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 September 30, 2023

or

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

For the transition period from to

Commission File Number: 001-39683

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 November 10, 2023.

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:

- 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 expense and other payments;
- our beliefs and assumptions relating to our liquidity position, including our ability to obtain additional financing;
- our ability to obtain regulatory approvals or remove regulatory holds for clinical trials and our drug candidates; 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, as well as "Risk Factors" in 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.

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)

	September 30, 2023	June 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 8,057	$ 16,036
Investments in marketable debt securities	90,673	85,860
Prepaid expenses and other	3,915	3,014
Total current assets	102,645	104,910
Long-term assets:		
Investments in marketable debt securities	8,144	16,470
Right-of-use assets	1,933	2,054
Property and equipment, net	129	139
Deposits and other	148	148
Total assets	$ 112,999	$ 123,721
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,432	$ 3,269
Accrued liabilities:		
Accrued clinical and other	2,557	507
Compensation and benefits	1,681	883
Current portion of operating lease liabilities	525	541
Total current liabilities	7,195	5,200
Long term liabilities:		
Operating lease liabilities, net of current portion	1,814	1,937
Embedded derivative liability	426	412
Total liabilities	9,435	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 36,827 shares as of September 30, 2023 and June 30, 2023	37	37
Additional paid-in capital	379,320	377,471
Accumulated other comprehensive loss	(284)	(351)
Accumulated deficit	(275,509)	(260,985)
Total shareholders' equity	103,564	116,172
Total liabilities and shareholders' equity	$ 112,999	$ 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 September 30,	
	2023	**2022**
Operating expenses:		
Research and development	$ 12,214	$ 7,704
General and administrative	3,700	2,514
Total operating expenses	15,914	10,218
Operating loss	(15,914)	(10,218)
Non-operating income (expense):		
Interest and other income, net	1,404	400
Loss from change in fair value of derivative liability	(14)	(13)
Total non-operating income, net	1,390	387
Net loss	(14,524)	(9,831)
Other comprehensive income:		
Net unrealized gain on available-for-sale marketable debt securities	67	—
Comprehensive loss	$ (14,457)	$ (9,831)
Net loss per common share:		
Basic and diluted	$ (0.28)	$ (0.19)
Weighted average number of common shares outstanding:		
Basic and diluted	51,409	50,528

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

Rezolute, Inc.

Unaudited Condensed Consolidated Statements of Shareholders' Equity
Three Months Ended September 30, 2023 and 2022
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Three Months Ended September 30, 2023:						
Balances, June 30, 2023	36,827	$ 37	$ 377,471	$ (351)	$ (260,985)	$ 116,172
Share-based compensation	—	—	1,849	—	—	1,849
Net change in accumulated other comprehensive loss	—	—	—	67	—	67
Net loss	—	—	—	—	(14,524)	(14,524)
Balances, September 30, 2023	36,827	$ 37	$ 379,320	$ (284)	$ (275,509)	$ 103,564
Three Months Ended September 30, 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	—	—	1,879	—	—	1,879
Net loss	—	—	—	—	(9,831)	(9,831)
Balances, September 30, 2022	36,827	$ 37	$ 372,082	$ —	$ (219,029)	$ 153,090

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)

	Three Months Ended September 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (14,524)	$ (9,831)
Share-based compensation expense	1,849	1,879
Non-cash lease expense	122	23
Loss from change in fair value of derivative liability	14	13
Accretion of discounts and amortization of premiums on marketable debt securities, net	973	—
Depreciation and amortization expense	10	3
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other assets	(902)	388
Decrease in accounts payable	(836)	(22)
Increase (decrease) in accrued liabilities	2,709	(42)
Net Cash Used in Operating Activities	(10,585)	(7,589)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable debt securities	(15,989)	—
Proceeds from maturities of marketable debt securities	18,595	—
Purchase of property and equipment	—	(70)
Total Cash Provided by (Used In) Investing Activities	2,606	(70)
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 offering costs	—	(759)
Net Cash Provided by Financing Activities	—	11,571
Net increase (decrease) in cash and cash equivalents	(7,979)	3,912
Cash and cash equivalents at beginning of period	16,036	150,410
Cash and cash equivalents at end of period	$ 8,057	$ 154,322
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	171	29

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 months ended September 30, 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 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 three months ended September 30, 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 $275.5 million as of September 30, 2023. For the three months ended September 30, 2023, the Company incurred a net loss of $14.5 million and net cash used in operating activities amounted to $10.6 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 September 30, 2023, the Company's capital resources consist of cash and cash equivalents of $8.1 million, short-term investments in marketable debt securities of $90.7 million and long-term investments in marketable debt securities of $8.1 million.

As of September 30, 2023, the Company has total liabilities of $9.4 million, including current liabilities of $7.2 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. The first patient dosing milestone event in connection with the RZ358 Phase 3 clinical trial is 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 November 2024, 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 consisting of the following (in thousands):

	September 30, 2023	June 30, 2023
Short-term investments	$ 90,673	$ 85,860
Long-term investments	8,144	16,470
Total investments	$ 98,817	$ 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 due to an adverse shift in interest rates, 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 September 30, 2023, investments in marketable debt securities with an aggregate fair value of $90.7 million are scheduled to mature during the 12-month period ending September 30, 2024. Substantially all of the remaining investments, with an aggregate fair value of $8.1 million, are scheduled to mature during the 12-month period ending September 30, 2025.

During the three months ended September 30, 2023, marketable debt securities for $18.6 million matured and approximately $16.0 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 three months ended September 30, 2023.

Accrued interest receivable on all marketable debt securities amounted to $0.4 million and $0.3 million as of September 30, 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 months ended September 30, 2023, the Company did not recognize any allowance for credit losses 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 September 30, 2023 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate commercial paper	$ 40,944	$ —	$ (45)	$ 40,899
Obligations of U.S. government agencies	24,698	1	(59)	24,640
U.S. Treasury obligations	5,478	—	(13)	5,465
Corporate notes and bonds	23,742	—	(163)	23,579
Asset-backed securities	4,239	5	(10)	4,234
Total	$ 99,101	$ 6	$ (290)	$ 98,817

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 4 — OPERATING LEASES

The Company's right-of-use assets and operating lease liabilities are as follows (in thousands):

	September 30, 2023	June 30, 2023
Right-of-use assets	$ 1,933	$ 2,054
Operating lease liabilities:		
Current	$ 525	$ 541
Long-term	1,814	1,937
Total	$ 2,339	$ 2,478

For the three months ended September 30, 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):

	2023	2022
Research and development	$ 131	$ 77
General and administrative	42	23
Total	$ 173	$ 100

As of September 30, 2023, the weighted average remaining lease term under operating leases was 4.1 years, and the weighted average discount rate for operating lease liabilities was 6.8%. Future cash payments under all operating lease agreements as of September 30, 2023 are as follows (in thousands):

Fiscal year ending June 30,	
Remainder of fiscal year 2024	$ 509
2025	627
2026	646
2027	666
Thereafter	224
Total lease payments	2,672
Less imputed interest	(333)
Present value of operating lease liabilities	$ 2,339

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.

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

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

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 September 30, 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 nonoperating gain or loss.

NOTE 7 — SHAREHOLDERS' EQUITY

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 September 30, 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	8,769	1,931
Total		11,040	9,109	1,931

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 September 30, 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 three months ended September 30, 2023 (shares in thousands):

	Shares	Price [1]	Term [2]
Outstanding, June 30, 2023	8,745	$ 4.56	8.8
Grants to employees	415	1.51	
Expired	(27)	12.67	
Forfeited	(24)	4.06	
Outstanding, September 30, 2023	9,109	4.40	8.6
Vested, September 30, 2023	3,188	6.21	8.2

(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 three months ended September 30, 2023, the aggregate fair value of stock options granted for approximately 0.4 million shares of common stock amounted to $0.5 million or approximately $1.18 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 three months ended September 30, 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	$ 1.51
Expected volatility	94 %
Risk free interest rate	4.2 %
Expected term (years)	6.1
Dividend yield	0 %

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Share-based compensation expense for the three months ended September 30, 2023 and 2022 is included under the following captions in the unaudited condensed consolidated statements of operations and comprehensive loss (in thousands):

	2023	2022
Research and development	$ 840	$ 870
General and administrative	1,009	1,009
Total	$ 1,849	$ 1,879

Unrecognized share-based compensation expense is approximately $15.4 million as of September 30, 2023. This amount is expected to be recognized over a weighted average period of 2.7 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"). As of September 30, 2023, all of the 2022 PFWs may be exercised at any time by paying the exercise price of $0.001 per share, subject to certain ownership restrictions.

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.

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 September 30, 2023, all of the warrants were vested.

For the three months ended September 30, 2023, no warrants were granted, exercised or expired. Excluding the 2021 PFWs and the 2022 PFWs discussed above, the following table sets forth a summary of all other warrants for the three months ended September 30, 2023 (shares in thousands):

	Shares	Price [1]	Term [2]
Outstanding, June 30, 2023	888	$ 22.10	4.1
Outstanding, September 30, 2023	888	22.10	3.8

(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 September 30, 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 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 months ended September 30, 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 months ended September 30, 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 exercisable. Accordingly, the weighted average number of shares outstanding is computed as follows for the three months ended September 30, 2023 and 2022 (in thousands):

	2023	2022
Common Stock	36,827	35,946
2021 PFWs	1,661	1,661
2022 PFWs:		
Class A PFWs	1,974	1,974
Class B PFWs	10,947	10,947
Total	51,409	50,528

For the three months ended September 30, 2023 and 2022, basic and diluted net loss per share were the same since all other common stock equivalents were anti-dilutive.

As of September 30, 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	9,109	8,482
Other warrants	888	1,150
Total	9,997	9,632

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 September 30, 2023 and June 30, 2023 (in thousands):

	Fair Value Measurement of Assets as of September 30, 2023			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents:				
Money market funds	$ 5,323	$ 5,323	$ —	$ —
Marketable debt securities:				
Corporate commercial paper	40,899	—	40,899	—
U.S. Government agencies	24,640	—	24,640	—
U.S. Government treasuries	5,465	5,465	—	—
Corporate notes and bonds	23,579	—	23,579	—
Asset-backed securities	4,234	—	4,234	—
Total	$ 104,140	$ 10,788	$ 93,352	$ —

	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 September 30, 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. The following table sets forth changes in the fair value of the Company's embedded derivative liability for the three months ended September 30, 2023 and 2022 (in thousands):

	2023	2022
Fair value, beginning of period	$ 412	$ 407
Loss from change in fair value	14	13
Fair value, end of period	$ 426	$ 420

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 September 30, 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 September 30, 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 months ended September 30, 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 accounts at a high-quality financial institution. As of and for the three months ended September 30, 2023 and 2022, cash deposits have exceeded the amount of insurance provided on such deposits by the Federal Deposit Insurance Corporation.

As of September 30, 2023, the Company has an aggregate of $41.9 million invested in the debt securities of issuers in the banking and financial services industries, and an aggregate of $24.6 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.

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.

As a Company, we are focused on advancing our compounds through clinical studies. Our lead clinical asset, RZ358, is a potential antibody treatment for congenital hyperinsulinism ("HI"), an ultra-rare pediatric genetic disorder characterized by excessive production of insulin by the pancreas. Our second clinical asset, RZ402, is a selective and potent plasma kallikrein inhibitor ("PKI") being developed as a potential oral therapy for the chronic treatment of diabetic macular edema ("DME").

Clinical Development

Our key objectives in the fourth quarter of 2023 are completing enrollment for the RZ402 Phase 2 study in DME as well as initiation of the sunRIZE Phase 3 study for RZ358.

RZ358 Regulatory Status

As discussed in our disclosures on Current Reports on Form 8-K filed with the SEC, toxicology studies in rats and monkeys were conducted as part of the early RZ358 development program and in these studies, rats demonstrated a microvascular liver injury at potentially clinically relevant doses and exposures ("rat findings"). However, there were no adverse liver findings in monkeys at dose levels that were more than 10 times higher than doses that were toxic in rats, and more than 4 times higher than human doses evaluated in clinical studies. Based on the absence of liver toxicity in monkeys and the lack of adverse liver findings in closely monitored human trials, the Company believes that the toxicity is unique to rats and unlikely relevant to humans.

As is customary in pediatric drug development, there is a progression of the inclusion of younger participants as a program advances through different stages and continues to demonstrate a good safety profile and a prospect of benefit for children based on previous stages. After the completion of Phase 1 adult healthy volunteer studies for RZ358, Phase 2a single-dose proof of concept studies ("Phase 2a") were conducted in participants with congenital HI who were 12 years of age and older in countries governed by the Regulatory Authorities in the European Union and elsewhere in Europe. In the U.S., the Food and Drug Administration ("FDA") restricted enrollment in Phase 2a to participants 18 years of age and older and, based on the rat findings, imposed a human drug exposure limit equating to repeat doses of approximately 3 mg/kg per week ("exposure cap").

Subsequently, in the RIZE study European Authorities and other regulatory bodies continued the expected downward age progression, lowering the age for study participants down from 12 years of age to 2 years of age and older. At the start of the RIZE study the clinical program in the U.S. remained under the 18 years of age and older restriction as well as the exposure cap. However, in the first half of 2020, while the RIZE study was underway, we reached agreement with FDA to proceed with the RIZE study in the U.S. at all dose levels (no exposure cap) and in younger participants (ages 12 and older). Following these developments, the study protocol was harmonized globally, other than a regional difference in the minimum permitted age (12 years and older in the US versus 2 years and older in all other geographies).

After the completion of the RIZE study, in the second half of 2022 and the first half of 2023, the Company conducted scientific advice meetings with the Regulatory Authorities in Europe which resulted in alignment with our proposed Phase 3 program including overall study design, dosing regimen, endpoints, sample size and patient population. Notably, with all available nonclinical (including the rat findings) and clinical information under review, European Authorities aligned with a further downward age progression whereby participants 3 months of age and older will be permitted to be enrolled in the Phase 3 study.

Prior to engaging FDA on Phase 3 planning in the U.S., we began interacting with the agency in the second half of 2022 to further liberalize the age restriction to achieve alignment with the parameters established by the European Authorities in the RIZE study. Over

the course of these post-RIZE regulatory interactions with FDA, the agency revisited prior concerns regarding the rat findings and, despite the absence of new clinical or nonclinical data (other than the RIZE data), the agency decided to maintain the age restriction of 12 years and above and re-imposed the previous exposure cap which had been removed during the RIZE study (collectively, "New Restrictions"). In the second half of 2022 and the first half of 2023, we interacted with FDA to resolve the New Restrictions, particularly in the context of the advancement of the clinical program in the rest of the world. Nonetheless, FDA affirmed the New Restrictions at a meeting held with us on May 24, 2023.

We have concluded pre-Phase 3 regulatory and scientific advice meetings with Regulatory Authorities outside of the U.S. and have reached agreement on the design of the Phase 3 study that will include participants 3 months of age and older. We believe that the New Restrictions make it infeasible to include the U.S. in the Phase 3 study at this time, particularly given that the pediatric population with congenital HI has the greatest therapeutic need. We are evaluating potential nonclinical studies to address FDA's concerns in parallel with the initiation and advancement of the Phase 3 study outside of the U.S.

Specifically, in the fourth quarter of 2023, we plan to initiate the Phase 3 sunRIZE clinical study of RZ358 which will be a randomized, double-blind, placebo-controlled, parallel arm evaluation of RZ358 in participants with congenital HI who are not adequately responding to standard of care medical therapies. Topline results from the study are anticipated to be available in the first half of 2025.

RZ402

In December 2022, we initiated a Phase 2 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 are being 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. The study is expected to enroll up to approximately 100 patients overall, across approximately 25 investigational sites in the United States. The principal endpoints of the trial include (i) changes in central subfield thickness of the macula, as measured by Spectral Domain Ocular Coherence Tomography, (ii) changes in 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. We expect to complete enrollment in 2023 and to provide an update on the study prior to year end.

Recent Developments

On October 4, 2023, an investor from our May 2022 registered direct offering provided notice of cashless exercise of their Class B PFWs. This resulted in the issuance of 2,797,704 shares of our common stock on October 6, 2023.

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 all stock options granted 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 September 30, 2023 and 2022

Revenue. As a clinical stage company, we did not generate any revenue for the three months ended September 30, 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 September 30, 2023 and 2022 were as follows (in thousands, except percentages):

			Increase	
	2023	2022	Amount	Percent
Total R&D expenses	$ 12,214	$ 7,704	$ 4,510	59 %

The increase in R&D expenses of $4.5 million for the three months ended September 30, 2023 was primarily attributable to an increase of RZ358 related program costs of approximately $3.1 million. The increased expense consisted of an increase in manufacturing and preclinical costs of $2.0 million and clinical trial expense of $1.1 million. RZ358 costs increased due to Phase 3 clinical readiness activities. Compensation and benefits for our R&D workforce increased by approximately $1.0 million. Cash-based compensation and benefits increased by approximately $1.0 million that was primarily attributable to the ratable accrual of annual performance bonuses and an increase in the average number of R&D employees from 34 for the three months ended September 30, 2022 to 36 for the three months ended September 30, 2023. RZ402 program costs increased by approximately $0.5 million, primarily due to Phase 2 clinical trial costs associated with the dosing of its first patients in February 2023.

General and administrative expenses. G&A expenses for the three months ended September 30, 2023 and 2022 were as follows (in thousands, except percentages):

	2023	2022	Increase Amount	Increase Percent
Total G&A expenses	$ 3,700	$ 2,514	$ 1,186	47 %

The increase in G&A expenses of $1.2 million for the three months ended September 30, 2023 was primarily attributable to increases in (i) cash-based compensation expense of $0.5 million and (ii) market research expense of $0.2 million. Cash based compensation expense was due to an increase in the average number of employees from 10 for the three months ended September 30, 2022 to 14 employees for the three months ended September 30, 2023. Market research expense increased due to the preparation for a post approval launch of RZ358, such as conducting global market assessments. Remaining increases of $0.4 million in G&A expenses are primarily attributable to facilities and other employee related costs.

Interest and Other Income. Interest and other income amounted to $1.4 million for the three months ended September 30, 2023, compared to $0.4 million for the three months ended September 30, 2022. This increase 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 three months ended September 30, 2022 provided for earnings that were less than 1.0%.

Income Taxes. For the three months ended September 30, 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 September 30, 2023, we had cash and cash equivalents of $8.1 million, short-term marketable debt securities of $90.7 million and working capital was approximately $95.5 million. We have incurred cumulative net losses of $275.5 million since our inception and as a clinical stage company we have not generated any meaningful revenue to date.

Accordingly, our primary source of liquidity has historically been from the completion of private and public offerings of our securities. For the three months ended September 30, 2023, no financing activities were consummated. For the fiscal year ended June 30, 2023, we received net proceeds from the issuance of equity securities of $11.6 million. The completion of equity financings during the fiscal year ended June 30, 2022 was the primary factor that resulted in our cash and cash equivalents balance of $8.1 million and short-term marketable debt securities investment balance of $90.7 million as of September 30, 2023.

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. Remaining cash payments related to existing contractual obligations for the 12-months ending September 30, 2024 include approximately (i) $0.5 million under all of our operating lease agreements, and (ii) a potential milestone payment to XOMA of $5.0 million that will be due upon dosing of the first patient in a Phase 3 clinical trial for RZ358 and (iii) a potential milestone payment to XOMA of $5.0 million that will be due upon dosing of the last patient in a Phase 3 clinical trial for RZ358 that we expect will occur in the next twelve months. Due to uncertainties in the timing associated with clinical trial activities, it is possible that this milestone payment to XOMA could be delayed beyond September 30, 2024

Our most significant contractual obligations consist of milestone payments pursuant to licensing agreements with XOMA Corporation (“XOMA”) and ActiveSite Pharmaceuticals, Inc. (“ActiveSite”) discussed below. Based on our expectations for the dates when certain clinical and regulatory milestones will be achieved, we anticipate that $10.0 million will be payable to XOMA within the next twelve months.

Based on our cash and cash equivalents balance of $8.1 million and short-term investment balance of $90.8 million as of September 30, 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 this total, we expect that $10.0 million will be payable to XOMA during the 12-months period ending September 30, 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 be 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 sales-based and alternative indication regulatory approvals to XOMA and ActiveSite for an additional $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 either of 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 $0.6 million to $0.7 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 contractual obligations and conduct all planned activities to advance our clinical trials at least through the third quarter of calendar year 2025. Therefore, we will need to obtain additional equity or debt financing in order to fund all of our long-term liquidity requirements.

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 September 30, 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 September 30, 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 September 30, 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 three months ended September 30, 2023 and 2022 (in thousands):

	2023	2022	Change
Net cash provided by (used in):			
Operating activities	$ (10,585)	$ (7,589)	$ (2,996)
Investing activities	2,606	(70)	2,676
Financing activities	—	11,571	(11,571)

Cash Used in Operating Activities

For the three months ended September 30, 2023 and 2022, cash used in operating activities amounted to $10.6 million and $7.6 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	$ (14,524)	$ (9,831)	$ (4,693)
Non-cash expenses	2,968	1,918	1,050
Changes in operating assets and liabilities, net	971	324	647
Total	$ (10,585)	$ (7,589)	$ (2,996)

For the three months ended September 30, 2023, our net loss was $14.5 million compared to $9.8 million for the three months ended September 30, 2022. For further discussion about changes in our operating results for the three months ended September 30, 2023 and 2022, please refer to *Results of Operations* above.

For the three months ended September 30, 2023 and 2022, our non-cash expenses of $3.0 million and $1.9 million, respectively, were primarily attributable to share-based compensation expense, accretion of discounts and amortization of premiums on marketable debt securities and non-cash lease expense. For the three months ended September 30, 2023, net changes in operating assets and liabilities increased operating cash flow by $1.0 million, primarily driven by an increase of $1.9 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 $0.9 million. For the three months ended September 30, 2022, net changes in operating assets and liabilities decreased operating cash flow by $0.3 million, primarily driven by an increase in prepaid expenses and other assets of $0.4 million, offset by a net decrease of $0.1 million in accounts payable and other accrued liabilities.

Cash Provided by Investing Activities

For the three months ended September 30, 2023, our net cash provided by investing activities amounted to $2.6 million, primarily related to the maturity of marketable debt securities $18.6 million partially offset by $16.0 million of purchases of marketable debt securities.

For the three months ended September 30, 2022, our net cash utilized in investing activities amounted to $70,000, related to the purchase of furniture and equipment.

Cash Provided by Financing Activities

There was no net cash provided by financing activities for the three months ended September 30, 2023.

Net cash provided by financing activities for the three months ended September 30, 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 September 30, 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.

The Israel-Hamas conflict may have a material impact on our clinical trial site plans.

The recent Israel-Hamas conflict could have a negative impact on our clinical trial site plans. Prior to October 7, 2023, we had plans to locate one of the sites for our RZ358 clinical trials in Israel. In the event the Israel-Hamas conflict continues for an extended period of time or if we deem the conditions to be unsafe for trial participants or our contractors, we will have to change these plans and seek an alternative site which could delay our timing and could impact our expected timing to receive clinical data.

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
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: November 13, 2023

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: November 13, 2023

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 September 30, 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: Novembe 13, 2023

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.