Table of Contents

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

FORM 10-Q

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

For the quarterly period ended December 31, 2023

or

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

For the transition period from to

Commission File Number: 001-39683

REZOLUTE, INC.

(Exact Name of Registrant as Specified in its Charter)

Nevada	**27-3440894**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
275 Shoreline Drive, Suite 500, Redwood City, California	**94065**
(Address of principal executive offices)	(Zip Code)

(650) 206-4507
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	RZLT	Nasdaq Capital Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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, and 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 17(a)(2)(B) of the Securities Act. ☐

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

The registrant had 39,625,271 shares of its $0.001 par value common stock outstanding as of February 9, 2024.

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Report") contains statements reflecting assumptions, expectations, projections, intentions or beliefs about future events that are intended as "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements included or incorporated by reference in this Report, other than statements of historical fact, that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. These statements appear in a number of places, including, but not limited to "Management's Discussion and Analysis of Financial Condition and Results of Operations." These statements represent our reasonable judgment of the future based on various factors and using numerous assumptions and are subject to known and unknown risks, uncertainties and other factors that could cause our actual results and financial position to differ materially from those contemplated by the statements. You can identify these statements by the fact that they do not relate strictly to historical or current facts, and use words such as "anticipate," "believe," "estimate," "expect," "forecast," "may," "should," "plan," "project" and other words of similar meaning. In particular, these include, but are not limited to, statements relating to the following:

- our ability to obtain regulatory approvals or remove regulatory holds for clinical trials and our drug candidates;
- expectations regarding clinical development and the timing of clinical trials in the United States and outside of the United States;
- projected operating or financial results, including anticipated cash flows to be used in operating activities;
- expectations regarding capital expenditures, research and development expenses and the timing of milestone payments required under license agreements;
- our beliefs and assumptions relating to our liquidity position, including our ability to obtain additional financing; and
- our future dependence on third party manufacturers or strategic partners to manufacture any of our pharmaceutical drugs and diagnostics that receive regulatory approval, and our ability to identify strategic partners and enter into license, co-development, collaboration or similar arrangements.

Any or all of our forward-looking statements may turn out to be wrong. They can be affected by inaccurate assumptions or by known and unknown risks, uncertainties and other factors including, but not limited to, the risks described in Part II, Item 1.A Risk Factors, of this report as well as "Risk Factors" described in (i) Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended June 30, 2023 (the "2023 Form 10-K"), filed with the Securities and Exchange Commission ("SEC") on September 14, 2023, and (ii) in Part I, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 filed with the SEC on November 13, 2023.

In addition, there may be other factors that could cause our actual results to be materially different from the results referenced in the forward-looking statements, some of which are included elsewhere in this Report, including "Management's Discussion and Analysis of Financial Condition and Results of Operations." Many of these factors will be important in determining our actual future results. Consequently, no forward-looking statement can be guaranteed. Our actual future results may vary materially from those expressed or implied in any forward-looking statements. All forward-looking statements contained in this Report are qualified in their entirety by this cautionary statement. Forward-looking statements speak only as of the date they are made, and we disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of this Report, except as otherwise required by applicable law.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

Rezolute, Inc.

Unaudited Condensed Consolidated Balance Sheets
(In thousands, except per share amounts)

	December 31, 2023	June 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 12,504	$ 16,036
Investments in marketable debt securities	80,094	85,860
Prepaid expenses and other	3,487	3,014
Total current assets	96,085	104,910
Long-term assets:		
Investments in marketable debt securities	3,352	16,470
Right-of-use assets	2,130	2,054
Property and equipment, net	119	139
Deposits and other	464	148
Total assets	$ 102,150	$ 123,721
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 3,593	$ 3,269
Accrued liabilities:		
Accrued clinical and other	1,394	507
Compensation and benefits	2,483	883
Current portion of operating lease liabilities	538	541
Total current liabilities	8,008	5,200
Long term liabilities:		
Operating lease liabilities, net of current portion	1,975	1,937
Embedded derivative liability	439	412
Total liabilities	10,422	7,549
Commitments and contingencies (Notes 5, 9 and 10)		
Shareholders' equity:		
Preferred stock, $0.001 par value; 400 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 100,000 shares authorized; issued and outstanding 39,625 and 36,827 shares as of December 31, 2023 and June 30, 2023, respectively	40	37
Additional paid-in capital	381,154	377,471
Accumulated other comprehensive loss	(48)	(351)
Accumulated deficit	(289,418)	(260,985)
Total shareholders' equity	91,728	116,172
Total liabilities and shareholders' equity	$ 102,150	$ 123,721

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Rezolute, Inc.

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 12,039	$ 10,945	$ 24,253	$ 18,649
General and administrative	3,155	3,447	6,855	5,961
Total operating expenses	15,194	14,392	31,108	24,610
Operating loss	(15,194)	(14,392)	(31,108)	(24,610)
Non-operating income (expense):				
Interest and other income, net	1,303	849	2,707	1,249
Loss from change in fair value of derivative liability	(18)	(13)	(32)	(26)
Total non-operating income, net	1,285	836	2,675	1,223
Net loss	(13,909)	(13,556)	(28,433)	(23,387)
Other comprehensive income:				
Net unrealized gain on available-for-sale marketable debt securities	236	—	303	—
Comprehensive loss	$ (13,673)	$ (13,556)	$ (28,130)	$ (23,387)
Net loss per common share:				
Basic and diluted	$ (0.27)	$ (0.26)	$ (0.55)	$ (0.46)
Weighted average number of common shares outstanding:				
Basic and diluted	51,408	51,410	51,409	50,969

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Rezolute, Inc.

Unaudited Condensed Consolidated Statements of Shareholders' Equity
Six Months Ended December 31, 2023 and 2022
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Six Months Ended December 31, 2023:						
Balances, June 30, 2023	36,827	$ 37	$ 377,471	$ (351)	$ (260,985)	$ 116,172
Share-based compensation	—	—	3,686	—	—	3,686
Exercise of pre-funded warrants	2,798	3	(3)	—	—	—
Net change in accumulated other comprehensive loss	—	—	—	303	—	303
Net loss	—	—	—	—	(28,433)	(28,433)
Balances, December 31, 2023	39,625	$ 40	$ 381,154	$ (48)	$ (289,418)	$ 91,728
Six Months Ended December 31, 2022:						
Balances, June 30, 2022	33,582	$ 34	$ 358,635	$ —	$ (209,198)	$ 149,471
Gross proceeds from issuance of common stock for cash in 2022 Private Placement	3,245	3	12,327	—	—	12,330
Underwriting commissions and other equity offering costs	—	—	(759)	—	—	(759)
Share-based compensation	—	—	3,610	—	—	3,610
Net loss	—	—	—	—	(23,387)	(23,387)
Balances, December 31, 2022	36,827	$ 37	$ 373,813	$ —	$ (232,585)	$ 141,265

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Rezolute, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows
(In thousands)

	Six Months Ended December 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (28,433)	$ (23,387)
Share-based compensation expense	3,686	3,610
Non-cash lease expense	276	112
Loss from change in fair value of derivative liability	27	26
Accretion of discounts and amortization of premiums on marketable debt securities, net	(1,181)	—
Depreciation and amortization expense	20	10
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other assets	(494)	783
Increase in accounts payable	325	1,708
Increase in accrued liabilities	2,169	2,056
Net Cash Used in Operating Activities	(23,605)	(15,082)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable debt securities	(40,156)	—
Proceeds from maturities of marketable debt securities	60,522	—
Purchase of property and equipment	—	(153)
Total Cash Provided by (Used in) Investing Activities	20,366	(153)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Gross proceeds from issuance of common stock for cash in 2022 Private Placement	—	12,330
Payment of commissions and other deferred offering costs	(293)	(759)
Net Cash Provided by (Used in) Financing Activities	(293)	11,571
Net decrease in cash and cash equivalents	(3,532)	(3,664)
Cash and cash equivalents at beginning of period	16,036	150,410
Cash and cash equivalents at end of period	$ 12,504	$ 146,746
SUPPLEMENTARY CASH FLOW INFORMATION:		
Cash paid for interest	$ —	$ —
Cash paid for income taxes	—	—
Cash paid for amounts included in the measurement of operating lease liabilities	361	58
Operating lease liabilities incurred in exchange for right-of-use-assets	352	2,204
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Payables for deferred offering costs	$ 22	$ —

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations

Rezolute, Inc. (the "Company") is a clinical stage biopharmaceutical business developing transformative therapies for metabolic diseases related to chronic glucose imbalance. The Company's primary clinical assets consist of (i) RZ358, which is a potential treatment for congenital hyperinsulinism, an ultra-rare pediatric genetic disorder characterized by excessive production of insulin by the pancreas, and (ii) RZ402, which is an oral plasma kallikrein inhibitor ("PKI") being developed as a potential therapy for the chronic treatment of diabetic macular edema.

Basis of Presentation

The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"), the rules and regulations of the SEC for interim financial information, and the instructions to Form 10-Q and Article 8 of Regulation S-X.

The condensed consolidated balance sheet as of June 30, 2023, has been derived from the Company's audited consolidated financial statements. The unaudited interim financial statements should be read in conjunction with the Company's 2023 Form 10-K, which contains the Company's audited financial statements and notes thereto, together with the Management's Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended June 30, 2023.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted, pursuant to the rules and regulations of the SEC for interim financial reporting. Accordingly, they do not include all information and footnote disclosures necessary for a comprehensive presentation of financial position, results of operations, and cash flows. It is management's opinion, however, that all material adjustments (consisting of normal recurring adjustments) that are necessary for a fair financial statement presentation have been made. The interim results for the three and six months ended December 31, 2023 are not necessarily indicative of the financial condition and results of operations that may be expected for any future interim period or for the fiscal year ending June 30, 2024.

Consolidation

The Company has two wholly owned subsidiaries consisting of Rezolute (Bio) Ireland Limited, and Rezolute Bio UK, Ltd. The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts in the unaudited condensed consolidated financial statements and the accompanying notes. The Company bases its estimates and assumptions on current facts, historical experience, and various other factors that it believes are reasonable under the circumstances, to determine the carrying values of assets and liabilities that are not readily apparent from other sources. The Company's significant accounting estimates include, but are not necessarily limited to, determination if an allowance for credit losses is required or if other than temporary impairment exists for marketable debt securities, the fair value of an embedded derivative liability, fair value of share-based payments, management's assessment of going concern, and estimates related to clinical trial accrued liabilities. Actual results could differ from those estimates.

Risks and Uncertainties

The Company's operations may be subject to significant risks and uncertainties including financial, operational, regulatory, international conflicts and wars, pandemics and other risks associated with a clinical stage business.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Significant Accounting Policies

The Company's significant accounting policies are described in Note 1 to the financial statements in Item 8 of the 2023 Form 10-K.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.* ASU 2016-13 amends the guidance on the impairment of financial instruments. This update adds an impairment model (known as the current expected credit losses model) that is based on expected losses rather than incurred losses. Under the expected credit loss model, if declines in fair value below amortized costs are due to the deterioration of an issuer's credit quality, the Company is required to record an allowance for credit losses related to such investments with a corresponding loss recognized in the consolidated statements of operations. Allowances for credit losses may be reversed in subsequent periods if conditions improve and credit-related losses are no longer expected. For declines in fair value that are solely due to changes in interest rates, impairment is not recognized if the Company has the ability and intent to hold the investment until maturity. Effective as of July 1, 2023, the Company implemented the guidance in ASU 2016-13. The adoption of ASU 2016-13 did not have any impact on the Company's unaudited condensed consolidated financial statements for the six months ended December 31, 2023.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not currently expected to have a material impact on the Company's financial statements upon adoption.

NOTE 2 — LIQUIDITY

As a clinical stage business, the Company has not yet generated any revenues and had an accumulated deficit of $289.4 million as of December 31, 2023. For the six months ended December 31, 2023, the Company incurred a net loss of $28.4 million and net cash used in operating activities amounted to $23.6 million. For the fiscal year ended June 30, 2023, the Company incurred a net loss of $51.8 million and net cash used in operating activities amounted to $44.5 million. As of December 31, 2023, the Company's capital resources consist of cash and cash equivalents of $12.5 million, short-term investments in marketable debt securities of $80.1 million and long-term investments in marketable debt securities of $3.4 million.

As discussed in Note 7, in November 2023 the Company entered into an agreement for an "at-the-market" offering for the sale of up to $50.0 million in shares of common stock. The net proceeds from the "at-the-market" offering, if any, will be used to fund a portion of the Company's liquidity requirements. However, even if the entire $50.0 million is obtained in the "at-the-market" offering, the Company will need to obtain additional equity or debt financing in order to fund all of its long-term capital requirements.

As of December 31, 2023, the Company has total liabilities of $10.4 million, including current liabilities of $8.0 million. As discussed in Note 5, the Company is subject to license agreements that provide for future contractual payments upon achievement of various milestone events. Pursuant to the XOMA License Agreement (as defined below), a $5.0 million milestone payment will be due upon dosing of the first patient in a Phase 3 clinical trial for RZ358, and an additional $5.0 million milestone payment will be due upon the dosing of the last patient in a Phase 3 clinical trial for RZ358. Both the first patient dosing milestone and last patient dosing milestone events in connection with the RZ358 Phase 3 clinical trial are expected to occur within the next 12 months.

Management believes the Company's existing cash and cash equivalents and investments in marketable debt securities will be adequate to meet the Company's contractual obligations and carry out ongoing clinical trials and other planned activities through February 2025, at a minimum.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 3 —INVESTMENTS IN MARKETABLE DEBT SECURITIES

Investments in marketable debt securities, are accounted for as available-for-sale investments and consist of the following (in thousands):

	December 31, 2023	June 30, 2023
Short-term investments	$ 80,094	$ 85,860
Long-term investments	3,352	16,470
Total investments	$ 83,446	$ 102,330

The Company's investments in debt securities are subject to interest rate risk and credit risk that results in differences between amortized cost basis and the fair value of investments. To minimize the exposure to reductions in fair value if long term interest rates rise, the Company generally invests in securities with expected maturities of two years or less and maintains a weighted average maturity of one year or less. As of December 31, 2023, investments in marketable debt securities with an aggregate fair value of $80.1 million are scheduled to mature during the 12-month period ending December 31, 2024. Substantially all of the remaining investments, with an aggregate fair value of $3.4 million, are scheduled to mature during the 12-month period ending December 31, 2025.

During the six months ended December 31, 2023, marketable debt securities for $60.5 million matured and approximately $40.2 million of the proceeds were reinvested in additional marketable debt securities. The Company did not sell any marketable debt securities prior to the scheduled maturity dates for the six months ended December 31, 2023.

Accrued interest receivable on all marketable debt securities amounted to $0.3 million as of December 31, 2023 and June 30, 2023, respectively. Accrued interest receivable is included in other current assets in the accompanying condensed consolidated balance sheets.

For the three and six months ended December 31, 2023, the Company did not recognize any allowance for credit losses or other than temporary impairment related to investments in marketable debt securities. The following table summarizes the cumulative unrealized gains and losses that result in differences between the amortized cost basis and fair value of the Company's marketable debt securities held as of December 31, 2023 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate commercial paper	$ 32,733	$ 29	$ (10)	$ 32,752
Obligations of U.S. government agencies	18,770	—	(21)	18,749
U.S. Treasury obligations	1,002	—	(5)	997
Corporate notes and bonds	27,645	8	(57)	27,596
Asset-backed securities	3,344	11	(3)	3,352
Total	$ 83,494	$ 48	$ (96)	$ 83,446

NOTE 4 — OPERATING LEASES

In October 2023, the Company entered into an addendum to the lease agreement for its office in Bend, Oregon. The addendum provided for a 36-month extension, which extends the lease through February 2027. The average base rent payable over the remaining lease term

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

is approximately $9,000. Upon execution of the addendum, the Company re-measured the Bend, Oregon operating lease liability at approximately $345,000 using a discount rate of 10.0%, and the related right-of-use asset was recognized for approximately $351,000.

The carrying values of all right-of-use assets and operating lease liabilities is as follows (in thousands):

	December 31, 2023	June 30, 2023
Right-of-use assets	$ 2,130	$ 2,054
Operating lease liabilities:		
Current	$ 538	$ 541
Long-term	1,975	1,937
Total	$ 2,513	$ 2,478

For the three and six months ended December 31, 2023 and 2022, operating lease expense is included under the following captions in the accompanying condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2023	2022	2023	2022
Research and development	$ 130	$ 115	$ 261	$ 192
General and administrative	39	48	81	71
Total	$ 169	$ 163	$ 342	$ 263

As of December 31, 2023, the weighted average remaining lease term under operating leases was 3.8 years, and the weighted average discount rate for operating lease liabilities was 7.2%. Future cash payments under all operating lease agreements as of December 31, 2023 are as follows (in thousands):

Fiscal year ending June 30,	
Remainder of fiscal year 2024	$ 367
2025	748
2026	770
2027	750
Thereafter	224
Total lease payments	2,859
Less imputed interest	(346)
Present value of operating lease liabilities	$ 2,513

NOTE 5 — LICENSE AGREEMENTS

XOMA License Agreement

In December 2017, the Company entered into a license agreement (the "XOMA License Agreement") with XOMA Corporation ("XOMA"), through its wholly-owned subsidiary, XOMA (US) LLC, pursuant to which XOMA granted an exclusive global license to the Company to develop and commercialize XOMA 358 (formerly X358, now RZ358) for all indications.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

In January 2022, the Company was required to make a milestone payment under the XOMA License Agreement of $2.0 million that became due upon the dosing of the last patient in the Company's Phase 2b Clinical Trial for RZ358. Upon the achievement of certain clinical and regulatory events under the XOMA License Agreement, the Company will be required to make additional milestone payments to XOMA up to $35.0 million. After the clinical and regulatory milestones, the Company will be required, upon the future commercialization of RZ358, to pay royalties to XOMA based on the net sales of the related products and additional milestone payments to XOMA up to $185.0 million related to annual net sales amounts. There have been no events that would result in any royalty payments owed under the XOMA License Agreement to date. The next milestone payment of $5.0 million will be due upon dosing of the first patient in a Phase 3 clinical trial for RZ358.

ActiveSite License Agreement

In August 2017, the Company entered into a Development and License Agreement (the "ActiveSite License Agreement") with ActiveSite Pharmaceuticals, Inc. ("ActiveSite") pursuant to which the Company acquired the rights to ActiveSite's Plasma Kallikrein Inhibitor program ("PKI Portfolio"). The Company is initially using the PKI Portfolio to develop an oral PKI therapeutic for diabetic macular edema (RZ402) and may use the PKI Portfolio to develop other therapeutics for different indications. The ActiveSite License Agreement requires various milestone payments up to $46.5 million, if all milestones are achieved. The first milestone payment for $1.0 million was paid in December 2020 after clearance was received for an Initial Drug Application, or IND, filed with the U.S. Food and Drug Administration ("FDA"). The second milestone payment of $3.0 million was paid in February 2023 after dosing of the first patient in a Phase 2 clinical trial for RZ402. The next milestone payment of $5.0 million will be due upon dosing of the first patient in a Phase 3 clinical trial. The Company is also required to pay royalties equal to 2.0% of any sales of products that use the PKI Portfolio. There have been no events that would result in any royalty payments owed under the ActiveSite License Agreement to date.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 6 — EMBEDDED DERIVATIVE LIABILITY

On April 14, 2021, the Company entered into a $30.0 million Loan and Security Agreement (the "Loan Agreement") with SLR Investment Corp. and certain other lenders (collectively, the "Lenders"). The Lenders agreed to loan up to $30.0 million but the actual amount borrowed by the Company amounted to $15.0 million. The maturity date of the outstanding borrowings was April 1, 2026 (the "Maturity Date"), but the Company elected to repay the entire amount and terminated the Loan Agreement on June 30, 2022.

Concurrently with the execution of the Loan Agreement, the Company entered into an exit fee agreement (the "Exit Fee Agreement") that provides for a fee of 4.00% of the funded principal balance for a total of $0.6 million in the event certain transactions (defined as "Exit Events") occur prior to April 13, 2031. The Exit Fee Agreement was not impacted by the termination of the Loan Agreement discussed above. The Company is accounting for the Exit Fee Agreement as an embedded derivative liability with an estimated fair value of $0.4 million as of December 31, 2023 and June 30, 2023. Exit Events include, but are not limited to, sales of substantially all assets, certain mergers, change of control transactions, and issuances of common stock that result in new investors owning more than 35% of the Company's shares. Fair value of this embedded derivative liability is reassessed at the end of each reporting period with changes in fair value recognized as a non-operating gain or loss.

NOTE 7 — SHAREHOLDERS' EQUITY

Changes in Shareholders' Equity for the Three Months Ended December 31, 2023 and 2022

The following table presents changes in shareholders' equity for the three months ended December 31, 2023 and 2022:

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Three Months Ended December 31, 2023:						
Balances, September 30, 2023	36,827	$ 37	$ 379,320	$ (284)	$ (275,509)	$ 103,564
Share-based compensation	—	—	1,837	—	—	1,837
Exercise of pre-funded warrants	2,798	3	(3)	—	—	—
Net change in accumulated other comprehensive loss	—	—	—	236	—	236
Net loss	—	—	—	—	(13,909)	(13,909)
Balances, December 31, 2023	39,625	$ 40	$ 381,154	$ (48)	$ (289,418)	$ 91,728
Three Months Ended December 31, 2022:						
Balances, September 30, 2022	36,827	$ 37	$ 372,082	$ —	$ (219,029)	$ 153,090
Share-based compensation	—	—	1,731	—	—	1,731
Net loss	—	—	—	—	(13,556)	(13,556)
Balances, December 31, 2022	36,827	$ 37	$ 373,813	$ —	$ (232,585)	$ 141,265

Jefferies Open Market Sales Agreement

On November 14, 2023, the Company and Jefferies LLC (the "Agent) entered into an Open Market Sale Agreement℠ (the "Sales Agreement") that provides for an "at the market" offering for the sale of up to $50.0 million in shares of the Company's common stock (the "Placement Shares") through the Agent. The Agent is acting as sales agent and is required to use commercially reasonable efforts to sell all of the Placement Shares requested to be sold by the Company, consistent with the Agent's normal trading and sales practices,

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

on mutually agreed terms between the Agent and the Company. The Sales Agreement will terminate when all of the Placement Shares have been sold, or earlier upon the election of either the Company or the Agent.

The Company has no obligation to sell any of the Placement Shares under the Sales Agreement. The Company intends to use the net proceeds, if any, from amounts sold under the Sales Agreement for general corporate purposes, including working capital. Under the terms of the Sales Agreement, the Company agreed to pay the Agent a commission equal to 3.0% of the gross sales price of the Placement Shares plus certain expenses incurred by the Agent in connection with the offering.

For the six months ended December 31, 2023, the Company sold no shares of its common stock pursuant to the Sales Agreement. Accordingly, the maximum amount remaining for sale under the Sales Agreement amounts to $50.0 million as of December 31, 2023.

2022 Class B PFW Exercise

As discussed in Note 8, in October 2023, a holder of Class B PFW's provided notice of cashless exercise of their 2,800,000 Class B PFW's, resulting in the issuance of 2,797,404 shares of common stock on October 6, 2023.

2022 Private Placement

In May 2022, the Company entered into securities purchase agreements ("SPAs") with Handok, Inc. ("Handok") and certain of its affiliates. Handok is an affiliate of a member of the Company's Board of Directors. In July 2022, the Company entered into amended SPAs for a private placement of common stock (the "2022 Private Placement"). The 2022 Private Placement resulted in gross proceeds of $12.3 million in exchange for the issuance of approximately 3.2 million shares of common stock. The Company incurred approximately $0.8 million for underwriting commissions and other offering costs, resulting in net proceeds of $11.5 million.

NOTE 8 — SHARE-BASED COMPENSATION AND WARRANTS

Stock Option Plans

Presented below is a summary of the number of shares authorized, outstanding, and available for future grants under each of the Company's stock option plans as of December 31, 2023 (in thousands):

Description	Plan Termination Date	Number of Shares		
		Authorized	Outstanding	Available
2015 Plan	February 2020	17	17	—
2016 Plan	October 2021	123	123	—
2019 Plan	July 2029	200	200	—
2021 Plan	March 2031	10,700	8,673	2,027
Total		11,040	9,013	2,027

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

2022 Employee Stock Purchase Plan

On June 16, 2022, the Company's shareholders approved the adoption of the 2022 Employee Stock Purchase Plan (the "2022 ESPP"). The 2022 ESPP provides an opportunity for employees to purchase the Company's common stock through accumulated payroll deductions.

The 2022 ESPP has consecutive offering periods that begin approximately every 6 months commencing on the first trading day on or after July 1 and terminating on the last trading day of the offering period ending on December 31 and commencing on the first trading day on or after January 1 and terminating on the last trading day of the offering period ending on June 30. The 2022 ESPP reserves 0.5 million shares for purchases. There have been no offering periods under the 2022 ESPP through December 31, 2023.

Stock Options Outstanding

The following table sets forth a summary of the activity under all of the Company's stock option plans for the six months ended December 31, 2023 (shares in thousands):

	Shares	Price [1]	Term [2]
Outstanding, June 30, 2023	8,745	$ 4.56	8.8
Grants to employees	475	1.44	
Expired	(42)	9.49	
Forfeited	(165)	2.11	
Outstanding, December 31, 2023	9,013	4.42	8.4
Vested, December 31, 2023	3,726	5.91	8.1

(1) Represents the weighted average exercise price.
(2) Represents the weighted average remaining contractual term for the number of years until the stock options expire.

For the six months ended December 31, 2023, the aggregate fair value of stock options granted for approximately 0.5 million shares of common stock amounted to $0.5 million or approximately $1.13 per share as of the grant dates. Fair value was computed using the Black-Scholes-Merton ("BSM") option-pricing model and will result in the recognition of compensation cost ratably over the expected vesting period of the stock options.

For the six months ended December 31, 2023, the fair value of stock options was estimated on the respective dates of grant, with the following weighted-average assumptions:

Market price of common stock on grant date	$ 1.44
Expected volatility	95 %
Risk free interest rate	4.3 %
Expected term (years)	6.1
Dividend yield	0 %

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Share-based compensation expense for the three and six months ended December 31, 2023 and 2022 is included under the following captions in the unaudited condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2023	2022	2023	2022
Research and development	$ 841	$ 730	$ 1,681	$ 1,600
General and administrative	996	1,001	2,005	2,010
Total	$ 1,837	$ 1,731	$ 3,686	$ 3,610

Unrecognized share-based compensation expense is approximately $13.5 million as of December 31, 2023. This amount is expected to be recognized over a weighted average period of 2.5 years.

Pre-Funded Warrants

In connection with an underwritten offering in October 2021, the Company issued 1,661,461 pre-funded warrants ("PFWs") to purchase 1,661,461 shares of common stock at an issuance price of $6.49 per warrant for gross proceeds of $10.8 million (the "2021 PFWs"). The 2021 PFWs may be exercised at any time by paying the exercise price of $0.01 per share, subject to certain ownership restrictions.

In connection with a registered direct offering in May 2022, the Company issued 1,973,684 Class A PFWs and 10,947,371 Class B PFWs to purchase an aggregate of 12,921,055 shares of common stock at an issuance price of $3.799 per warrant (collectively, the "2022 PFWs"). On October 4, 2023, a holder of Class B PFW's provided notice of cashless exercise of their 2,800,000 Class B PFW's, resulting in the issuance of 2,797,404 shares of common stock on October 6, 2023. No cash proceeds were received by the Company as a result of this exercise.

As of December 31, 2023, there are 10,121,055 of the 2022 PFWs which may be exercised at any time by paying the exercise price of $0.001 per share, subject to certain ownership restrictions.

Other Warrants

In connection with an equity financing in October 2020, the Company issued warrants entitling the holders to purchase approximately 0.8 million shares of common stock. The warrants are exercisable at $19.50 per share for a period of seven years, may be exercised on a cash or cashless basis at the election of the holders, and holders are entitled to share in any dividends or distributions payable to holders of common stock on an as-converted basis. In addition, the Company has issued warrants in conjunction with various debt and equity financings and for services. As of December 31, 2023, all of the warrants were vested.

For the six months ended December 31, 2023, no warrants were granted or exercised. Excluding the 2021 PFWs and the 2022 PFWs discussed above, the following table sets forth a summary of all other warrants for the six months ended December 31, 2023 (shares in thousands):

	Shares	Price [1]	Term [2]
Outstanding, June 30, 2023	888	$ 22.10	4.1
Expirations	(27)	78.60	
Outstanding, December 31, 2023	861	20.28	3.7

(1) Represents the weighted average exercise price.
(2) Represents the weighted average remaining contractual term for the number of years until the warrants expire.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 9 — COMMITMENTS AND CONTINGENCIES

Licensing Commitments

Please refer to Note 5 for further discussion of commitments to make milestone payments and to pay royalties under license agreements with XOMA and ActiveSite.

Legal Matters

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of December 31, 2023, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the Company's results of operations. At each reporting period, the Company evaluates known claims to determine whether a potential loss amount or a potential range of loss is probable and reasonably estimable under ASC 450, *Contingencies*. Legal fees are expensed as incurred.

NOTE 10 — RELATED PARTY TRANSACTIONS

Related Party Licensing Agreement

On September 15, 2020, the Company and Handok entered into an exclusive license agreement (the "Handok License") for the territory of the Republic of Korea. The Handok License relates to pharmaceutical products in final dosage form containing the pharmaceutical compounds developed or to be developed by the Company, including those related to RZ358 and RZ402. The Handok License is in effect for a period of 20 years after the first commercial sale of each product and requires (i) milestone payments to the Company of $0.5 million upon approval of a New Drug Application ("NDA") for each product in the territory, and (ii) the Company will sell products ordered by Handok at a transfer price equal to 70% of the net selling price of the products. To date, no milestone payments have been earned by the Company.

Investors in 2022 Private Placement

Handok and certain of its affiliates were the sole investors in the 2022 Private Placement and the Registered Direct Offering discussed in Note 7.

NOTE 11 — INCOME TAXES

Income tax expense during interim periods is based on applying an estimated annualized effective income tax rate applied to the respective quarterly periods, adjusted for discrete tax items in the period in which they occur. The computation of the annualized estimated effective tax rate for each interim period requires certain estimates and significant judgment including, but not limited to, the expected operating results for the year, projections of the proportion of income earned and taxed in various jurisdictions, permanent and temporary differences, and the likelihood of recovering deferred income tax assets generated in the current year. The accounting estimates used to compute the provision for income taxes may change as new events occur, more experience is obtained, additional information becomes known or as the tax environment changes.

For the three and six months ended December 31, 2023 and 2022, the Company did not recognize any income tax benefit due to a full valuation allowance on its deferred income tax assets. The Company did not have any material changes to its conclusions regarding valuation allowances for deferred income tax assets or uncertain tax positions for the three and six months ended December 31, 2023 and 2022.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 12 — NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares, 2021 PFWs and 2022 PFWs outstanding during the period, without consideration for other potentially dilutive securities. PFWs are included in the computation of basic and diluted net loss per share since the exercise price is negligible and all of the PFWs are fully vested and immediately exercisable. Accordingly, the weighted average number of shares outstanding is computed as follows for the three and six months ended December 31, 2023 and 2022 (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2023	2022	2023	2022
Common Stock	39,443	36,828	38,135	36,387
2021 PFWs	1,661	1,661	1,661	1,661
2022 PFWs:				
Class A PFWs	1,974	1,974	1,974	1,974
Class B PFWs	8,330	10,947	9,639	10,947
Total	51,408	51,410	51,409	50,969

For the three and six months ended December 31, 2023 and 2022, basic and diluted net loss per share were the same since all other common stock equivalents were anti-dilutive.

As of December 31, 2023 and 2022, the following outstanding potential common stock equivalents were excluded from the computation of diluted net loss per share since the impact of inclusion was anti-dilutive (in thousands):

	2023	2022
Stock options	9,013	8,500
Other warrants	861	1,145
Total	9,874	9,645

NOTE 13 — FINANCIAL INSTRUMENTS AND SIGNIFICANT CONCENTRATIONS

Fair Value Measurements

Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. When determining fair value, the Company considers the principal or most advantageous market in which it transacts and considers assumptions that market participants would use when pricing the asset or liability. The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement:

Level 1—Quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.

Level 2—Other than quoted prices included in Level 1 that are observable for the asset and liability, either directly or indirectly through market corroboration, for substantially the full term of the asset or liability.

Level 3—Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any market activity for the asset or liability at the measurement date.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

The following table presents information about the Company's financial assets measured at fair value on a recurring basis and indicates the fair value hierarchy classification of such fair values as of December 31, 2023 and June 30, 2023 (in thousands):

	Fair Value Measurement of Assets as of December 31, 2023			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents:				
Money market funds	$ 5,272	$ 5,272	$ —	$ —
U.S. Government treasuries	3,500	3,500	—	—
Corporate commercial paper	1,990	1,990	—	—
Marketable debt securities:				
Corporate commercial paper	32,752	—	32,752	—
U.S. Government agencies	18,749	—	18,749	—
U.S. Government treasuries	997	997	—	—
Corporate notes and bonds	27,596	—	27,596	—
Asset-backed securities	3,352	—	3,352	—
Total	$ 94,208	$ 11,759	$ 82,449	$ —

	Fair Value Measurement of Assets as of June 30, 2023			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents:				
Money market funds	$ 5,464	$ 5,464	$ —	$ —
Corporate commercial paper	4,481	4,481	—	—
Marketable debt securities:				
Corporate commercial paper	41,597	—	41,597	—
U.S. Government agencies	26,394	—	26,394	—
U.S. Government treasuries	10,404	10,404	—	—
Corporate notes and bonds	19,240	—	19,240	—
Asset-backed securities	4,694	—	4,694	—
Total	$ 112,274	$ 20,349	$ 91,925	$ -

Marketable debt securities classified as Level 2 within the valuation hierarchy generally consist of U.S. government agency securities, corporate bonds, and commercial paper. The Company determines the fair value of marketable debt securities based upon valuations obtained from third-party pricing sources. Except for the amounts shown in the table above, the Company did not have any other assets measured at fair value on a recurring basis as of December 31, 2023 and June 30, 2023.

The Company's embedded derivative liability discussed in Note 6 is classified under Level 3 of the fair value hierarchy and is required to be measured and recorded at fair value on a recurring basis. Fair value is determined based on management's assessment of the probability and timing of occurrence for the Exit Events discussed in Note 6 using a discount rate equal to the effective interest rate under the Loan Agreement prior to termination. The following table sets forth changes in the fair value of the Company's embedded derivative liability for the six months ended December 31, 2023 and 2022 (in thousands):

	2023	2022
Fair value, beginning of period	$ 412	$ 407
Loss from change in fair value	27	26
Fair value, end of period	$ 439	$ 433

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Except for the embedded derivative liability, the Company did not have any other liabilities measured at fair value on a recurring basis as of December 31, 2023 and June 30, 2023.

Due to the relatively short maturity of the respective instruments, the fair value of cash, accounts payable, and accrued liabilities approximated their carrying values as of December 31, 2023 and June 30, 2023.

The Company's policy is to recognize asset or liability transfers among Level 1, Level 2 and Level 3 as of the actual date of the events or change in circumstances that caused the transfer. During the three and six months ended December 31, 2023 and 2022, the Company did not have any transfers of its assets or liabilities between levels of the fair value hierarchy.

Significant Concentrations

Financial instruments that subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and investments in marketable debt securities. The Company maintains cash in demand deposit accounts at a high-quality financial institution. As of and for the six months ended December 31, 2023 and 2022, cash deposits have exceeded the amount of insurance provided on such deposits by the Federal Deposit Insurance Corporation.

As of December 31, 2023, the Company has an aggregate of $33.2 million invested in the debt securities of issuers in the banking and financial services industries, and an aggregate of $18.8 million invested in the debt securities of a single agency of the U.S. government. While the Company's investment policy requires investments in highly rated securities, a wide variety of broad economic factors and issuer-specific factors could result in credit agency downgrades below the Company's minimum credit rating requirements that could result in losses regardless of whether the Company elects to sell the securities or hold them until maturity. To date, the Company has not experienced any credit losses or impairments of marketable debt securities due to credit rating agency downgrades.

NOTE 14 — SUBSEQUENT EVENTS

Inducement Grant

On January 23, 2024, the Company's Board of Directors appointed Daron Evans to serve as the Company's Chief Financial Officer. In connection with the appointment, Mr. Evans received an inducement grant (the "Inducement Grant") pursuant to Nasdaq Listing Rule 5635(c)(4) in the form of a stock option to purchase 275,000 shares of the Company's common stock at an exercise price of $1.02 in connection with his employment. The Inducement Grant is exercisable until January 23, 2029 and vests as follows: one-fourth on the one-year anniversary of the grant date and one thirty-sixth of the remaining options shall vest on the same day of each month thereafter until the Inducement Grant is 100% vested.

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

Certain figures, such as interest rates and other percentages included in this section have been rounded for ease of presentation. Percentage figures included in this section have not in all cases been calculated on the basis of such rounded figures but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this section may vary slightly from those obtained by performing the same calculations using the figures in our unaudited condensed consolidated financial statements or in the associated text. Certain other amounts that appear in this section may similarly not sum due to rounding. As used in the discussion below, "we," "our," "us," and the "Company" refers to Rezolute, Inc.

Rezolute is developing transformative therapies for devastating rare and chronic metabolic diseases. Our lead compound, RZ358, is a fully human monoclonal antibody for the treatment of hypoglycemia resulting from excessive pancreatic secretion of insulin ("hyperinsulinism" or "HI"). We have commenced a global Phase 3 study ("sunRIZE") for congenital HI ("cHI"), an ultra-rare pediatric and genetic form of HI. In addition, through our expanded access program ("EAP"), U.S. physician-investigators have been administering RZ358 on a compassionate use basis for the management of their patients suffering with tumor-associated hyperinsulinism ("taHI"), due to pancreatic neuroendocrine tumors ("insulinomas"). We are also developing an oral plasma kallikrein inhibitor, RZ402, which is currently in a Phase 2 study in participants with diabetic macular edema ("DME").

Our primary objectives for the first half of 2024 are to complete the Phase 2 study for RZ402 to enable announcement of topline results in second quarter of 2024, as well as to initiate a majority of our global clinical trial sites and enroll patients into sunRIZE to support our goal of completing enrollment by the end of this calendar year.

RZ358 for cHI

cHI

cHI is the most common cause of recurrent and persistent hypoglycemia in children. Individuals with cHI typically present with signs or symptoms of hypoglycemia within the first month of life. These episodes can result in significant brain injury and death if not recognized and managed appropriately. Additionally, recurrent, or cumulative, hypoglycemia can lead to progressive and irreversible damage over time, including serious and devastating brain injury, seizures, neuro-developmental problems, feeding difficulties, and significant impact on patient and family quality of life. In cases of cHI that are unresponsive to medical management, surgical removal of the pancreas may be required. In those with diffuse cHI where the whole pancreas is affected, a near-total pancreatectomy can be undertaken, although about half of these children will continue to have hypoglycemia and require medical treatment for cHI.

sunRIZE Phase 3 Study

In December 2023, we announced that we initiated sunRIZE, a randomized, double-blind, placebo-controlled, parallel arm evaluation of RZ358 in participants with cHI who are not adequately responding to standard of care medical therapies. We plan to enroll approximately 56 participants from up to approximately 20 clinical trial sites in more than 15 countries in Europe, the Middle East, Asia and North America, and to complete enrollment by the end of calendar year 2024, to enable announcement of topline results in mid-2025.

sunRIZE is currently not being studied in the U.S. because of partial clinical holds ("PCHs") imposed by the U.S. Food and Drug Administration's ("FDA's") Office of Cardiology, Hematology, Endocrinology and Nephrology – Division of Diabetes, Lipid Disorders, and Obesity ("Division"). As part of the preclinical program for RZ358, Sprague Dawley rats ("SD rats") demonstrated a microvascular injury in liver sinusoidal endothelial cells ("LSECs") at potentially clinically relevant doses and exposures ("rat findings"). Consequently, the Division- mandated PCHs that prevent us from dosing participants under the age of 12 and restrict us from dosing participants above the lowest dose studied to date, 3mg/kg. We do not believe that the toxicity observed in SD rats is relevant to humans particularly since no adverse liver findings were observed in monkeys during the preclinical program at significantly higher RZ358 dose levels (up to 90 mg/kg tested) with drug levels that were more than 10 times higher than those that showed toxicity in SD rats. Moreover, in clinical studies conducted to date, human doses and exposures were more than four times higher than the SD rat and there have been no adverse human liver findings.

We have been, and continue to be, actively engaged with the Division in the attempt to resolve the PCHs. To that end, in the attempt to understand the mechanism of toxicity in the SD rat, we have retained a former senior FDA pharmacology-toxicology official as a consultant and partnered with a research group with LSEC biology expertise. In the second half of 2023, we conducted additional in-vivo and in-vitro non-clinical studies to enhance our understanding of the mechanism of toxicity in SD rats and its potential relevance to humans, including experiments in SD rat LSECs studies and a toxicology study in another rodent species. We have been unable to reproduce or characterize the toxicity observed in SD rat toxicology studies in our LSEC experiments and we therefore believe that the mechanism of toxicity cannot be characterized in vitro. In addition, we conducted a CD-1 mice study to determine if we could reproduce the toxicity (rat findings) in a different rodent species. CD-1 mice were administered significantly higher dose levels of RZ358 (up to 120 mg/kg tested) with drug levels that were more than 20 times higher than those that caused the rat findings. No adverse liver findings were observed in this study at any dose level. We believe that the lack of findings in CD-1 mice further bolsters the hypothesis that such findings are specific to rats. While the precise mechanism of liver microvascular injury in SD rats remains unknown, we believe that the SD rat may be hypersensitive to exaggerated pharmacology and severe insulin resistance with RZ358, due to its baseline predisposition to obesity, metabolic syndrome, and insulin resistance. Notably, individuals who suffer with cHI are the opposite of insulin resistant – they have excessive insulin activity.

We plan to continue to work with the Division to explore strategies for lifting the PCHs and potentially enabling the inclusion of U.S. patients in the sunRIZE study. There can be no assurance that the Division will agree to remove the holds or that removal of the holds would be sufficiently timely to enable enrollment of patients in the U.S. To the extent the holds are not removed by the Division to allow for the inclusion of U.S. clinical sites, we believe if we generate positive data ex-U.S. in the sunRIZE study, this data could be supportive of a potential submission to FDA for approval for RZ358 for cHI should sunRIZE meet its efficacy objectives, with a good safety profile.

RZ358 has received Orphan Drug Designation in the U.S. and European Union for the treatment of cHI, as well as Pediatric Rare Disease Designation in the U.S., a prerequisite for a request for Rare Pediatric Disease Priority Review Voucher upon Biologics License Application (“BLA”) submission. In the Phase 2 RIZE study, participants with cHI ages 2 and older nearly universally achieved significant improvements in hypoglycemia across multiple endpoints, including the primary and key secondary endpoints planned for the sunRIZE study. At doses and exposures that are planned for the Phase 3 study, RZ358 was generally safe and well-tolerated, and resulted in median improvements in hypoglycemia exceeding 80%. Based on the RIZE clinical trial outcomes and the evidence of benefit in this serious condition with substantial unmet medical need, RZ358 was subsequently granted a priority medicines (“PRIME”) designation by the European Medicines Agency (“EMA”) and an Innovation Passport designation by the UK Innovative Licensing and Access Pathway (“ILAP”) Steering Group for the treatment of cHI.

RZ358 for taHI

Tumor-associated Hyperinsulinism (taHI)

Insulinomas can cause hypoglycemia through the excessive secretion of insulin with subsequent activation of the insulin receptor (insulin-mediated HI). Insulinomas are the most common type of functional pancreatic neuroendocrine tumor and tend to be small and challenging to diagnose. Current therapies for insulinomas can be grouped into two main categories: (a) tumor directed therapies (e.g. surgery, chemotherapy, or radiotherapy), which may indirectly and/or eventually lead to improved control of taHI and related hypoglycemia as a result of tumor de-bulking; and/or (b) medical therapies that directly treat taHI and the associated hypoglycemia. Tumor-directed therapies do not directly target or treat the HI and resulting hypoglycemia caused by insulinomas. In many cases, tumor-directed therapies are administered concurrently with medical therapies for hypoglycemia and in other cases successful treatment of hypoglycemia often enables the initiation and/or continuation of tumor-directed therapies, as indicated. During the period from diagnosis to surgical treatment, or if surgery is contraindicated or refused, medical treatments are often necessary to directly manage the HI and hypoglycemia induced by the tumor. Additionally, chronic medical management of refractory hypoglycemia is often necessary for patients who cannot be cured by surgery, such as those with extensive disease of the pancreas, multi-focal insulinomas, inoperable or unresectable benign or malignant insulinomas, metastatic Insulinomas, or non-pancreatic insulinomas. There are approximately 10,000-15,000 patients in the U.S. living with Insulinoma, of which approximately 10 percent have malignant/unresectable tumors requiring chronic treatment to control their HI.

A significant unmet need exists for treatment options with improved efficacy and tolerability as normalization of glucose levels is crucial to ensure patients are fit to receive cancer treatment and to reduce mortality. Unfortunately, some patients are unresponsive to the current standard of care medical therapies for taHI and experience debilitating hypoglycemia that is otherwise untreatable. Currently available medical therapies are directed at reducing or eliminating insulin production and/or secretion from tumors, which may be challenging when the tumor is differentiated or dysregulated, and therefore not responding to usual control mechanisms for

suppressing insulin production. In some cases, commonly utilized somatostatin analog therapies may even worsen hypoglycemia due to suppression of glucagon. Therefore, currently available medical therapies, directed at suppressing insulin production, may have limited effectiveness in taHI, and individuals with insulinoma may have refractory hypoglycemia.

Expanded Access Program

RZ358 has been shown to counteract excessive insulin action downstream, at the insulin-receptor on target organs. The unique mechanism of action of RZ358 makes the therapy a potential universal treatment for any form of hyperinsulinism, including taHI resulting from insulinoma.

We maintain an EAP for a variety of HI indications for the purpose of making RZ358 available on a compassionate use basis when available therapeutic options have failed and an individual's hypoglycemia is unmanageable. In the fourth quarter of 2022, we received and approved an EAP request from Dr. Mary Elizabeth Patti, Director of the Hypoglycemia Clinic at the Harvard Medical School and Beth Israel Medical Center-affiliated Joslin Diabetes Center, for a patient with intractable hypoglycemia caused by a metastatic insulinoma. Dr. Patti received a single patient investigational new drug ("IND") approval from the Division to treat the patient with RZ358. Dr. Patti reported that the patient safely achieved correction of hypoglycemia with RZ358, enabling the patient to wean off continuous intravenous dextrose and several other medications for hypoglycemia, leave the hospital after a prolonged stay, and resume receiving concurrent treatment for his cancer with tumor-directed therapies. The patient remained on RZ358 for more than a year until he eventually passed away due to progression of his underlying malignant/metastatic insulinoma.

Dr. Patti's use of RZ358 in a patient with insulinoma under our EAP, marked the first usage of RZ358 in the taHI setting. Dr. Patti submitted a late-breaking abstract and presented her case report titled, "Treatment of Severe Refractory Hypoglycemia Due to Malignant Insulinoma With A Novel Anti-insulin Receptor Antibody," in poster form in June 2023 at the 105th Annual Scientific Meeting of the Endocrine Society. Subsequently, in August 2023, Dr. Patti's case report was also published in the New England Journal of Medicine as a letter to the editor titled, "Anti-Insulin Receptor Antibody for Malignant Insulinoma and Refractory Hypoglycemia."

Following publication of Dr. Patti's report, we have received and approved four additional requests for use of RZ358 in patients with taHI caused by metastatic insulinomas and other insulin secreting metastatic cancer (cervical). In the U.S., these requests have all been approved by the Division. These patients have been refractory to usual standard of care therapies for chronic management of hypoglycemia and required continuous high volume/concentration intravenous dextrose or nutritional infusion and were hospitalized and in life-threatening or hospice-bound condition because of uncontrollable hypoglycemia. Further treatment with tumor-directed therapies (e.g., embolization, radiotherapy, chemotherapy) had been deferred as a result of the debilitating hypoglycemia.

Generally, dosing for taHI patients has been either 6 mg/kg or 9 mg/kg every 1-2 weeks. In all cases to date, RZ358 has led to substantial improvement in hypoglycemia and has been well tolerated. Within a relatively short period of time after administration of RZ358, continuous intravenous dextrose was discontinued and hospitalized patients were able to be discharged and receive maintenance RZ358 doses on an outpatient basis, with durable benefit. In most cases, other background medical therapies for hypoglycemia were able to be weaned or stopped, and patients were able to resume tumor-directed therapies for treatment of their underlying cancer. Patients with metastatic taHI often have underlying hepatic injury (abnormal enzymes) at baseline due to hepatic metastases or previous tumor-directed treatments (e.g., partial liver resection or embolization). The patients with hepatic injury that have been treated under the EAP have not exhibited any indication of hepatic toxicity with the use of RZ358.

Evaluation of a Clinical and Regulatory Development Path

On January 11, 2024, we had a Type B pre-IND meeting with the Division to discuss a potential IND application and a clinical and regulatory development strategy for taHI. The Division acknowledged the unmet need in taHI as well as the potential therapeutic benefit of RZ358 as demonstrated by the cases under the EAP as well as the efficacy demonstrated in previous clinical experience in cHI. The Division is aligned with us that RZ358 could be next studied in an IND-opening late-stage (registrational) clinical trial, which we are currently evaluating as a development program and second rare disease indication for RZ358.

In addition to other factors that impact a decision and timing of initiation of a new development program, we are not resourced to support an additional late stage registrational study. While we are optimistic about the positive impact RZ358 is already having on the lives of taHI patients, there can be no assurance that we will expand its pipeline to include taHI as a new indication for RZ358 nor can there be

any assurance that such a program will be successful in a registrational study to support commercial approval for use of RZ358 in taHI by FDA or other regulatory authorities worldwide.

RZ402 for DME

In December 2022, we initiated a Phase 2 U.S. multi-center, randomized, double-masked, placebo-controlled, parallel-arm study to evaluate the safety, efficacy, and pharmacokinetics of RZ402 administered as a monotherapy over a 12-week treatment period in participants with DME who are naïve to, or have received limited anti-VEGF injections. The study population is comprised of DME patients with mild to moderate non-proliferative diabetic retinopathy. Eligible participants were randomized equally, to one of three RZ402 active treatment arms at doses of 50, 200, and 400 mg, or a placebo control arm, to receive study drug once daily for 12 weeks, before completing a four-week follow-up. We have completed enrollment of 94 participants in the study, and the study remains ongoing. The principal endpoints of the trial include (i) change in study eye macular central subfield thickness, as measured by Spectral Domain Ocular Coherence Tomography, (ii) change in study eye visual acuity as measured by the early treatment diabetic retinopathy scale, (iii) the repeat dose pharmacokinetics of RZ402 in patients with DME, and (iv) the safety and tolerability of RZ402. Since RZ402 is an oral therapy and achieves systemic exposure to the retinal blood vessels in both eyes, key endpoints will also incorporate the non-study eye. We are on track to announce topline results in second quarter of 2024.

Recent Developments

Appointment of Chief Financial Officer

On January 23, 2024, the Board of Directors approved the appointment of Daron Evans to serve as our Chief Financial Officer. In connection with the appointment, we extended Mr. Evans an employment offer letter (the "Offer Letter"). The Offer Letter provides for the following compensation: (i) an annual base salary of $275,000; (ii) eligibility to receive an annual performance bonus with a target of 50% of Mr. Evans' base salary, on December 31st of each year; and (iii) an inducement grant pursuant to Nasdaq Listing Rule 5635(c)(4) in the form of stock options to purchase 275,000 shares (the "Inducement Grant") of our common stock. The stock options issued as the Inducement Grant will vest and become exercisable as to 25% of the underlying shares on the first anniversary of the grant date, and will vest and become exercisable as to the remaining 75% of the underlying shares in 36 equal monthly installments from the first anniversary of the grant date, subject to his continued employment on such vesting dates. If we are acquired during his employment, all remaining options will automatically vest. In connection with the appointment of Daron Evans to serve as our Chief Financial Officer, our board of directors determined that Mr. Elam will remain both our principal executive and principal financial officer for purposes of the certifications filed with this Quarterly Report on Form 10-Q as required pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Jefferies Open Market Sales Agreement

On November 14, 2023, we entered into an Open Market Sale Agreement℠ (the "Sales Agreement") with Jefferies LLC (the "Agent) that provides for an "at the market" offering for the sale of up to $50.0 million in shares of our common stock (the "Placement Shares") through the Agent. The Agent is acting as sales agent and is required to use commercially reasonable efforts to sell all of the Placement Shares requested to be sold by us, consistent with the Agent's normal trading and sales practices, on mutually agreed terms between the us and the Agent. The Sales Agreement will terminate when all of the Placement Shares have been sold, or earlier upon the election of either us or the Agent.

We have no obligation to sell any of the Placement Shares under the Sales Agreement. We intend to use the net proceeds, if any, from amounts sold under the Sales Agreement for general corporate purposes, including working capital. Under the terms of the Sales Agreement, we agreed to pay the Agent a commission equal to 3.0% of the gross sales price of the Placement Shares plus certain expenses incurred by the Agent in connection with the offering**.** No shares were sold under the Sales Agreement as of December 31, 2023.

Class B Prefunded Warrant Exercise

On October 4, 2023, an investor from our May 2022 registered direct offering provided notice of cashless exercise of their Class B PFWs. We issued 2,797,704 shares of our common stock on October 6, 2023, and we did not receive any cash proceeds from the exercise.

Factors Impacting our Results of Operations

We have not generated any meaningful revenues since our inception in March 2010. Over the last several years, we have conducted private placements and public offerings to raise additional capital, adopted a licensing model to pursue development of product candidates, conducted pre-clinical and clinical trials, and conducted other research and development activities on our pipeline of product candidates.

Due to the time required to conduct clinical trials and obtain regulatory approval for our product candidates, we anticipate it will be several years before we generate substantial revenues, if ever. We expect to incur operating losses for the foreseeable future; therefore, we expect to continue efforts to raise additional capital to maintain our current operating plans over the next several years. We cannot assure you that we will secure such financing or that it will be adequate for the long-term execution of our business strategy. Even if we obtain additional financing, it may be costly and may require us to agree to covenants or other provisions that will favor new investors over our existing shareholders.

Key Components of Consolidated Statements of Operations and Comprehensive Loss

Research and development expenses. Research and development ("R&D") expenses consist primarily of compensation and benefits for our personnel engaged in R&D activities, clinical trial costs, licensing costs, and consulting and outside services. Our R&D compensation costs include an allocable portion of our cash and share-based compensation, employee benefits, and consulting costs related to personnel engaged in the design and development of product candidates and other scientific research projects. We also allocate a portion of our facilities and overhead costs based on the personnel and other resources devoted to R&D activities.

General and administrative expenses. General and administrative ("G&A") expenses consist primarily of (i) an allocable portion of our cash and share-based compensation and employee benefits related to personnel engaged in our administrative, finance, accounting, and executive functions, and (ii) an allocable portion of our facilities and overhead costs related to such personnel. G&A expenses also include travel, legal, auditing, consulting, investor relations and other costs primarily related to our status as a public company.

Interest and other income. Interest and other income consist primarily of interest income earned on marketable debt securities and temporary cash investments, amortization of investment premiums and accretion of investment discounts.

Loss from change in fair value of derivative liability. We recognize liabilities for financial instruments that are required to be accounted for as derivatives, as well as embedded derivatives in our debt agreements. Derivative liabilities are adjusted to fair value at the end of each reporting period until the contracts are settled, expire, or otherwise meet the conditions for equity classification. Changes in fair value are reflected as a gain or loss in our unaudited condensed consolidated statements of operations and comprehensive loss.

Critical Accounting Policies and Significant Judgments and Estimates

Overview

The discussion herein is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these unaudited condensed consolidated financial statements requires us to make 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 consolidated financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on 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. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

With respect to our significant accounting policies that are described in Note 1 to our consolidated financial statements included in Item 8 of our 2023 Form 10-K, we believe that the following accounting policies involve a greater degree of judgment and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of operations.

Investments in Marketable Debt Securities

We account for investments in marketable debt securities as available-for-sale securities whereby they are recorded in our consolidated balance sheets at fair value. Interest income consists of accrued interest earned based on the coupon rate of the security, plus the impact of accreting discounts and amortizing premiums to maturity using the straight-line method which approximates the interest method. Unrealized gains and losses due to subsequent changes in fair value of the investments are reported in shareholders' equity as a component of accumulated other comprehensive income (loss). The individual debt securities in our portfolio are subject to credit risk in the event of default by the issuers. We review the components of our portfolio of available-for-sale debt securities, using both quantitative and qualitative factors, to determine if declines in fair value below amortized cost have resulted from a credit-related loss or other factors. To the extent that declines in fair value are due to a deterioration of credit quality of the issuer, we will recognize an allowance for credit losses related to such investments with a corresponding loss in the consolidated statements of operations. Allowances for credit losses may be reversed in subsequent periods if conditions improve and credit-related losses are no longer expected. For a decline in fair value that is solely due to changes in interest rates, impairment is not recognized if we have the ability and intent to hold the investment until maturity. The cost basis of any securities sold prior to maturity will be determined using the specific identification method.

Research and Development

R&D costs are expensed as incurred. Intangible assets related to in-licensing costs under license agreements with third parties are charged to expense unless we are able to determine that the licensing rights have an alternative future use in other R&D projects or otherwise.

Clinical Trial Accruals

Clinical trial costs are a component of R&D expenses. We accrue and recognize expenses for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with clinical research organizations and clinical trial sites. We determine the estimates through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. Nonrefundable advance payments for goods and services that will be used or rendered in future R&D activities, are deferred and recognized as expense in the period that the related goods are delivered, or services are performed.

Share-Based Compensation Expense

We measure the fair value of services received in exchange for grants of stock options based on the fair value of the award as of the grant date. We compute the fair value of stock options with time-based vesting using the BSM option-pricing model and recognize the cost of the equity awards over the period that services are provided to earn the award. For awards that contain a graded vesting schedule, and the only condition for vesting is a service condition, compensation cost is recognized on a straight-line basis over the requisite service period as if the award was, in substance, a single award. We recognize the impact of forfeitures in the period that the forfeiture occurs, rather than estimating the number of awards that are not expected to vest in accounting for share-based compensation. For stock options that are voluntarily surrendered by employees, all unrecognized compensation is immediately recognized in the period the options are cancelled.

Results of Operations

Three months ended December 31, 2023 and 2022

Revenue. As a clinical stage company, we did not generate any revenue for the three months ended December 31, 2023 and 2022. We are at an early stage of development and do not currently have any commercial products. Our existing product candidates will require extensive additional clinical evaluation, regulatory review, significant marketing efforts and substantial investment before they generate any revenues. We do not expect to be able to generate revenue from any of our product candidates for several years.

Research and development expenses. R&D expenses for the three months ended December 31, 2023 and 2022 were as follows (in thousands, except percentages):

	2023	2022	Increase Amount	Increase Percent
Total R&D expenses	$ 12,039	$ 10,945	$ 1,094	10 %

The increase in R&D expenses of $1.1 million for the three months ended December 31, 2023 was attributable to a net increase of in RZ358 related program costs of approximately $1.1 million. The increased expense consisted of increases in clinical trial expense of $0.9 million, manufacturing costs of $0.1 million and preclinical costs of $0.5 million. RZ358 costs increased due to Phase 3 clinical readiness activities. These increases were partially offset by a decrease in RZ358 related clinical development activities of $0.4 million since clinical feasibility studies were completed in the prior year in preparation for the Phase 3 study.

General and administrative expenses. G&A expenses for the three months ended December 31, 2023 and 2022 were as follows (in thousands, except percentages):

	2023	2022	Increase Amount	Increase Percent
Total G&A expenses	$ 3,155	$ 3,447	$ (292)	(8)%

The decrease in G&A expenses of $0.3 million for the three months ended December 31, 2023 was primarily attributable to decrease in cash-based compensation expense related to reduced performance bonuses.

Interest and Other Income. Interest and other income amounted to $1.3 million for the three months ended December 31, 2023, compared to $0.8 million for the three months ended December 31, 2022. This increase of $0.5 million was primarily due to our decision in January 2023 to invest an aggregate of approximately $115.0 million in marketable debt securities and an overnight money market mutual fund that earned interest at a weighted average effective rate of approximately 5.0%, whereas our temporary cash investments for the three months ended December 31, 2022 provided for earnings that were less than 3.0%. The impact of higher interest rates for the three months ended December 31, 2023 was partially offset by a reduction in the average funds that were invested. Investments in marketable debt securities are our primary source of liquidity to fund clinical expenditures and other operating expenses.

Income Taxes. For the three months ended December 31, 2023 and 2022, we did not recognize any income tax benefit due to our net losses, and our determination that a valuation allowance was required for all of our deferred tax assets.

Six months ended December 31, 2023 and 2022

Revenue. As a clinical stage company, we did not generate any revenue for the six months ended December 31, 2023 and 2022. We are at an early stage of development and do not currently have any commercial products. Our existing product candidates will require extensive additional clinical evaluation, regulatory review, significant marketing efforts and substantial investment before they generate any revenues. We do not expect to be able to generate revenue from any of our product candidates for several years.

Research and development expenses. R&D expenses for the six months ended December 31, 2023 and 2022 were as follows (in thousands, except percentages):

	2023	2022	Increase Amount	Increase Percent
Total R&D expenses	$ 24,253	$ 18,649	$ 5,604	30 %

The increase in R&D expenses of $5.6 million for the six months ended December 31, 2023 was primarily attributable to an increase of RZ358 related program costs of approximately $4.1 million. The increased expense consisted of an increase in manufacturing and preclinical costs of $2.7 million and clinical trial expense of $1.8 million. RZ358 costs increased due to Phase 3 clinical readiness activities, which was initiated in December 2023. These increases were partially offset by a decrease of $0.4 million RZ358 related clinical development activities, as clinical feasibility studies were completed in the prior year in preparation for the Phase 3 study.

Costs related to RZ402 and other R&D costs increased by approximately $0.5 million for the six months ended December 31, 2023, which was primarily attributable to an increase in clinical costs related to the ongoing Phase 2 study, which completed enrollment in December 2022. The RZ402 Phase 2 study is ongoing with topline results expected to be available in the second quarter of calendar 2024.

Additionally, compensation and benefits for our R&D workforce increased by approximately $1.0 million. Cash-based compensation and benefits increased by approximately $0.9 million that was primarily attributable to an increase in the average number of R&D employees from an average of 34 employees for the six months ended December 31, 2022 to an average of 43 employees for the six months ended December 31, 2023.

General and administrative expenses. G&A expenses for the six months ended December 31, 2023 and 2022 were as follows (in thousands, except percentages):

			Increase	
	2023	2022	Amount	Percent
Total G&A expenses	$ 6,855	$ 5,961	$ 894	15 %

G&A expenses increased by approximately $0.9 million for the six months ended December 31, 2023. This increase was attributable to $0.4 million of increased professional fee due to higher market research costs, $0.3 million of increased information technology and other costs to support our growing organization. Additionally, compensation and benefits for our G&A workforce increased by approximately $0.2 million due to an increase in average number of G&A employees from 12 for the six months ended December 31, 2022 to an average of 14 employees for the six months ended December 31, 2023.

Interest and Other Income. Interest and other income amounted to $2.7 million for the six months ended December 31, 2023, compared to $1.3 million for the six months ended December 31, 2022. This increase of $1.4 million was primarily due to our decision in January 2023 to invest an aggregate of approximately $115.0 million in marketable debt securities and an overnight money market mutual fund that bear interest at a weighted average effective rate of approximately 5.0%, whereas our temporary cash investments for the six months ended December 31, 2022 provided for earnings that were less than 3.0%. The impact of higher interest rates for the six months ended December 31, 2023 was partially offset by a reduction in the average funds that were invested. Investments in marketable debt securities are our primary source of liquidity to fund clinical expenditures and other operating expenses.

Income Taxes. For the six months ended December 31, 2023 and 2022, we did not recognize any income tax benefit due to our net losses, and our determination that a valuation allowance was required for all of our deferred tax assets.

Liquidity and Capital Resources

Short-term Liquidity Requirements

As of December 31, 2023, we had cash and cash equivalents of $12.5 million, short-term marketable debt securities of $80.1 million and working capital was approximately $88.1 million. We have incurred cumulative net losses of $289.4 million since our inception and as a clinical stage company we have not generated any meaningful revenue to date. Our most significant contractual obligations consist of milestone payments pursuant to licensing agreements with XOMA Corporation (“XOMA”) and ActiveSite Pharmaceuticals, Inc. (“ActiveSite”) discussed below.

Our primary source of liquidity has historically been from the completion of private and public offerings of our debt and equity securities. For the six months ended December 31, 2023, we did not receive any proceeds from our financing activities. For the fiscal year ended

June 30, 2023, we received net proceeds from the issuance of equity securities of $11.6 million. During the fiscal year ended June 30, 2022, we completed several equity financings that generated aggregate net proceeds of approximately $149.0 million after repayment of our Loan Agreement. These equity financings have been our primary source of liquidity to enable our funding of ongoing clinical expenditures and other operating expenses.

In April 2022 we entered into a lease agreement for a new corporate headquarters facility in Redwood City, California. This lease, which commenced in October 2022, provides for total base rent payments of approximately $2.9 million through the expected expiration of the lease in July 2027. Additionally, in October 2023 we extended the lease agreement for our office facility in Bend, Oregon. This lease extension provides for additional base rent payment of approximately $0.4 million through the expiration date of the lease in February 2027.

Remaining cash payments related to existing contractual obligations for the 12-months ending December 31, 2024 include approximately (i) $0.7 million under all of our operating lease agreements, (ii) a milestone payment to XOMA of $5.0 million due upon dosing of the first patient in our planned Phase 3 clinical trial for RZ358 and (iii) and an additional payment to XOMA of $5.0 million due upon dosing of the last patient in our planned Phase 3 clinical trial for RZ358. Due to uncertainties in the timing associated with clinical trial activities, it is possible that the milestone payment due upon dosing of the last patient could be delayed beyond December 31, 2024.

Based on our cash and cash equivalents balance of $12.5 million and investments in short-term marketable debt securities balance of $80.1 million as of December 31, 2023, we believe we have adequate capital resources to meet all of our contractual obligations and conduct all planned activities to advance our clinical trials at least through the next 12 months.

Long-term Liquidity Requirements

Our most significant long-term contractual obligations consist of additional clinical and regulatory milestone payments up to $35.0 million payable to XOMA and additional milestone payments up to $25.0 million payable to ActiveSite. Of these amounts, we expect that $10.0 million will be payable to XOMA during the 12-month period ending December 31, 2024 as discussed above under the caption Short-term Liquidity Requirements. Up to $50.0 million of the remaining milestone payments that may become payable are considered a long-term liquidity requirement. Due to uncertainties in the timing associated with clinical trial activities and regulatory approvals, there is even greater uncertainty in forecasting the timing of future clinical and regulatory milestone payments to XOMA and ActiveSite that may extend beyond the next 12 months.

In addition to the clinical and regulatory milestone payments discussed above, upon the future commercialization of RZ358 and RZ402 we will be obligated to pay additional milestone payments and royalties based on the net sales of the related products and alternative indication regulatory approvals to XOMA and ActiveSite for an aggregate up to $202.5 million. These future milestones include $185.0 million in potential payments to XOMA and $17.5 million to ActiveSite for various sales-based milestones and alternative indication regulatory approvals. No assurance can be provided that commercialization will ever be achieved for RZ358 and RZ402, whereby none of these future payments may ever be required.

In addition to our licensing obligations, we also have long-term contractual obligations under existing operating lease agreements ranging between approximately $0.2 million to $0.8 million for each of the fiscal years ending June 30, 2025 through 2027. Based on our current forecast, we expect that our existing cash, cash equivalents and investments in marketable debt securities will be sufficient to fund our long-term contractual obligations and conduct all planned activities to advance our clinical trials at least through the third quarter of calendar year 2025.

As discussed above under the caption Recent Developments, in November 2023 we entered into the Sales Agreement that provides for an “at-the-market” offering for the sale of up to $50.0 million in shares of our common stock. The net proceeds under the Sales Agreement, if any, will be used to fund a portion of our long-term liquidity requirements including payments for general corporate purposes and to meet our working capital requirements. To date, we have not elected to sell any shares of our common stock pursuant to the Sales Agreement. Even if we elect to sell the entire $50.0 million of shares under the Sales Agreement, we will need to obtain additional equity or debt financing in order to fund all of our long-term liquidity requirements. Accordingly, no assurance can be provided that we will be able to obtain sufficient sources of equity and debt financing on terms that are acceptable to our Board of Directors and stockholders.

Presented below is an additional discussion about the ongoing requirements pursuant to our license agreements with XOMA and ActiveSite, along with additional information about our ongoing financing activities that impacted our liquidity and capital resources through December 31, 2023.

XOMA License Agreement

In December 2017, we entered into a license agreement (the "XOMA License Agreement") with XOMA through its wholly-owned subsidiary, XOMA (US) LLC, pursuant to which XOMA granted an exclusive global license to develop and commercialize XOMA 358 (formerly X358, now RZ358) for all indications. In January 2019, the XOMA License Agreement was amended with an updated payment schedule, as well as revised the amount we were required to expend on development of RZ358 and related licensed products, and revised provisions with respect to our diligence efforts in conducting clinical studies.

Upon the achievement of certain clinical and regulatory events, we will be required to make up to $37.0 million in aggregate milestone payments to XOMA. The first such milestone payment of $2.0 million was triggered upon enrollment of the last patient in our ongoing phase 2 clinical study in January 2022. The next milestone payments of $5.0 million each, will be due upon the enrollment of the first patient in a Phase 3 study and the dosing of the last patient in a Phase 3 study, which we believe will occur in the next twelve months. Additionally, upon the future commercialization of RZ358, we will be required to pay royalties to XOMA based on the net sales of the related products, and milestone payments up to an additional $185.0 million if future annual sales related to RZ358 exceed targets ranging from $100.0 million to $1.0 billion. Through December 31, 2023, no events have occurred that would result in the requirement to make additional milestone payments and no royalties have been incurred.

ActiveSite License Agreement

In August 2017, we entered into a Development and License Agreement with ActiveSite ("ActiveSite License Agreement") pursuant to which we acquired the rights to ActiveSite's PKI portfolio. We are planning to use the PKI Program to develop, file, manufacture, market and sell products for diabetic macular edema and other therapeutic indications. The ActiveSite License Agreement requires various milestone payments ranging from $1.0 million to $10.0 million when milestone events occur, up to an aggregate of $46.5 million of aggregate milestone payments. The first milestone payment for $1.0 million was paid in December 2020 after completion of preclinical work and submission of an IND to the FDA for RZ402. The second milestone payment for $3.0 million became due upon dosing of the first patient in a Phase 2 study in February 2023. Remaining milestone payments under the ActiveSite License Agreement for various clinical and regulatory milestones amount to $25.0 million and milestones after commercial success or alternative indication approvals amount to $17.5 million. We will also be required to pay royalties equal to 2.0% of any sales of products that use the PKI Program. Through December 31, 2023, no events have occurred that would result in the requirement to make additional milestone payments and no royalties have been incurred.

Cash Flows Summary

Presented below is a summary of our operating, investing, and financing cash flows for the six months ended December 31, 2023 and 2022 (in thousands):

	2023	2022	Change
Net cash provided by (used in):			
Operating activities	$ (23,605)	$ (15,082)	$ (8,523)
Investing activities	20,366	(153)	20,519
Financing activities	(293)	11,571	(11,864)

Cash Used in Operating Activities

For the six months ended December 31, 2023 and 2022, cash used in operating activities amounted to $23.6 million and $15.1 million, respectively. The key components in the calculation of our cash used in operating activities are as follows (in thousands):

	2023	2022	Change

Net loss	$ (28,433)	$ (23,387)	$ (5,046)
Non-cash expenses	4,009	3,758	251
Accretion of discounts and amortization of premiums on marketable debt securities, net	(1,181)	—	(1,181)
Changes in operating assets and liabilities, net	2,000	4,547	(2,547)
Total	$ (23,605)	$ (15,082)	$ (8,523)

For the six months ended December 31, 2023, our net loss was $28.4 million compared to $23.4 million for the six months ended December 31, 2022. For further discussion about changes in our operating results for the six months ended December 31, 2023 and 2022, please refer to *Results of Operations* above.

For the six months ended December 31, 2023 and 2022, our non-cash expenses of $4.0 million and $3.8 million, respectively, were primarily attributable to share-based compensation expense. For the six months ended December 31, 2023, accretion of discounts and amortization of premiums on marketable debt securities amounted to $1.2 million and were due to our decision in January 2023 to generate higher interest income by investing in marketable debt securities. For the six months ended December 31, 2023, net changes in operating assets and liabilities increased operating cash flow by $2.0 million, primarily driven by an increase of $2.5 million in accounts payable and other accrued liabilities. This amount was partially offset by cash outflows resulting from an increase in prepaid expenses and other assets of $0.5 million.

Cash Provided by Investing Activities

For the six months ended December 31, 2023, our net cash provided by investing activities amounted to $20.4 million, primarily related to the maturity of marketable debt securities of $60.5 million partially offset by cash outflows of $40.2 million to reinvest in marketable debt securities.

For the six months ended December 31, 2022, our net cash utilized in investing activities amounted to $153,000, related to the purchase of furniture and equipment primarily for use in our new office location in Redwood City, California.

Cash Provided by or Used in Financing Activities

For the six months ended December 31, 2023, our net cash utilized in financing activities was $0.3 million and was solely attributable to deferred offering costs to put the Sales Agreement in place and register the underlying shares of common stock that may be issued.

Net cash provided by financing activities for the six months ended December 31, 2022 amounted to $11.6 million. This amount consisted of proceeds of $12.3 million from the 2022 Private Placement. The total proceeds from the 2022 Private Placement of $12.3 million were partially offset by payments of $0.8 million for underwriting commissions and other costs related to this offering.

Recent Accounting Pronouncements

Please refer to Note 1 to our unaudited condensed consolidated financial statements in Part I, Item 1 of this Report regarding the impact of recent accounting pronouncements.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet transactions for the periods covered by this Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive and financial officer), of the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended ("Exchange Act"). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute assurance of achieving the desired objectives. Also, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Based on that assessment under those criteria, our management has determined that our internal control over financial reporting was effective as of December 31, 2023.

Changes in internal controls over financial reporting

During the period covered by this Quarterly Report on Form 10-Q, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

Our risk factors are set forth under "Item 1A. Risk Factors" in our 2023 Form 10-K (referred to as our "Legacy Risk Factor Disclosures"). As of the date of this Report, there have been no material changes with respect to Legacy Risk Factor Disclosures except for the risk factor set forth below.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

On November 21, 2023, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that we are not in compliance with Nasdaq Listing Rule 5550(a)(2), which requires companies listed on The Nasdaq Stock Market to maintain a minimum bid price of $1 per share for continued listing. Nasdaq's letter has no immediate impact on the listing of our common stock, which will continue to be listed and traded on Nasdaq, subject to our compliance with the other continued listing requirements. Nasdaq has granted us a period of 180 calendar days, or until May 20, 2024, to regain compliance with the rule. We may regain compliance at any time during this compliance period if the minimum bid price for our common stock is at least $1 for a minimum of ten consecutive business days.

Until Nasdaq has reached a final determination that we have regained compliance with all of the applicable continued listing requirements, there can be no assurances regarding the continued listing of our common stock or warrants on Nasdaq. The delisting of our common stock and warrants from Nasdaq would have a material adverse effect on our access to capital markets, and any limitation on market liquidity or reduction in the price of its common stock as a result of that delisting would adversely affect our ability to raise capital on terms acceptable to us, if at all.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The following exhibits are incorporated by reference or filed as part of this Quarterly Report on Form 10-Q:

Exhibit Number	Description of Exhibits
10.1	Open Market Sale Agreement by and between Rezolute, Inc. and Jefferies, LLC (*included as Exhibit 1.2 to the Registration Statement on Form S-3 filed on November 11, 2023 and incorporated herein by reference*).
10.2	Offer Letter with Daron Evans (*included as Exhibit 10.1 to the Current Report on Form 8-K filed on January 29, 2024 and incorporated herein by reference*).
31.1*	Certification of Chief Executive and Principal Financial Officer as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1*	Certification of Chief Executive and Principal Financial Officer as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS*	Inline XBRL Instance Document
101.SC*	Inline XBRL Taxonomy Extension Schema
101.CA*	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase
101.LA*	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File, formatted in Inline XBRL (included as Exhibit 101)

* Filed herewith.

SIGNATURES

In accordance with Section 12 of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REZOLUTE, INC.

Date: February 13, 2024

By: /s/ Nevan Charles Elam
Nevan Charles Elam
Chief Executive Officer
(Principal Executive and Financial Officer)

EXHIBIT 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Nevan Charles Elam, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Rezolute, 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. As the Registrant's certifying officer, I am 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 (fourth 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. As the Registrant's certifying officer, I have disclosed, based on my 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:

   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: February 13, 2024

By: /s/ Nevan Charles Elam
Nevan Charles Elam
Chief Executive Officer
(Principal Executive and 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

In connection with the quarterly report of Rezolute, Inc. (the "Company") on Form 10-Q for the period ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nevan Elam, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: February 13, 2024

By: /s/ Nevan Charles Elam
Nevan Charles Elam
Chief Executive Officer
(Principal Executive and Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Rezolute, Inc. and will be retained by Rezolute, Inc. to be furnished to the Securities and Exchange Commission or its staff upon request.