drug designations or exclusivity for our product candidates, which could limit the potential profitability of our product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000, there is no reasonable expectation that sales of the drug in the United States will be sufficient to offset the costs of developing and making the drug available in the United States. If a drug with an orphan drug designation subsequently receives the first marketing approval for use in the rare disease or condition for which it was designated, then the sponsor is eligible for a seven-year period of marketing during which the FDA may not approve another sponsor's marketing application for a drug with the same active moiety and intended for the same use or indication as the approved orphan drug, except in limited circumstances, such as if a subsequent sponsor demonstrates its product is clinically superior. During a sponsor's orphan drug exclusivity period, however, competitors may receive approval for drugs with different active moieties for the same indication as the approved orphan drug, or for drugs with the same active moiety as the approved orphan drug, but for different indications. Further, if a designated orphan drug receives marketing approval for an indication broader than the rare disease or condition for which it received orphan drug designation, it may not be entitled to exclusivity.

We intend to pursue orphan drug designation for zetomipzomib in the treatment of autoimmune hepatitis and any other rare immune-mediated disease indications we pursue for development. Obtaining orphan drug designation in additional indications and other jurisdictions may be difficult, and we may not be successful in doing so. The exclusivity for our orphan drug designations, and for any other designations that we may obtain in the future, may not effectively protect the drug from the competition of different drugs for the same condition, which could have already been approved or could be approved before or during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. The failure to obtain an orphan drug designation for any product candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval for our product candidates outside of the United States, which would limit our market opportunities and could harm our business.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of zetomipzomib outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable foreign regulatory authorities also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any product candidates, if approved, is also subject to approval. Obtaining approval for zetomipzomib in the European Union from the European Commission following the opinion of the European Medicines Agency, if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a product candidate is approved, the FDA or the European Commission, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of zetomipzomib and any future product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for our product candidates may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects could be harmed.

Even if we obtain regulatory approval for any of our product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain regulatory approvals for our product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. For example, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. Additionally, any regulatory approvals that we receive for our product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the drug. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval.

In addition, drug manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and comparable foreign regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or comparable foreign marketing application or any supplements thereto submitted by us or our partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or

•refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and harm our business, financial condition, results of operations and prospects.

The FDA's and comparable foreign regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

Even if our product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if our product candidates receive marketing approval, they may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of zetomipzomib and any future product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

•the efficacy and potential advantages compared to alternative treatments and therapies;

•the effectiveness of sales and marketing efforts;

•the strength of our relationships with patient communities;

•the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments;

•our ability to offer such drug for sale at competitive prices;

•the convenience and ease of administration compared to alternative treatments and therapies;

•the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

•the strength of marketing and distribution support;

•the availability of third-party coverage and adequate reimbursement;

•the prevalence and severity of any side effects; and

•any restrictions on the use of the drug together with other medications.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business. In addition, if we enter into a strategic collaboration regarding any of our product candidates, our rights to receive milestone payments and royalties related to such product candidates will depend on our collaborators' abilities to achieve market acceptance of those product candidates.

We are dependent upon our collaboration with Everest to further develop and commercialize zetomipzomib in the Greater China region, South Korea and select Southeast Asian countries. If we or Everest fail to perform as expected, the potential for us to generate future revenues under the collaboration could be significantly reduced, the development and commercialization of zetomipzomib may be substantially delayed, and our business could be adversely affected.

In September 2023, we entered into the Everest License Agreement granting Everest an exclusive license to develop and commercialize zetomipzomib in the greater China region, South Korea, and select Southeast Asian countries. Under the terms of the Everest License Agreement, we received an initial upfront payment of $7.0 million and are entitled to receive milestone payments upon achievement of certain development, regulatory and commercial milestone events, for total potential milestone payments of up to $125.5 million. In addition, Everest will pay to the Company tiered royalties on the net sales of zetomipzomib in the territory during the term of the Everest License Agreement ranging from the single digit to the low-teens, subject to certain reductions.

Everest is responsible for, at its own cost, and is required to use commercially reasonable efforts to, develop and commercialize zetomipzomib in the licensed territory. In addition, we agreed to collaborate with Everest on the PALIZADE trial, where Everest would have primary responsibility for clinical development and regulatory activities in the licensed territory and would reimburse the Company for clinical trial costs incurred in the licensed territory. Everest will also have the opportunity to participate in the Company's future global clinical trials involving zetomipzomib. The Company has agreed to supply zetomipzomib to Everest during the term of the Everest License Agreement, subject to Everest's option to manufacture zetomipzomib for its own use in the licensed territory following completion of the PALIZADE trial.

There can be no assurance that the parties will achieve any of the regulatory, development or sales milestones, or that we will receive any future milestone or royalty payments under the Everest License Agreement. Everest's activities may be influenced by, among other things, the efforts and allocation of resources by Everest, which we cannot control. If Everest does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, manufacturing, regulatory approval, and commercialization efforts related to zetomipzomib could be substantially delayed.

In addition, our collaboration with Everest may be unsuccessful due to other factors, including, without limitation, the following:

- Everest may terminate the agreement for convenience at any time following the October 2024 termination of the PALIZADE trial;
- Everest may change the focus of its development and commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to zetomipzomib;
- Everest may, within its commercially reasonable discretion, choose not to develop and commercialize zetomipzomib in any part of the licensed territory or for one or more indications, if at all; and
- if Everest is acquired during the term of our collaboration, the acquirer may have competing programs or different strategic priorities that could cause it to reduce its commitment to our collaboration or to terminate the collaboration.

The actions of Everest and any other current or future licensees could adversely affect our business.

We currently exclusively license zetomipzomib to Everest to develop and commercialize zetomipzomib in the greater China region, South Korea and select Southeast Asian countries. It is possible that any clinical trials conducted by Everest or any other current or future licensees in its respective licensed territories could have negative results, which in turn could have a material adverse effect on the development and commercialization of zetomipzomib in the United States and the rest of the world. In addition, we will depend on Everest or any other current or future licensee to comply with all applicable laws relative to the development and commercialization of zetomipzomib in its respective licensed territories. If Everest were to violate, or was alleged to have violated, any laws or regulations during the performance of its obligations to us, it is possible we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences. In addition, in the event of any termination, breach or expiration of the Everest License Agreement, we may be required to devote additional efforts and to incur additional costs associated with pursuing the development and commercialization of zetomipzomib in the greater China region, South Korea and select Southeast Asian countries.

We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.

The development and commercialization of new drugs is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of product candidates for the treatment of the indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

More established companies may have a competitive advantage over us due to their greater size, resources and institutional experience. In particular, these companies have greater experience and expertise in securing reimbursement, government contracts and relationships with key opinion leaders, conducting testing and clinical trials, obtaining and maintaining regulatory approvals and distribution relationships to market products and marketing approved drugs. These companies also have significantly greater research and marketing capabilities than we do. If we are not able to compete effectively against existing and potential competitors, our business and financial condition may be harmed.

As a result of these factors, our competitors may obtain regulatory approval of their drugs before we are able to, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop therapies that are safer, more effective, more widely accepted or less expensive than ours, or may be more successful than we are in manufacturing and marketing their drugs.

These advantages could render our product candidates obsolete or non-competitive before we can recover the costs of such product candidates' development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, medical, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing such product candidates, if and when they are approved.

To successfully commercialize any product candidate that may result from our development programs, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any product candidate we may develop will be expensive and time-consuming and could delay any drug launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may seek to enter into collaborations with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any current or future collaborators do not commit sufficient resources to commercialize our product candidates, or we are unable to develop the necessary capabilities on our own, we may be unable to generate sufficient revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We will likely also face competition if we seek third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we seek to commercialize our product candidates outside of the United States, a variety of risks associated with international operations could harm our business.

If we seek to commercialize our product candidates outside of the United States, we expect that we will be subject to additional risks including:

- different regulatory requirements for approval of therapies in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, war, terrorism, natural disasters and public health epidemics.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in and outside of Europe with which we will need to comply. Many biopharmaceutical companies have found the process of marketing their own products in foreign countries to be very challenging.

Coverage and adequate reimbursement may not be available for zetomipzomib or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which coverage and reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One

third-party payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each third-party payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a third-party payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize zetomipzomib or any future product candidates that we develop. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials, both within and outside of the United States, and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- increased insurance costs;
- the inability to commercialize any product candidate that we may develop; and
- injury to our reputation and significant negative media attention.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we advance through clinical development and if we are able to successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Regulatory Compliance

Our relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

•the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, formulary managers and others, on the other hand. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;

•federal civil and criminal false claims laws, including, without limitation, the federal civil False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, implicate the federal civil False Claims Act;

•the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal civil and criminal statutes that prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program, or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);

•HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on health plans, health care clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates and their subcontractors that perform certain services involving the use or disclosure of individually identifiable health information;

•federal transparency laws, including the federal Physician Payments Sunshine Act, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members; and

•state and foreign law equivalents of each of the above federal laws, state laws that require manufacturers to report information related to payments and other "transfers of value" to physicians and other healthcare providers, marketing expenditures, or drug pricing, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and state and local laws that require the registration of pharmaceutical sales representatives, or that otherwise restrict payments that may be made to healthcare providers; as well as state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things: (i) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) established annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its passage, there have been varied executive, judicial and Congressional challenges to certain provisions of the PPACA. In addition, Congress has considered, and may consider in the future, legislation to repeal or repeal and replace all or part of the PPACA. While Congress has not passed any comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have been signed into law. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the PPACA and our business.

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2032 unless additional congressional action is taken. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which included a number of significant drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services, or HHS, that would require pharmaceutical manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation, and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs and Part D beneficiaries' annual out-of-pocket spending will be capped at $2,000 beginning in 2025, although the Medicare drug price negotiation program is currently subject to legal challenges. The U.S. Department of Health and Human Services has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although they may be the Medicare drug price negotiation program is currently subject to legal challenges. It is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In

Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which introduced a merit-based incentive bonus program for Medicare physicians, also referred to as the Quality Payment Program. The Quality Payment Program consists of two payment tracks that eligible clinicians can participate in: Advanced Alternative Payment Models and the Merit-Based Incentive Payment System. Under both the Advanced Alternative Payment Models and the Merit-Based Incentive Payment System, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices and directed HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether these this executive order or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Risks Related to Our Dependence on Third Parties

We will rely on third parties to manufacture clinical and commercial supplies of zetomipzomib and any future product candidates.

We do not own or operate facilities for drug manufacturing, testing, storage or distribution. We are dependent on third parties to manufacture the clinical supplies of our product candidates. Moreover, under the Everest License Agreement, we have committed to providing Everest with supply of zetomipzomib for the development and commercialization of zetomipzomib in the greater China region, South Korea and certain Southeast Asian countries, which we will have to source from third-party manufacturers. Any significant delay in the supply of a product candidate or raw material components for an ongoing clinical trial due to the need to replace a third-party CMO could considerably delay the completion of our clinical trials or cause us to breach our obligations under the Everest License Agreement. We are completely dependent on our CMOs for compliance with cGMP for manufacture of both active drug substances and finished drug products. If our CMOs cannot successfully manufacture active drug substances and finished drug product that conform to our specifications and the strict regulatory requirements of the FDA and comparable foreign regulatory authorities, we will not be able to secure or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our timelines and ability to develop, obtain regulatory approval for or market our product candidates, if approved.

For any activities conducted in China, we are exposed to the increased possibility of supply disruptions and higher costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic conditions including sanctions on China or any of our China-based suppliers. Our manufacturing costs could also increase as a result of future appreciation of the local currency in China or increased labor costs if the demand for skilled laborers increases and/or the availability of skilled labor declines in China. In addition, certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the recently proposed BIOSECURE Act introduced in the U.S. House of Representatives, and a substantially similar bill in the U.S. Senate, target U.S. government contracts, grants, and loans for entities that use equipment and services from certain named Chinese biotechnology companies and authorizes the U.S. government to include additional Chinese biotechnology companies of concern. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies to work with certain Chinese biotechnology companies of

concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. Such disruption could have adverse effects on the development of our product candidates and our business operations.

The facilities used by our CMOs to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA for any of our product candidates. We also expect to rely on third-party manufacturers to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization.

Our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- our third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our third-party manufacturers may fail to comply with cGMP and other inspections by the FDA or comparable foreign regulatory authorities;
- our inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for drug components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- our third-party manufacturers may not devote sufficient resources to our product candidates;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

Any of these events could lead to clinical trial delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure, or total or partial suspension of production.

We rely on third parties to conduct, supervise and monitor our clinical trials and preclinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We do not currently have the ability to independently conduct clinical trials. We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance. We rely upon CROs to monitor and manage data for our clinical programs. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. For example, we engaged and used a single CRO to manage the PALIZADE trial, and although we oversaw their performance and maintained certain regulatory responsibilities, we were dependent in large part on the CRO's performance.

We and our CROs are required to comply with the good laboratory practices and good clinical practices, or GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Council for Harmonisation guidelines for any of our product candidates that are in preclinical and clinical development, respectively. The regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with GCP, the clinical data generated in

our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our reliance on third parties to conduct clinical trials results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with CROs and other third parties can be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. In addition, such parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- not devote sufficient time and resources to our clinical trials;
- experience regulatory compliance issues; or
- undergo changes in priorities or become financially distressed.

These factors may materially adversely affect the timelines of our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, fail to comply with regulatory requirements, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, the product candidate being developed. As a result, our financial results and commercial prospects would be harmed, our costs could increase, and our ability to generate revenue from the product candidate could be delayed. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities which could compete with recruitment of our clinical trials.

If our relationship with any of these CROs terminates, we may be delayed in entering into new arrangements with alternative CROs or unable to do so on commercially reasonable terms. Changing CROs during an ongoing clinical trial involves substantial cost, requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition and prospects.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates.

Risks Related to Our Intellectual Property

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach the Onyx License Agreement, we could lose the ability to continue the development and commercialization of zetomipzomib.

The licensing of intellectual property is of critical importance to our business and to our current and future product candidates, and we expect to enter into additional such agreements in the future. In particular, our immunoproteasome program, including zetomipzomib, is dependent on the Onyx License Agreement. Pursuant to the Onyx License Agreement, Onyx granted us an exclusive license under certain patent rights, and a non-exclusive license to certain know-how, in each case controlled by Onyx, to develop, manufacture and commercialize certain types of compounds, including zetomipzomib, that are selective inhibitors of the immunoproteasome for any and all uses, other than those related to the diagnosis or treatment in humans of cancerous or pre-cancerous diseases or conditions, including those related to hematological diseases or conditions.

The licensed compounds, including zetomipzomib, are selective for the immunoproteasome and therefore are not known or believed, based on scientific literature and the Company's own research and development activities, to have any application in cancer or pre-cancerous conditions. However, notwithstanding these known characteristics of the licensed compounds, Onyx retains all rights under the licensed intellectual property rights that are not granted to the Company, and therefore Onyx retains rights under such intellectual property rights to develop and commercialize the licensed compounds in connection with the diagnosis or treatment in humans of cancerous or pre-cancerous diseases or conditions, including those related to hematological diseases or conditions, and also has the

rights to transfer these rights to a third-party. If Onyx or its licensee develops and commercializes any of the licensed compounds in cancer or pre-cancerous indications that are commercially interchangeable with our product candidates, including zetomipzomib, sales by Onyx or its licensee of such compounds for cancer and pre-cancerous indications could result in the threat of off-label use in our licensed field, potentially diminishing our sales of the applicable licensed compounds in our licensed field.

The Onyx License Agreement may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. Specifically, under the Onyx License Agreement, Onyx has a right of first negotiation under certain circumstances to obtain a license or a similar transfer of rights, if we are seeking to out-license rights to develop and/or commercialize certain licensed products.

Disputes may arise between us and any of these counterparties regarding intellectual property rights that are subject to such agreements, including, but not limited to:

- the scope of rights granted under the agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign our license; and
- the effects of termination.

These or other disputes over intellectual property that we have licensed, or will license or acquire in the future, may prevent or impair our ability to maintain our current arrangements on acceptable terms or may impair the value of the arrangement to us. Any such dispute could have an adverse effect on our business.

If we fail to meet our obligations under these agreements in any material respect, the counterparty may have the right to terminate the respective agreement. Any uncured, material breach under a license could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for each of our product candidates. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the technology licensed to or acquired by us, we may not be able to do so in a timely manner, at an acceptable cost or at all.

Furthermore, certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to obtain and maintain patent protection for zetomipzomib or any future product candidates, or if the scope of the patent protection obtained is not sufficiently broad, or if our patents are insufficient to protect our product candidates for an adequate amount of time, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to zetomipzomib and any future product candidates. We seek to protect our proprietary position by, among other methods, filing patent applications in the United States and abroad related to our current and future research programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

We file patent applications directed to our product candidates in an effort to establish intellectual property positions directed to their compositions of matter as well as uses of these product candidates in the treatment of diseases. Our intellectual property includes patents and patent applications that we own as well as patents and patent applications that we in-license. For example, we have a field-specific exclusive license under the Onyx License Agreement to certain patents and patent applications relating to zetomipzomib.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. In addition, we cannot be sure that any of our

pending patent applications will issue or that, if issued, they have or will issue in a form that will be advantageous to us. The United States Patent and Trademark Office, or the USPTO, international patent offices or judicial bodies may deny or significantly narrow claims made under our patent applications and our issued patents may be successfully challenged, may be designed around, or may otherwise be of insufficient scope to provide us with protection for our commercial products.

It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO may be significantly narrowed by the time they issue, if issued at all. The claims of our issued patents or patent applications when issued may not cover our current or future product candidates, or even if such patents provide coverage, the coverage obtained may not provide any competitive advantage. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current or any future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our current or any future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in clinical trials or regulatory approvals, the period of time during which we could market our product candidates under patent protection would be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for zetomipzomib or any future product candidates, it could dissuade companies from collaborating with us to develop and commercialize product candidates and future drugs and threaten our ability to commercialize, future drugs. Any such outcome could have a negative effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Furthermore, other parties may have developed or may develop technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our patent applications or issued patents. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after the initial filing. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions until such publication dates have passed. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drugs, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to the United States patent law. These include provisions that affect the way patent applications are prosecuted and may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize zetomipzomib or any future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO challenging the priority of an invention claimed within one of our patents, which submissions may also be made prior to a patent's issuance, precluding the granting of any of our pending patent applications. An adverse

determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, or limit the duration of the patent protection of our technology and drugs. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years from the earliest filing date of a non-provisional patent application. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Upon the expiration of patent protection for zetomipzomib or any future product candidates, we may be open to competition from generic versions of such drugs. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

Even if they are unchallenged, our patents may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third-party may develop a competitive drug that is structurally similar to one or more of our product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by our patents is not sufficiently broad to impede such competition, or if the breadth, strength or term (including any extensions or adjustments) of protection provided by our patents is successfully challenged, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new product candidates such as zetomipzomib, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication, or any additional indications approved during the period of extension. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will have to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and applications and any patent rights we may own or license in the future. We rely on our outside counsel or our licensing partners to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our products or technologies, we may not be able to stop a competitor from marketing products that are the same as or similar to our product candidates, which would have a material adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patents. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, any of the foregoing could expose us to liability to the applicable patent owner.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of our future collaborators to develop, manufacture, market and sell zetomipzomib without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to zetomipzomib and any future product candidates and technology, including interference proceedings, post grant review and inter partes review before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize zetomipzomib or any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Many companies and research institutions have filed, and continue to file, patent applications related to selective immunoproteasome inhibitors and protein secretion inhibitors. Some of these patent applications have already been allowed or issued, and others may issue in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes our product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some or all of our business operations, which could materially harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time consuming and would divert management's attention from our core business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do

not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is or will be no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license, and such a license may not be on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The United States has recently enacted and implemented wide ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Since we rely on third parties to develop and manufacture our product candidates, and if we collaborate with third parties for the development of our research programs or product candidates, we must, at times, share trade secrets with them. We may also conduct collaborative research and development programs that may require us to share trade secrets and proprietary know how. We seek to protect our proprietary information by entering into agreements containing confidentiality obligations and ownership provisions relating to intellectual property prior to disclosing proprietary information or beginning research projects with third-party collaborators. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, the unauthorized disclosure or use of our confidential information could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees, investigators, contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, advisors, employees, investigators, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering zetomipzomib and any future product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents, should they issue, that we own or control;

•we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control;

•we might not have been the first to file patent applications covering certain of our inventions;

•others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

•it is possible that our pending patent applications will not lead to issued patents;

•issued patents that we own or control may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;

•our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets;

•we may not develop additional proprietary technologies that are patentable; and

•the patents of others may prevent us from fully exploiting our product candidates or technologies.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

We are highly dependent on the services of our executive officers, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

Recruiting and retaining senior executives, qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will 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. Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. 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 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. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As the clinical development of our product candidates progresses, we also expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, medical affairs, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We are subject to stringent and changing U.S. and foreign laws, regulations and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. As a result of our data processing activities, we are or may become subject to numerous data privacy and security obligations, such as

various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors). In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts. Additionally, in the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR and the United Kingdom's GDPR, or UK GDPR impose strict requirements for processing the personal data of individuals located, respectively within the European Economic Area, or EEA and the United Kingdom, or UK. For example, under GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros under the EU GDPR or 17.5 million pounds sterling under the UK GDPR, or, in each case, 4% of annual global revenue, whichever is greater. Further, companies may face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, the Personal Information Protection and Electronic Documents Act and various related provincial laws, as well as Canada's Anti-Spam Legislation, may apply to our operations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Although there are various mechanisms that may be used in some cases to lawfully transfer personal data to the United States or other countries, these mechanisms are subject to legal challenges and may not be available to us. An inability or material limitation on our ability to transfer personal data to the United States or other countries could materially impact our business operations. In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security are quickly changing and are becoming increasingly stringent, and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, including, without limitation, financial and time-related resources. These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail, or be perceived to have failed, to do so which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation, including class-related claims and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations, including clinical trials; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

Significant disruptions of our, or our contractors' or vendors', information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

In the ordinary course of our business, we and the third parties upon which we rely process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information). Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail

to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident could disrupt our ability (and that of third parties upon whom we rely) to conduct our business. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and data. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Additionally, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and comparable foreign regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or comparable foreign regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses, as deemed appropriate to carry out our business plan. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and drugs of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we engage in future acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or drugs that may be important to the development of our business.

Risks Related to Ownership of Our Common Stock and Other General Matters

The market price of our common stock may be volatile and fluctuate substantially, and you could lose all or part of your investment.

The market price of our common stock has at times experienced price volatility and may continue to be volatile. For example, during 2023, the closing price of our common stock on The Nasdaq Global Select Market prior to our one-for-ten Reverse Stock Split ranged from $7.31 per share to $0.72 per share. The stock market in general and the market for biopharmaceutical and pharmaceutical companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions, including higher inflation rates and changes in interest rates, and other adverse effects or developments, may negatively affect the market price of our common stock, regardless of our actual operating performance. As a result of this volatility, you may not be able to sell your common stock at or above the price paid for the shares. In addition to the factors discussed in this "Risk Factors" section, the market price for our common stock may be influenced by the following:

- the commencement, enrollment or results of our planned or future clinical trials of zetomipzomib and any future product candidates;
- the clinical or commercial success of competitive drugs, therapies or technologies;
- regulatory or legal developments in the United States and other countries;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain and maintain patent protection for our technologies;
- negative or inconclusive results from our clinical trials, such as the May 2022 topline data from the PRESIDIO Phase 2 clinical trial;
- failure or discontinuation of any of our clinical development or research programs, such as the termination of our PALIZADE Phase 2b clinical trial of zetomipzomib in patients with LN after the trial was placed on clinical hold by the FDA;
- the recruitment or departure of key personnel;

- the level of expenses related to our product candidates and clinical development or research programs;
- our ability to discover, develop and broaden our pipeline beyond our current product candidates;
- commencement or termination of collaborations for our research and development programs;
- actual or anticipated changes in estimates as to financial results or development timelines;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- our inability to obtain or delays in manufacturing adequate supply for our clinical trials or the inability to do so at acceptable costs;
- significant lawsuits, including patent or stockholder litigation or products liability claims;
- variations in our financial results or those of companies that are perceived to be similar to us;
- announcement, expectation or completion of additional financing efforts;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad, including as a result of bank failures, public health crises or geopolitical tensions; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports, about our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or financial analysts publish about us or our business. Equity research analysts may discontinue research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. We do not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, changes in interest rates and uncertainty about economic stability. For example, the Russia-Ukraine war and the Israel-Hamas war created volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of recent bank failures, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in

our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply and clinical trial disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our common stock is thinly traded and our stockholders may be unable to sell their shares quickly or at market price.

Although we have had periods of high-volume daily trading in our common stock, generally our stock is thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. Our common stock price could, for example, decline significantly as a result of sales of a large number of shares of our common stock on the market without commensurate demand, as compared to a seasoned issuer that could better absorb those sales without adverse impact on its share price, or from the perception that these sales could occur.

We cannot predict the ultimate effect on our common stock share price of the one-for-ten reverse stock split of our common stock that was effected on October 29, 2024, or the Reverse Stock Split. The Reverse Stock Split may decrease the liquidity of our common stock and magnify any decrease in our overall market capitalization.

The ultimate effect of the Reverse Stock Split on the market price of our common stock cannot be predicted with any certainty, and we cannot assure you that the Reverse Stock Split will result in any or all of the benefits we expect, including enabling the Company to regain compliance with the Nasdaq listing standards, for any meaningful period of time, or at all. While we expect that the reduction in the number of outstanding shares of common stock will proportionally increase the market price of our common stock, we cannot assure you that the Reverse Stock Split will increase the market price of our common stock by a multiple of the Reverse Stock Split ratio or result in any permanent or sustained increase in the market price of our common stock. The market price of our common stock depends on multiple factors, many of which are unrelated to the number of shares outstanding, including our business and financial performance, general market conditions and prospects for future success, any of which could have a counteracting effect to the Reverse Stock Split on the per share price.

In addition, the Reverse Stock Split also reduced the total number of outstanding shares of common stock, which may lead to reduced trading for our common stock, which is already generally thinly traded. As a result of a lower number of shares outstanding, the market for our common stock may also become more volatile. The Reverse Stock Split also increased the number of stockholders who own “odd lots” of less than 100 shares of common stock. A purchase or sale of less than 100 shares of common stock (an “odd lot” transaction) may result in incrementally higher trading costs through certain brokers, particularly “full service” brokers. Therefore, those stockholders who own fewer than 100 shares of common stock following the Reverse Stock Split may be required to pay higher transaction costs if they sell their common stock.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based upon our shares of our common stock outstanding as of September 30, 2024, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock do, in the aggregate, beneficially own shares representing approximately 33% of our outstanding common stock. If our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock acted together, they may be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways with which other stockholders disagree.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid cash dividends on our capital stock. Furthermore, our ability to pay cash dividends is currently restricted by the terms of the Loan Agreement. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In

addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to such companies may make our common stock less attractive to investors.

We are a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended. We take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by nonaffiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

We will continue to incur increased costs as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting, insurance and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes-Oxley Act and related rules implemented by the SEC and The Nasdaq Stock Market. Our management and other personnel will need to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting, external audit and financial compliance costs and have made and will continue to make some activities more time consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we assess and document the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, Section 404(a) of the Sarbanes-Oxley Act, or Section 404(a), requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. Section 404(b) of Sarbanes-Oxley Act, or Section 404(b), also requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement and maintain corporate governance practices and comply with reporting requirements. However, while we remain a smaller reporting company that is not an accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be affected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings; and
- require the approval of the holders of at least 66 $^{2}/_{3}$% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

In addition, our charter contains a provision that authorizes our board of directors to issue preferred stock without stockholder approval, which has been and could in the future be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors. In October 2024, our board of directors implemented a limited duration stockholder rights plan and declared a dividend of one preferred share purchase right, or a Right, for each outstanding share of the Company’s common stock as of the close of business on October 28, 2024, or the Rights Plan. The Rights Plan was adopted in response to (i) the unsolicited, non-binding proposal from Concentra Biosciences, LLC, or Concentra, to acquire all of the outstanding shares of Company’s common stock for cash consideration of $1.10 per share, plus a contingent value right that represents the right to receive 80% of the net proceeds from any out-license or disposition of the Company’s development programs or intellectual property, and (ii) Concentra and its affiliates’ rapid accumulation of 9.9% of the outstanding Company’s common stock. The Rights Plan may have the effect of discouraging or preventing a change of control by, among other things, making it uneconomical for a third party to acquire us without the consent of our board of directors, although there can be no guarantee that the Rights Plan will fulfill its intended purpose. The Rights will expire on October 17, 2025, unless the Rights are earlier redeemed or exchanged by us.

Furthermore, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us or any of our directors, officers, employees or agents arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us or any of our directors, officers, employees or agents that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive-forum provisions may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Item 5. Other Information.

Insider Trading Arrangements

During the fiscal quarter ended September 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f)) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38542), filed with the SEC on June 26, 2018).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38542), filed with the SEC on June 16, 2023).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38542), filed with the SEC on October 28, 2024).
3.4	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38542), filed with the SEC on October 17, 2024).
3.5	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38542), filed with the SEC on June 26, 2018).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 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 - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents.
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibit 101).

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Exchange Act, and shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act (whether made before or after the date of this Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

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.

Kezar Life Sciences, Inc.
(Registrant)

Date: November 12, 2024

By: /s/ Christopher Kirk, Ph.D.
Christopher Kirk, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2024

By: /s/ Marc Belsky
Marc Belsky
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher Kirk, Ph.D., certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Kezar Life Sciences, 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(s) 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(s) 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.

Date: November 12, 2024

By: /s/ Christopher Kirk, Ph.D.
Christopher Kirk, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Marc Belsky, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Kezar Life Sciences, 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(s) 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(s) 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.

Date: November 12, 2024

By: /s/ Marc Belsky
Marc Belsky
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Christopher Kirk, Ph.D., Chief Executive Officer of Kezar Life Sciences, Inc. (the "Company"), and Marc Belsky, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

(1)The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Date: November 12, 2024

/s/ Christopher Kirk, Ph.D.
Christopher Kirk, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

/s/ Marc Belsky
Marc Belsky
Chief Financial Officer
(Principal Financial Officer)