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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 March 31, 2025

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 85,519,318 shares of its $0.001 par value common stock outstanding as of May 9, 2025.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2025 (the "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 for our drug candidates;
- our expectations regarding clinical development and the timing of clinical trials in the United States and outside of the United States;
- our projected operating or financial results, including anticipated cash flows to be used in operating activities;
- our expectations regarding capital expenditures, research and development ("R&D") 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;
- 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 1A. 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, 2024 (the "2024 Form 10-K"), filed with the Securities and Exchange Commission ("SEC") on September 19, 2024 and (ii) in Part II, Item 1A of our Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2024 filed with the SEC on February 12, 2025.

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 future results. Consequently, no forward-looking statement can be guaranteed. Our 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 share and per share amounts)

	March 31, 2025	June 30, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 14,596	$ 70,396
Investments in marketable debt securities	72,296	56,478
Prepaid expenses and other	1,843	1,779
Total current assets	88,735	128,653
Long-term assets:		
Deposits and other	2,925	1,838
Investments in marketable debt securities	1,514	263
Right-of-use assets	1,485	1,880
Property and equipment, net	80	103
Total assets	$ 94,739	$ 132,737
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 6,502	$ 4,901
Accrued liabilities:		
Accrued clinical and other	2,366	2,325
Compensation and benefits	1,044	1,812
Current portion of operating lease liabilities	615	568
Total current liabilities	10,527	9,606
Long-term liabilities:		
Operating lease liabilities, net of current portion	1,160	1,660
Embedded derivative liability	483	468
Total liabilities	12,170	11,734
Commitments and contingencies (Notes 5, 9 and 10)		
Shareholders' equity:		
Preferred stock, $0.001 par value; 400,000 shares authorized; no shares issued	—	—
Common stock, $0.001 par value; 165,000,000 and 100,000,000 shares authorized; issued and outstanding 60,542,914 and 53,245,824 shares as of March 31, 2025 and as of June 30, 2024, respectively	61	53
Additional paid-in capital	461,931	450,473
Accumulated other comprehensive income (loss)	43	(79)
Accumulated deficit	(379,466)	(329,444)
Total shareholders' equity	82,569	121,003
Total liabilities and shareholders' equity	$ 94,739	$ 132,737

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 share and per share amounts)

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 15,283	$ 12,401	$ 40,664	$ 36,654
General and administrative	4,740	3,812	13,380	10,667
Total operating expenses	20,023	16,213	54,044	47,321
Operating loss	(20,023)	(16,213)	(54,044)	(47,321)
Non-operating income (expense):				
Interest and other income, net	1,115	1,122	4,037	3,829
Loss from change in fair value of derivative liabilities	(6)	(1,959)	(15)	(1,991)
Total non-operating income (expense), net	1,109	(837)	4,022	1,838
Net loss	(18,914)	(17,050)	(50,022)	(45,483)
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable debt securities	(21)	(30)	122	273
Comprehensive loss	$ (18,935)	$ (17,080)	$ (49,900)	$ (45,210)
Net loss per common share:				
Basic and diluted	$ (0.27)	$ (0.34)	$ (0.72)	$ (0.89)
Weighted average number of common shares outstanding:				
Basic and diluted	70,031,041	50,812,332	69,901,565	51,211,564

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

Rezolute, Inc.

Unaudited Condensed Consolidated Statements of Shareholders' Equity
Nine Months Ended March 31, 2025 and 2024
(In thousands, except share and per share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Nine Months Ended March 31, 2025:						
Balances, June 30, 2024	53,245,824	$ 53	$ 450,473	$ (79)	$ (329,444)	$ 121,003
Gross proceeds from issuance of common stock for cash in 2024 Private Placement	1,500,000	1	5,999	—	—	6,000
Commissions and other offering costs	—	—	(45)	—	—	(45)
Issuance of common stock upon exercise of stock options	271,823	1	760	—	—	761
Share-based compensation	—	—	4,750	—	—	4,750
Cashless exercise of pre-funded warrants	5,525,267	6	(6)	—	—	—
Net change in accumulated other comprehensive income (loss)	—	—	—	122	—	122
Net loss	—	—	—	—	(50,022)	(50,022)
Balances, March 31, 2025	60,542,914	$ 61	$ 461,931	$ 43	$ (379,466)	$ 82,569
Nine Months Ended March 31, 2024:						
Balances, June 30, 2023	36,827,567	$ 37	$ 377,471	$ (351)	$ (260,985)	$ 116,172
Issuance of common stock upon exercise of stock options	5,000	—	10	—	—	10
Share-based compensation	—	—	5,589	—	—	5,589
Cashless exercise of pre-funded warrants	6,300,080	6	(6)	—	—	—
Acquisition and retirement of treasury shares pursuant to Exchange Agreement	(3,000,000)	(3)	(5,697)	—	—	(5,700)
Net change in accumulated other comprehensive income (loss)	—	—	—	273	—	273
Net loss	—	—	—	—	(45,483)	(45,483)
Balances, March 31, 2024	40,132,647	$ 40	$ 377,367	$ (78)	$ (306,468)	$ 70,861

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)

	Nine Months Ended March 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (50,022)	$ (45,483)
Share-based compensation expense	4,750	5,589
Loss from change in fair value of warrant derivative liability	—	1,950
Loss from change in fair value of embedded derivative liability	15	41
Non-cash lease expense	395	399
Accretion of discounts and amortization of premiums on marketable debt securities, net	(2,059)	(2,100)
Depreciation expense	23	29
Changes in operating assets and liabilities:		
Increase in prepaid expenses, deposits, and other assets	(1,152)	(558)
Increase in accounts payable	2,151	230
Increase (decrease) in accrued liabilities	(1,181)	1,057
Net Cash Used in Operating Activities	(47,080)	(38,846)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable debt securities	(100,686)	(56,730)
Proceeds from maturities of marketable debt securities	85,799	85,766
Total Cash Provided by (Used in) Investing Activities	(14,887)	29,036
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	761	—
Net cash payment pursuant to Exchange Agreement	—	(3)
Gross proceeds from issuance of common stock in 2024 Private Placement	6,000	—
Payment of offering costs	(594)	(293)
Net Cash Provided by (Used in) Financing Activities	6,167	(296)
Net decrease in cash and cash equivalents	(55,800)	(10,106)
Cash and cash equivalents at beginning of period	70,396	16,036
Cash and cash equivalents at end of period	$ 14,596	$ 5,930
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	559	544
Operating lease liabilities incurred in exchange for right-of-use-assets	—	352
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Acquisition of treasury shares in exchange for issuing pre-funded warrant liability	$ —	$ 5,697
Receivable from exercise of stock options	$ —	$ 10

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 late-stage rare disease company focused on significantly improving outcomes for individuals with hypoglycemia caused by hyperinsulinism. The Company's primary clinical assets consist of (i) ersodetug (formerly known as RZ358), which is a potential treatment for all forms of hyperinsulinism, including 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"), and the rules and regulations of the SEC for interim financial information, including the instructions to Form 10-Q and Article 8 of Regulation S-X.

The condensed consolidated balance sheet as of June 30, 2024, has been derived from the Company's audited consolidated financial statements. The unaudited interim financial statements should be read in conjunction with the 2024 Form 10-K, which contains the Company's audited financial statements and notes thereto, together with Management's Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended June 30, 2024.

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, the interim financial statements 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 nine months ended March 31, 2025, 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, 2025.

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 for marketable debt securities, the fair value of an embedded derivative liability, fair value of share-based compensation, 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 and other risks associated with a clinical stage company, including the potential risk of business failure discussed in Note 2.

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 2024 Form 10-K.

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which improves reportable segment disclosure requirements through enhanced disclosures about significant segment expenses. ASU 2023-07 expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items and interim disclosures of a reportable segment's profit or loss and assets. The Company is required to adopt ASU 2023-07 in its annual financial statements for the fiscal year ending June 30, 2025, and for interim periods thereafter. Adoption is required to be applied on a retrospective basis to all periods presented. The Company does not expect the adoption of ASU 2023-07 will have a material impact on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures* ("ASU 2023-09"), which expands income tax disclosures including changes in the rate reconciliation and income taxes paid information. This ASU is intended to enhance the transparency and decision usefulness of income tax disclosures. ASU 2023-09 is effective for annual periods beginning after December 15, 2024, and early adoption is permitted. The Company has not determined the timing for adoption of this standard.

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 $379.5 million as of March 31, 2025. For the nine months ended March 31, 2025, the Company incurred a net loss of $50.0 million and net cash used in operating activities amounted to $47.1 million. For the fiscal year ended June 30, 2024, the Company incurred a net loss of $68.5 million and net cash used in operating activities amounted to $57.4 million. As of March 31, 2025, the Company's capital resources consist of cash and cash equivalents of $14.6 million, short-term investments in marketable debt securities of $72.3 million and long-term investments in marketable debt securities of $1.5 million.

As discussed in Note 7, the Company completed the 2024 Private Placement in July 2024 that resulted in the sale of 1.5 million shares of common stock for gross cash proceeds of $6.0 million.

As of March 31, 2025, the Company has total liabilities of $12.2 million, including current liabilities of $10.5 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 last patient in a Phase 3 clinical trial for ersodetug. The commitment to pay the last patient dosing milestone of $5.0 million for the ersodetug Phase 3 clinical trial is expected to be recognized as a liability and corresponding expense within 12 months.

As discussed in Note 14, in April 2025 the Company completed the 2025 Underwritten Offering that resulted from the issuance of 24,940,769 shares of common stock at a price of $3.25 per share, and pre-funded warrants to purchase 6,905,385 shares of common stock at a public offering price of $3.249 per pre-funded warrant for net proceeds of $96.9 million after underwriting discounts and other offering costs.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Management believes the Company's existing cash, cash equivalents and investments in marketable debt securities, along with net proceeds from the 2025 Underwritten Offering, will be adequate to meet the Company's contractual obligations and carry out ongoing clinical trials and other planned activities through May 2026, at a minimum.

NOTE 3 —INVESTMENTS IN MARKETABLE DEBT SECURITIES

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

	March 31, 2025	June 30, 2024
Short-term investments	$ 72,296	$ 56,478
Long-term investments	1,514	263
Total investments	$ 73,810	$ 56,741

The Company only invests in liquid, high quality debt securities. Nonetheless, all of these investments are subject to interest rate and credit risk that may result in fluctuations in the fair value of the investments. To minimize exposure due to an adverse shift in interest rates, the Company generally invests in securities with expected maturities of two years or less while maintaining a weighted average maturity of one year or less. As of March 31, 2025, investments in marketable debt securities with an aggregate fair value of $72.3 million are scheduled to mature during the 12-month period ending March 31, 2026. All remaining investments, with an aggregate fair value of $1.5 million, are scheduled to mature during the 12-month period ending March 31, 2027.

During the nine months ended March 31, 2025, marketable debt securities for $85.8 million matured and were reinvested in additional marketable debt securities. The Company used $100.7 million of cash and cash equivalents to purchase investments in marketable debt securities during the nine months ended March 31, 2025. The Company did not sell any marketable debt securities prior to the scheduled maturity dates for the nine months ended March 31, 2025.

Accrued interest receivable on all marketable debt securities amounted to $0.5 million and $0.4 million as of March 31, 2025 and June 30, 2024, respectively. Accrued interest receivable is included in other current assets in the accompanying unaudited condensed consolidated balance sheets.

For the three and nine months ended March 31, 2025, 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 March 31, 2025 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate commercial paper	$ 18,457	$ 2	$ (3)	$ 18,456
Obligations of U.S. government agencies	4,940	4	(1)	4,943
Corporate notes and bonds	50,370	55	(14)	50,411
Total	$ 73,767	$ 61	$ (18)	$ 73,810

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 4 — OPERATING LEASES

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

	March 31, 2025	June 30, 2024
Right-of-use assets	$ 1,485	$ 1,880
Operating lease liabilities:		
Current	$ 615	$ 568
Long-term	1,160	1,660
Total	$ 1,775	$ 2,228

For the three and nine months ended March 31, 2025 and 2024, operating lease expense is included under the following captions in the accompanying unaudited condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2025	2024	2025	2024
Research and development	$ 115	$ 97	$ 353	$ 358
General and administrative	51	74	147	155
Total	$ 166	$ 171	$ 500	$ 513

As of March 31, 2025, the weighted average remaining lease term under operating leases was 2.5 years, and the weighted average discount rate for operating lease liabilities was 7.1%. Future cash payments under all operating lease agreements as of March 31, 2025 are as follows (in thousands):

Fiscal year ending June 30,	
Remainder of fiscal year 2025	$ 189
2026	770
2027	750
Thereafter	224
Total lease payments	1,933
Less imputed interest	(158)
Present value of operating lease liabilities	$ 1,775

NOTE 5 — LICENSE AGREEMENTS

XOMA License Agreement

In December 2017, the Company entered into a license agreement that has been subsequently amended ("XOMA License Agreement") with XOMA Corporation ("XOMA"), through its wholly-owned subsidiary, XOMA (U.S.) LLC, pursuant to which XOMA granted an exclusive global license to the Company to develop and commercialize XOMA 358 (formerly X358 or RZ358, now ersodetug) 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 ersodetug. In April 2024, the Company was required to make a milestone payment under the XOMA License Agreement of $5.0 million that became due upon dosing of the first patient in the Company's Phase 3 Clinical Trial for ersodetug. Upon the achievement of certain clinical and regulatory events under the

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

XOMA License Agreement, the Company will be required to make additional milestone payments to XOMA up to $30.0 million. After the clinical and regulatory milestones, the Company will be required, upon the future commercialization of ersodetug, 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 Company records a liability and corresponding expense for milestone payments under license agreements in the period that the milestone event is achieved. The next milestone payment of $5.0 million will be due upon dosing of the last patient in either of the Company's Phase 3 clinical trials for ersodetug.

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.

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 the Loan Agreement was terminated 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 $0.5 million as of March 31, 2025 and June 30, 2024. Exit Events include, but are not limited to, sales of substantially all assets, certain mergers, change of control transactions, and certain issuances of common stock whereby more than 35% of the Company's shares are issued to parties other than its existing investors in a single transaction or series of related transactions. 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.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 7 — SHAREHOLDERS' EQUITY

Changes in Shareholders' Equity for the Three Months Ended March 31, 2025 and 2024

The following tables present changes in shareholders' equity for the three months ended March 31, 2025 and 2024 (in thousands, except share and per share amounts):

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Three Months Ended March 31, 2025:						
Balances, December 31, 2024	60,534,695	$ 61	$ 460,016	$ 64	$ (360,552)	$ 99,589
Issuance of common stock upon exercise of stock options	8,219	—	10	—	—	10
Share-based compensation expense	—	—	1,905	—	—	1,905
Net change in accumulated other comprehensive income (loss)	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	(18,914)	(18,914)
Balances, March 31, 2025	60,542,914	$ 61	$ 461,931	$ 43	$ (379,466)	$ 82,569
Three Months Ended March 31, 2024:						
Balances, December 31, 2023	39,625,271	$ 40	$ 381,154	$ (48)	$ (289,418)	$ 91,728
Issuance of common stock upon exercise of stock options	5,000	—	10	—	—	10
Share-based compensation expense	—	—	1,903	—	—	1,903
Cashless exercise of pre-funded warrants	3,502,376	3	(3)	—	—	—
Acquisition and retirement of treasury shares pursuant to Exchange Agreement	(3,000,000)	(3)	(5,697)	—	—	(5,700)
Net change in accumulated other comprehensive income (loss)	—	—	—	(30)	—	(30)
Net loss	—	—	—	—	(17,050)	(17,050)
Balances, March 31, 2024	40,132,647	$ 40	$ 377,367	$ (78)	$ (306,468)	$ 70,861

Changes in Authorized Capital Stock

On December 5, 2024, the Company's shareholders approved an increase in the authorized number of common shares from 100.0 million shares to 165.0 million shares. Accordingly, as of March 31, 2025, the Company was authorized to issue 165.0 million shares of common stock and 0.4 million shares of preferred stock.

Pre-Funded Warrants

Between October 2021 and June 2024, the Company issued fully vested pre-funded warrants ("PFWs") exercisable to purchase an aggregate of 21.3 million shares of common stock. As of March 31, 2025, all outstanding PFWs meet the requirements to be classified in shareholders' equity under the caption *additional paid-in capital*. The PFWs do not entitle the holders thereof to any voting rights or any of the other rights or privileges to which holders of common stock are entitled. The exercise prices of the PFWs are subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting holders of common stock. In the event of certain fundamental corporate transactions, the holders of the PFWs are entitled to receive the kind and amount of securities, cash or other property that the holders would have received had they exercised the PFWs immediately prior to such transaction.

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The PFWs are exercisable at any time, subject to the then effective ownership blocker percentage (the "OBP") as elected by each of the holders of PFWs. The OBP is a percentage designated by the holders whereby the PFWs cannot be exercised if, after giving effect thereto, the holder would beneficially own more than the designated OBP. However, upon at least 61 days' prior notice to the Company, any holder of PFWs may elect to increase or decrease the OBP to any other percentage not to exceed 19.99%. Assuming the holders comply with the respective OBP terms, all of the PFWs may be exercised at any time by paying the respective exercise price or electing to exercise on a cashless basis.

As of June 30, 2024, the Company had an aggregate of 15,020,371 PFWs that were outstanding. The following table summarizes PFW activity for the nine months ended March 31, 2025:

	2021 PFWs	2022 PFWs	Exchange PFWs	2024 PFWs	Total
Outstanding, June 30, 2024	123,000 (1)	8,147,371 (2)	3,000,000 (3)	3,750,000 (4)	15,020,371
Cashless exercise of PFWs:					
Shares surrendered for exercise price	—	(435)(5)	(616)(6)	—	(1,051)
Shares of common stock issued	—	(2,525,883)(5)	(2,999,384)(6)	—	(5,525,267)
Outstanding, March 31, 2025	123,000	5,621,053	—	3,750,000	9,494,053

(1) In connection with an underwritten offering in October 2021, PFWs were issued to purchase 1,661,461 shares of common stock at an issuance price of $6.49 per share (the "2021 PFWs"). The exercise price of the 2021 PFWs is $0.01 per share. For the fiscal year ended June 30, 2024, the holders elected cashless exercises for a total of 1,538,461 of the 2021 PFWs resulting in 123,000 shares that remained outstanding as of June 30, 2024.

(2) 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 (the "2022 PFWs"). The exercise price of the 2022 PFWs is $0.001 per share. For the fiscal year ended June 30, 2024, the holders elected cashless exercises for a total of 4,773,684 of the 2022 PFWs resulting in 8,147,371 shares that remained outstanding as of June 30, 2024.

(3) As discussed below under the caption *Exchange Agreement*, the Company issued 3,000,000 Exchange PFWs on March 8, 2024. The exercise price of the Exchange PFWs is $0.001 per share. The Exchange PFWs were initially classified as a derivative liability until May 13, 2024 when the terms were amended to permit reclassification within shareholders' equity.

(4) As discussed below under the caption *2024 Underwritten Offering*, the Company issued 2024 PFWs for the purchase of 3,750,000 shares of common stock on June 17, 2024. The exercise price of the 2024 PFWs is $0.001 per share.

(5) In November 2024, a holder of certain 2022 PFWs provided notice of cashless exercise of 2,526,318 Class B PFWs that resulted in the issuance of 2,525,883 shares of common stock.

(6) In October 2024, all holders of Exchange PFWs provided notice of cashless exercises of 3,000,000 Exchange PFWs that resulted in the issuance of 2,999,384 shares of common stock in October 2024.

2024 Private Placement

In June 2024, the Company entered into a securities purchase agreement (the "2024 SPA") with Handok, Inc. and one other investor relating to a private placement (the "2024 Private Placement"), pursuant to which 1,500,000 shares of common stock were issued at a purchase price of $4.00 per share. Closing of the 2024 Private Placement occurred in July 2024, resulting in net proceeds of $6.0 million.

2024 Underwritten Offering

On June 13, 2024, the Company entered into an underwriting agreement with Jefferies LLC and Cantor Fitzgerald & Co. (the "Underwriters") for the planned issuance and sale of equity securities in an underwritten public offering (the "2024 Underwritten Offering"). The 2024 Underwritten Offering provided for the issuance of (i) 11,250,000 shares of common stock at a price of $4.00 per share for gross proceeds of $45.0 million, and (ii) pre-funded warrants to purchase 3,750,000 shares of common stock at a public offering price of $3.999 per pre-funded warrant (the "2024 PFWs") for gross proceeds of $15.0 million. The Company granted the Underwriters a 30-day option to purchase up to an additional 2,250,000 shares of its common stock in the 2024 Underwritten Offering at a public

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offering price of $4.00 per share (the "2024 Underwriters' Option"). The 2024 Underwriters' Option was partially exercised for 1,786,589 shares of common stock for gross proceeds of $7.1 million. Closing occurred on June 24, 2024, whereby the aggregate gross proceeds from the 2024 Underwritten Offering amounted to $67.1 million before deductions for underwriting commissions of 6.0% of the gross proceeds and other offering costs of approximately $0.5 million. After deducting total offering costs of $4.5 million, the net proceeds of the 2024 Underwritten Offering amounted to approximately $62.6 million.

Exchange Agreement

On March 8, 2024, the Company entered into a securities exchange agreement (the "March 2024 Exchange Agreement") with certain of its stockholders (the "Exchanging Shareholders"), whereby the Company purchased 3,000,000 shares of common stock representing approximately 7% of outstanding shares with an aggregate fair value of $5,700,000 (the "Retired Shares") from the Exchanging Shareholders. The Retired Shares were immediately cancelled whereby they will remain as authorized shares for future issuance in accordance with Nevada law. Consideration for the acquisition of the Retired Shares consisted of (i) a cash payment to the Exchanging Shareholders of $3,000, and (ii) the issuance of pre-funded warrants (the "Exchange PFWs") to the Exchanging Shareholders with an estimated fair value of $5,697,000. The Exchange PFWs do not expire and are exercisable to purchase an aggregate of 3,000,000 shares of the Company's outstanding common stock at an exercise price of $0.001 per share. As required pursuant to the Exchange Agreement, the Company filed a registration statement in August 2024 to register the shares issuable upon the exercise of the Exchange PFWs.

The Exchange PFWs originally required approval by the Company's shareholders if the exercise of the Exchange PFWs resulted in aggregate beneficial ownership by the holders in excess of 19.99%. Even though the Exchange PFWs only entitled the holders to purchase 7% of the Company's outstanding shares of common stock, the requirement to obtain shareholder approval for ownership in excess of 19.99% resulted in the treatment of the exchange PFWs as a warrant derivative liability of $5.7 million as of the issuance date. The fair value of this warrant derivative liability increased by approximately $2.9 million, for a total of approximately $8.5 million as of May 13, 2024 when the Exchange PFWs were amended to permit equity classification. Accordingly, the derivative liability was reclassified to shareholders' equity on May 13, 2024.

Jefferies Open Market Sales Agreement

On November 14, 2023, the Company and Jefferies LLC (the "Agent") entered into an open market sales 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, 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 nine months ended March 31, 2025, the Company did not elect to sell any 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 March 31, 2025.

NOTE 8 — SHARE-BASED COMPENSATION AND WARRANTS

Inducement Grant

In connection with the hiring of an employee of the Company in November 2024, the Board of Directors granted a stock option exercisable for the purchase of 150,000 shares of the Company's common stock at an exercise price of $5.04 per share. This stock option is considered an inducement grant (the "Inducement Grant") pursuant to Nasdaq Listing Rule 5635(c)(4) whereby the

underlying shares were not authorized under any of the Company's equity incentive plans. The Inducement Grant is exercisable until November 2034 and vests for (i) one-fourth of the option shares on the one-year anniversary of the employee start date, and (ii) one thirty-sixth of the remaining option shares vest on the same day of each month thereafter until the Inducement Grant is 100% vested. The fair value of the Inducement Grant of $0.6 million was computed using the Black-Scholes-Merton ("BSM") option pricing model.

Equity Incentive Plans

Presented below is a summary of the number of shares authorized, outstanding, and available for future grants under the Company's equity incentive plans as of March 31, 2025:

	Number of Shares		
Description	**Authorized**	**Outstanding**	**Available**
2015 Plan	15,500	15,500	—
2016 Plan	122,900	122,900	—
2019 Plan	200,000	200,000	—
2021 Plan	14,096,589	12,653,971	1,442,618
Inducement Awards	1,500,000	425,000	1,075,000
Total	15,934,989	13,417,371	2,517,618

The Company currently has one active equity incentive plan approved by shareholders which is the 2021 Plan. On December 5, 2024, the Company's shareholders approved an amendment to the 2021 Plan, increasing the number of shares of common stock to be issued under the plan up to 14,450,000 shares of common stock, before accounting for any reductions due to exercises. The 2021 Plan terminates on March 31, 2030. Pursuant to the 2021 Plan, no awards may be granted under the three legacy equity incentive plans shown in the table above, but all outstanding awards previously granted under those plans shall remain outstanding and subject to the terms of the respective plans. Awards outstanding under these plans expire pursuant to their contractual provisions on various dates through 2035.

In addition, inducement awards are allowed for grants of options pursuant to Nasdaq Listing Rule 5635(c)(4) whereby the underlying shares are not authorized under any of the Company's equity incentive plans. Through March 31, 2025, the Board of Directors has granted inducement awards for a total of 425,000 shares. The Board of Directors also has discretion to issue an additional 1,075,000 shares for future inducement awards.

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 500,000 shares for purchases. There have been no offering periods under the 2022 ESPP through March 31, 2025.

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Stock Options Outstanding

For the nine months ended March 31, 2025, the following table sets forth a summary of the combined stock option activity under the Company's equity incentive plans and inducement awards:

	Shares	Price [1]	Term [2]
Outstanding, June 30, 2024	10,890,540	$ 3.82	8.1
Granted	2,541,300	4.65	
Exercised	(271,823)[3]	2.80	
Expired	(43,000)	14.39	
Forfeited	(488,146)	2.95	
Outstanding, March 31, 2025	12,628,871[4]	4.01	7.7
Vested, March 31, 2025	6,604,569[5]	4.61	6.9

(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.
(3) The total intrinsic value (the amount by which the fair market value exceeded the exercise price) of stock options exercised during the nine months ended March 31, 2025, was $0.5 million.
(4) As of March 31, 2025, the intrinsic value of outstanding options was approximately $4.2 million.
(5) As of March 31, 2025, the aggregate intrinsic value of vested stock options was approximately $1.6 million.

For the nine months ended March 31, 2025, the aggregate fair value of stock options granted for approximately 2.5 million shares of common stock amounted to $8.6 million or approximately $3.38 per share as of the grant dates. Fair value was computed using the BSM option-pricing model and will result in the recognition of compensation cost ratably over the expected vesting period of the stock options. Unrecognized share-based compensation expense related to outstanding options is approximately $14.5 million as of March 31, 2025. This amount is expected to be recognized over a weighted average period of 1.7 years.

For the nine months ended March 31, 2025, 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	$ 4.65
Expected volatility	84 %
Risk free interest rate	4.3 %
Expected term (years)	5.9
Dividend yield	0 %

Restricted Stock Units ("RSUs")

For the nine months ended March 31, 2025, the following table sets forth a summary of the combined RSU activity under the Company's 2021 Plan:

	Shares	Price [1]
Unvested, June 30, 2024	—	$ —
Granted	788,500	4.61
Vested	—	—
Forfeited	—	—
Unvested, March 31, 2025	788,500	4.61

(1) Represents the weighted average grant price based on the closing market price of each of the stock grants.

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For the nine months ended March 31, 2025, the aggregate fair value of RSUs granted for approximately 0.8 million shares of common stock amounted to $3.6 million. RSUs granted vest over a period of one to three years. Fair value is based on the closing market price on the date of grant and will result in the recognition of compensation cost ratably over the vesting period of the RSUs. Unrecognized share-based compensation expense related to RSUs is approximately $3.5 million as of March 31, 2025. This amount is expected to be recognized over a weighted average period of 2.6 years.

Share-Based Compensation Expense

Share-based compensation expense for the nine months ended March 31, 2025 and 2024 is included under the following captions in the unaudited condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2025	2024	2025	2024
Research and development	$ 924	$ 863	$ 2,357	$ 2,544
General and administrative	981	1,040	2,393	3,045
Total	$ 1,905	$ 1,903	$ 4,750	$ 5,589

The aggregate unrecognized share-based compensation expense related to stock options and RSUs is approximately $18.0 million as of March 31, 2025. This amount is expected to be recognized over a weighted average period of 1.8 years.

Pre-Funded Warrants

PFWs are outstanding for a total of approximately 9.5 million shares as of March 31, 2025. Please refer to Note 7 for additional information about outstanding PFWs.

Legacy 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 the holders are entitled to share in any dividends or distributions payable to holders of common stock on an as-converted basis ("the Participating Warrants"). Additionally, the Company has issued warrants in conjunction with various debt and equity financings and for services. As of March 31, 2025, all of the warrants were vested. The Participating Warrants and other warrants are collectively referred to as the "Legacy Warrants."

For the nine months ended March 31, 2025, no Legacy Warrants were granted or exercised. The following table sets forth a summary of all Legacy Warrants for the nine months ended March 31, 2025:

	Shares	Price [1]	Term [2]
Outstanding, June 30, 2024	860,562	$ 20.28	3.2
Expirations	(10,000)	52.00	
Outstanding, March 31, 2025	850,562	19.90	2.5

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

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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. 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*. As of March 31, 2025, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the Company's results of operations. 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 ersodetug 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 2024 Private Placement

Handok was an investor in the 2024 Private Placement discussed in Note 7 for which the Company issued 1,250,000 shares of common stock at a purchase price of $4.00 resulting in gross proceeds of $5.0 million of the total $6.0 million gross proceeds.

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 nine months ended March 31, 2025 and 2024, 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 nine months ended March 31, 2025 and 2024.

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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 outstanding shares of common stock and PFWs during periods when the PFWs are accounted for as equity instruments. Common shares associated with PFWs that are accounted for as equity instruments 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 for basic and diluted net loss per share is computed as follows:

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2025	2024	2025	2024
Common Stock	60,536,988	39,910,160	58,229,644	38,722,544
2021 PFWs	123,000	1,323,338	123,000	1,549,573
2022 PFWs	5,621,053	9,578,834	6,828,891	10,939,447
Exchange PFWs	—	—	970,030	—
2024 PFWs	3,750,000	—	3,750,000	—
Total	70,031,041	50,812,332	69,901,565	51,211,564

For the three and nine months ended March 31, 2025 and 2024, basic and diluted net loss per share were the same since all other common stock equivalents were anti-dilutive. As of March 31, 2025 and 2024, 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:

	2025	2024
Stock options	12,628,871	10,907,747
RSUs	788,500	—
Exchange Warrants	—	3,000,000
Legacy Warrants	850,562	860,562
Total	14,267,933	14,768,309

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.

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The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicates the fair value hierarchy classification as of March 31, 2025 and June 30, 2024 (in thousands):

	Fair Value Measurement of Assets as of March 31, 2025			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents:				
Money market funds	$ 7,695	$ 7,695	$ —	$ —
Corporate commercial paper	3,496	—	3,496	—
Marketable debt securities:				
Corporate commercial paper	18,456	—	18,456	—
U.S. Government agencies	4,943	—	4,943	—
U.S. Government treasuries	—	—	—	—
Corporate notes and bonds	50,411	—	50,411	—
Total	$ 85,001	$ 7,695	$ 77,306	$ —

	Fair Value Measurement of Assets as of June 30, 2024			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents:				
Money market funds	$ 61,249	$ 61,249	$ —	$ —
Marketable debt securities:				
Corporate commercial paper	20,929	—	20,929	—
U.S. Government agencies	1,997	—	1,997	—
U.S. Government treasuries	2,720	—	2,720	—
Corporate notes and bonds	30,832	—	30,832	—
Asset-backed securities	263	—	263	—
Total	$ 117,990	$ 61,249	$ 56,741	$ —

Marketable debt securities classified as Level 2 within the valuation hierarchy generally consist of corporate bonds, commercial paper, and U.S. government agency securities. 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 March 31, 2025 and June 30, 2024.

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 warrant derivative liability discussed in Note 7 was classified under Level 2 of the fair value hierarchy. Fair value of the warrant derivative liability is predominantly based on the market price of the Company's shares of common stock. On the issuance date and as of March 31, 2024, the fair value of the Exchange PFWs was computed using the BSM option-pricing model. Key inputs to this valuation model as of March 31, 2024 included the exercise price of $0.001 per share, the market price of the Company's common stock of $2.55 per share, the risk-free interest rate of 4.1%, an expected term of 1-day, and historical volatility of 100%. Key inputs to this valuation model as of March 8, 2024 included the exercise price of $0.001 per share, the market price of the Company's common stock of $1.90 per share, the risk-free interest rate of 5.5%, an expected term of 1-day, and historical volatility of 100%.

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The following table sets forth changes in the fair value of the Company's liabilities for which fair value was determined on a recurring basis for the nine months ended March 31, 2025 and 2024 (in thousands):

	2025		2024	
	Warrant	Embedded	Warrant	Embedded
Fair value, beginning of period	$ —	$ 468	$ —	$ 412
Warrant liability incurred on March 8, 2024	—	—	5,697	—
Changes in fair value	—	15	1,950	41
Fair value, end of period	$ —	$ 483	$ 7,647	$ 453

Except for the embedded derivative liability, the Company did not have any other liabilities measured at fair value on a recurring basis as of March 31, 2025 and June 30, 2024.

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 March 31, 2025 and June 30, 2024.

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 nine months ended March 31, 2025 and 2024, 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 nine months ended March 31, 2025 and 2024, cash deposits have exceeded the amount of insurance provided on such deposits by the Federal Deposit Insurance Corporation.

As of March 31, 2025, the Company had an aggregate of $45.2 million invested in the debt securities of issuers in the banking and financial services industries. 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

2025 Underwritten Offering

On April 23, 2025, the Company entered into an underwriting agreement with Guggenheim Securities, LLC (the "2025 Underwriter") for the planned issuance and sale of equity securities in an underwritten public offering (the "2025 Underwritten Offering"). The 2025 Underwritten Offering resulted in the issuance of (i) 20,786,923 shares of common stock at a price of $3.25 per share for gross proceeds of approximately $67.6 million, (ii) 4,153,846 shares of its common stock pursuant to a 30-day option, which was fully exercised during closing, at a public offering price of $3.25 per share pursuant of $3.25 per share (the "2025 Underwriters' Option") for gross proceeds of $13.5 million, and (iii) pre-funded warrants to purchase 6,905,385 shares of common stock at a public offering price of $3.249 per pre-funded warrant (the "2025 PFWs") for gross proceeds of approximately $22.4 million. Closing occurred on April 24, 2025, whereby the aggregate gross proceeds from the 2025 Underwritten Offering amounted to approximately $103.5 million before deductions for underwriting commissions of 6.0% of the gross proceeds and other offering costs of approximately $0.4 million. After deducting total offering costs of approximately $6.6 million, the net proceeds of the 2025 Underwritten Offering amounted to approximately $96.9 million.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

The 2025 PFWs do not entitle the holders thereof to any voting rights or any of the other rights or privileges to which holders of Common Stock are entitled. The 2025 PFWs have an exercise price of $0.001 per share, which is subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting holders of common stock. In the event of certain fundamental corporate transactions, the holders of the PFWs are entitled to receive the kind and amount of securities, cash or other property that the holders would have received had they exercised the PFWs immediately prior to such transaction. The 2025 PFWs are fully vested and exercisable at any time, subject to the then effective OBP as elected by each of the holders of 2025 PFWs. The OBP is a percentage designated by the holders whereby the 2025 PFWs cannot be exercised if, after giving effect thereto, the holder would beneficially own more than the designated OBP. However, upon at least 61 days' prior notice to the Company, any holder of PFWs may elect to increase or decrease the OBP to any other percentage not to exceed 19.99%. Assuming the holders comply with the respective OBP terms, all of the PFWs may be exercised at any time by paying the respective exercise price or electing to exercise on a cashless basis. Management has not completed its analysis to determine if the 2025 PFWs will meet the requirements to be classified in shareholders' equity.

Subject to certain exceptions, the Company's executive officers and directors and certain of the Company's stockholders agreed not to sell or otherwise dispose of any of the shares of Common Stock held by them for a period beginning on the date of execution of the applicable lock-up agreements by each such executive officer, director and stockholder and ending on July 22, 2025 without first obtaining the written consent of the Underwriter.

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, Inc. ("Rezolute", the "Company", "we" or "us") is a late-stage rare disease company focused on significantly improving outcomes for individuals with hypoglycemia caused by hyperinsulinism ("HI").

Our priority in the first half of 2025 is to execute across our two Phase 3 clinical trials. Our goals include (i) complete enrollment of the sunRIZE study (as defined below) to enable topline data in December 2025, and (ii) advance study start-up activities and begin enrollment for the registrational tumor HI study in mid-2025.

Ersodetug for congenital hyperinsulinism (cHI)

Based on the multinational Phase 2b clinical trial ("RIZE") outcomes and the evidence of benefit in this serious condition with substantial unmet medical need, ersodetug was granted Breakthrough Therapy Designation by the Food and Drug Administration ("FDA") in the U.S.

sunRIZE Phase 3 Study

We are actively enrolling a pivotal Phase 3 clinical study (the "sunRIZE" study) of ersodetug for the treatment of hypoglycemia in participants with congenital HI, an ultra-rare pediatric genetic disorder characterized by excessive production of insulin by the pancreas. If untreated, the elevated insulin levels in patients suffering with congenital HI can induce extreme hypoglycemia (low blood sugar) events, increasing the risk of neurological and developmental complications, including persistent feeding problems, learning disabilities, recurrent seizures, brain damage or even death.

The sunRIZE study is a global, randomized, double-blind, placebo-controlled, parallel arm evaluation of ersodetug in participants 3 months of age and older with congenital HI who are not adequately responding to standard of care medical therapies. Specifically, the study is evaluating the safety and efficacy of ersodetug in participants who are unable to achieve control of low blood sugars ("hypoglycemia" [<70 mg/dL]). The study will determine the ability of ersodetug to correct hypoglycemia as assessed by (i) hypoglycemia events using self-monitored blood glucose ("SMBG") and (ii) time in hypoglycemia using continuous glucose monitoring ("CGM") over 24 weeks of treatment.

We are currently enrolling at all sites globally, including the U.S. Topline results from the study are anticipated to be available in December of calendar 2025, but the specific date of the availability of such results may vary.

On April 23, 2025, we announced a positive outcome from an interim analysis of the sunRIZE study. An independent Data Monitoring Committee (DMC) recommended to continue the study as planned in patients with congenital HI without an increase in the study sample size. We remain blinded to the results and information made available to the DMC to inform its decision making.

The interim analysis of the Phase 3 sunRIZE study was performed by an unblinded DMC and was based on a pre-specified analysis of the primary study endpoint (hypoglycemia events), after approximately half of enrolled patients completed the primary assessments. The analysis was intended to evaluate for study futility or otherwise to inform a potential sample size increase, for purposes of optimizing the study power and statistical confidence in the final analysis outcomes.

Congenital HI is the most common cause of recurrent and persistent hypoglycemia in children. Individuals with congenital HI typically present with signs or symptoms of hypoglycemia shortly after birth. Hypoglycemia 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 that are unresponsive to medical management, surgical removal of the pancreas may be required. In those with diffuse disease where the whole pancreas is affected, a near-total pancreatectomy can be undertaken, although ongoing medical treatment of hypoglycemia is generally required for several years after surgery, before eventual insulin-dependent diabetes ensues. There are no FDA approved therapies for all forms of congenital HI and the current standard of care treatments are suboptimal. The current treatments used by physicians include glucagon, diazoxide, somatostatin analogues and pancreatectomy. We estimate that in the U.S. alone the addressable market for congenital HI is more than 1,500 individuals.

Ersodetug has received Orphan Drug Designation in the U.S. and European Union for the treatment of congenital HI, as well as Rare Pediatric Disease Designation in the U.S., a prerequisite for a request for a Rare Pediatric Disease Priority Review Voucher upon Biologics License Application ("BLA") submission. Based on the multinational Phase 2b clinical trial outcomes and the evidence of benefit in this serious condition with substantial unmet medical need, ersodetug was subsequently granted a priority medicines ("PRIME") designation by the European Medicines Agency ("EMA"), an Innovation Passport designation by the UK Innovative Licensing and Access Pathway ("ILAP") Steering Group for the treatment of congenital HI, and the Breakthrough Therapy Designation by the FDA in the United States. Additionally, ersodetug has received PRIME and ILAP designations in the European Union and United Kingdom, respectively.

Ersodetug for tumor hyperinsulinism (tHI)

Based on clinical trial data across the overall HI program and a recognition of the mechanistic applicability to tumor HI, further validated by real-world experience in tumor HI patients who have been successfully treated with ersodetug throughout the U.S. in the Company's Expanded Access Program, ersodetug was granted Breakthrough Therapy Designation by the FDA in the U.S. in May 2025. Utilizing this designation, we plan to engage further with FDA to discuss the registrational trial, including the necessary data package to support a BLA filing and potential approval for the tumor HI indication, as an expansion of the congenital HI indication.

Registrational Study

We are initiating start-up activities for a registrational study of ersodetug for the treatment of hypoglycemia due to tumor HI, and patient enrollment is planned to commence in the middle of calendar 2025. Topline results from the study are anticipated to be available in the second half of calendar 2026, but the specific date of the availability of such results may vary.

The registrational study is a double-blind, randomized, placebo-controlled trial of 24 participants who have inadequately controlled hypoglycemia because of tumor HI. Eligible participants will be randomized in 1:1 fashion (12 per treatment arm) to receive ersodetug 9 mg/kg per week or matched placebo, as an add-on to standard of care. Up to 24 additional participants may be enrolled into an open-label arm, in participants whose hypoglycemia is being managed by IV glucose in a hospital setting. Following an 8-week pivotal treatment period, all participants may receive ersodetug in open-label extension. The primary endpoint is the change in Level 2 (moderate) and Level 3 (severe) hypoglycemia events by self-monitored blood glucose. Additional endpoints include overall hypoglycemia events, time in hypoglycemia by continuous glucose monitor, patient reported quality of life, hospitalizations, and change in glucose requirements for open-label hospitalized participants.

Utilizing Breakthrough Therapy Designation, we plan to engage further with FDA to discuss the registrational trial, including the necessary data package to support a BLA filing and potential approval for the tumor HI indication, as an expansion of the congenital HI indication.

Tumor HI may be caused by two distinct types of tumors: neuroendocrine islet cell tumors ("ICTs") and non-islet cell tumors ("NICTs"), both of which lead to hypoglycemia due to excessive activation of the insulin receptor. Insulinomas are the most common type of functional ICT and mediate hypoglycemia through excessive insulin production. NICTs are generally associated with relatively large, solid tumors such as hepatocellular carcinoma, fibrosarcoma and mesothelioma, and can cause hypoglycemia by producing and secreting insulin-like paraneoplastic substances such as IGF-2 or related variants that bind to and activate the insulin receptor. This form of hypoglycemia can occur in more than 15 different tumor types.

Current therapies for insulinomas and NICTs can be grouped into two main categories: (a) tumor-directed de-bulking therapies (e.g. surgery, chemotherapy, radiotherapy), which may indirectly and/or eventually lead to decreased levels of circulating insulin and/or insulin-like substances, and therefore control HI and related hypoglycemia; and/or (b) medical therapies such as glucocorticoids that are used to attempt to treat the hypoglycemia. Tumor-directed therapies do not directly treat hypoglycemia caused by insulinomas or NICTs.

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, non-pancreatic insulinomas, or NICT hypoglycemia resulting from a variety of other tumors.

A significant unmet need exists for treatment options with improved efficacy and tolerability as normalization of glucose levels is crucial to prevent serious signs and symptoms of hypoglycemia, improve patient quality of life and overall function, and even 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 tumor HI 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 tumor HI.

While we believe the total addressable market may be larger, the immediately addressable market for the combined indications causing tumor HI is estimated to be approximately 1,500 patients in the U.S. alone, including approximately 500 with islet cell tumor hypoglycemia (“ICTH”) and approximately 1,000 with non-islet cell tumor hypoglycemia (“NICTH”).

Expanded Access Program (“EAP”)

We maintain an EAP for a variety of HI indications for the purpose of making ersodetug available on a compassionate use basis when available therapeutic options have failed, and an individual’s hypoglycemia is unmanageable. In clinical and real-world experience, ersodetug has been shown to counteract excessive insulin action downstream, at the insulin-receptor on target organs. The unique mechanism of action of ersodetug makes the therapy a potential universal treatment for any form of HI. To date, we have received over 25 unsolicited inbound physician inquiries regarding the use of ersodetug in patients with tumor HI caused by metastatic insulinomas or non-islet cell tumors, which has thus far resulted in the request, approval, and initiation of ersodetug in nine patients with tumor HI. In the U.S., these requests have all been individually approved by the Division. The tumor HI patients dosed have been refractory to the standard of care therapies for chronic management of hypoglycemia. They generally required continuous intravenous dextrose or nutritional infusion in order to prevent severe hypoglycemia, and were typically hospitalized and in life-threatening or hospice-bound condition at the time of request. Further treatment with tumor-directed therapies (e.g., embolization, radiotherapy, chemotherapy) was often deferred as a result of the debilitating hypoglycemia.

Generally, dosing for tumor HI patients has been either 6 mg/kg or 9 mg/kg every 1-4 weeks. In all cases to date, ersodetug has led to substantial improvement in hypoglycemia and has been well tolerated. Within a relatively short period of time after administration of ersodetug, continuous intravenous dextrose was discontinued or substantially reduced and hospitalized patients were able to be discharged and receive maintenance ersodetug doses on an outpatient basis, with durable benefit. In several cases, other background medical therapies to prevent hypoglycemia were able to be weaned or stopped, and patients were able to resume tumor-directed therapies for treatment of their underlying cancer. No participants have discontinued the therapy due to lack of response or safety, and the duration of treatment has ranged from several months to more than 1 year in several instances, in this subset of tumor HI patients with significantly advanced and metastatic tumor burden. Presently, 3 patients are receiving ersodetug in an ongoing fashion, including one patient who has been successfully treated for more than one year, and several other patients have recently been brought to our attention and are currently under consideration for possible treatment.

Four patients with cHI are currently receiving ersodetug as part of our EAP, which has served to support patients on a compassionate use basis prior to availability of the Phase 3 sunRIZE clinical trial. These participants were refractory to usual therapies and include one infant patient where off-label or surgical (pancreatectomy) therapies were being considered. The duration of treatment in these participants ranges from 1 year to approximately 3 years, with ongoing benefit.

Recent Developments

2025 Underwritten Offering

On April 23, 2025, we entered into an underwriting agreement for the planned issuance and sale of equity securities in an underwritten public offering (the "2025 Underwritten Offering"). The 2025 Underwritten Offering resulted in the issuance of (i) 20,786,923 shares of common stock at a price of $3.25 per share for gross proceeds of $67.6 million, and (ii) pre-funded warrants to purchase 6,905,385 shares of common stock at a public offering price of $3.249 per pre-funded warrant (the "2025 PFWs") for gross proceeds of $22.4 million. The Company granted the underwriters a 30-day option to purchase up to an additional 4,153,846 shares of its common stock at a public offering price of $3.25 per share. The underwriters' option was fully exercised for all 4,153,846 shares of common stock for gross proceeds of $13.5 million. Closing occurred on April 24, 2025, whereby the aggregate gross proceeds amounted to $103.5 million. The net proceeds of the 2025 Underwritten Offering amounted to approximately $96.9 million, after deducting underwriting commissions and other offering costs.

2024 Underwritten Offering

On June 13, 2024, we entered into an underwriting agreement for the planned issuance and sale of equity securities in an underwritten public offering (the "2024 Underwritten Offering"). The 2024 Underwritten Offering provided for the issuance of (i) 11,250,000 shares of common stock at a price of $4.00 per share for gross proceeds of $45.0 million, and (ii) pre-funded warrants to purchase 3,750,000 shares of common stock at a public offering price of $3.999 per pre-funded warrant (the "2024 PFWs") for gross proceeds of $15.0 million. The Company granted the underwriters a 30-day option to purchase up to an additional 2,250,000 shares of its common stock at a public offering price of $4.00 per share. The underwriters' option was partially exercised for 1,786,589 shares of common stock for gross proceeds of $7.1 million. Closing occurred on June 24, 2024, whereby the aggregate gross proceeds amounted to $67.1 million. The net proceeds of the 2024 Underwritten Offering amounted to approximately $62.6 million, after deducting underwriting commissions and other offering costs. In July 2024, we utilized approximately $59.7 million of net proceeds from the 2024 Underwritten Offering to purchase investments in marketable debt securities with maturities that range from October 2024 through December 2025.

2024 Private Placement

In June 2024, we entered into a securities purchase agreement (the "2024 SPA") with Handok, Inc. and one other investor relating to a private placement (the "2024 Private Placement"), pursuant to which we agreed to sell 1,500,000 shares of common stock at a purchase price of $4.00 per share. Closing of the 2024 Private Placement occurred in July 2024, whereby we received proceeds of $6.0 million.

Exchange PFW Exercises

On July 23, 2024, an investor from our March 2024 Exchange Agreement provided notice of cashless exercise of their Exchange PFWs. We issued 610,273 shares of our common stock on July 24, 2024, and we did not receive any cash proceeds from this exercise. In October 2024, all the remaining holders of Exchange PFWs provided notice of cashless exercise of their PFWs. This resulted in the issuance of 2,389,111 shares of our common stock in October 2024. We did not receive any cash proceeds from this exercise.

Class B PFW Exercise

On November 6, 2024, 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 2,525,883 shares of our common stock in November 2024 and we did not receive any cash proceeds from this 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, and realized gains on investments in marketable debt securities.

Loss from change in fair value of derivative liabilities. 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 2024 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 share-based awards based on the fair value of the award as of the grant date. We compute the fair value of the equity awards 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, all unrecognized compensation is immediately recognized in the period the options are cancelled.

Results of Operations

Revenue. As a late-stage rare disease company, we did not generate any revenue for the three and nine months ended March 31, 2025 and 2024. We are at a late stage of clinical 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.

Three months ended March 31, 2025 and 2024

Research and development expenses. R&D expenses for the three months ended March 31, 2025 and 2024 were as follows (in thousands, except percentages):

	March 31,		Increase	
	2025	2024	Amount	Percent
Total R&D expenses	$ 15,283	$ 12,401	$ 2,882	23 %

The increase in R&D expenses of $2.9 million for the three months ended March 31, 2025 was primarily attributable to (i) a $3.5 million increase in ersodetug R&D costs, and (ii) a $1.0 million increase in R&D headcount costs, partially offset by a decrease of $1.7 million in RZ402 and other R&D related costs.

The increase in ersodetug R&D costs was driven by (i) $1.9 million of manufacturing related costs for process performance qualification batch production of drug product, (ii) $1.0 million in clinical costs due to startup activities in 2024 for the tumor HI phase 3 study which we are in preparation for first patient enrollment anticipated in the second quarter of calendar 2025, and (iii) a $0.9 million increase in clinical trial costs due to the ongoing enrollment of patients in the cHI phase 3 clinical study. These increases amount to $3.8 million and were partially offset by a $0.3 million decrease in preclinical, toxicology and other ersodetug costs after the partial clinical hold on the sunRIZE study was lifted by the FDA in September 2024, requiring no further toxicology studies for that specific purpose. For the three months ended March 31, 2024, there were no clinical costs incurred for tumor HI related program spend as this study had yet to be initiated and there were fewer clinical costs for cHI as we had not enrolled any patients in the sunRIZE study as of March 31, 2024.

The increase in R&D facilities and headcount related costs of $1.0 million was driven by (i) $0.7 million increase in R&D compensation costs attributable to an increase in the average number of R&D employees from 39 for the three months ended March 31, 2024 to 48 employees for the three months ended March 31, 2025 and (ii) increase in R&D facilities costs to support the increased headcount.

RZ402 costs decreased by $1.7 million for the three months ended March 31, 2025 compared to the three months ended March 31, 2024. This decrease was due to a $1.7 million reduction in RZ402 clinical costs as we completed the Phase 2 study in the prior year and are actively in discussion with potential partners to continue clinical development leading to minimal program costs in the current period.

General and administrative expenses. G&A expenses for the three months ended March 31, 2025 and 2024 were as follows (in thousands, except percentages):

	March 31,		Increase	
	2025	2024	Amount	Percent
Total G&A expenses	$ 4,740	$ 3,812	$ 928	24 %

The increase in G&A expenses of $0.9 million for the three months ended March 31, 2025, was primarily attributable to an increase of $0.5 million in compensation and benefits for our G&A workforce, and an increase in consulting expenses of $0.4 million related to business development and market planning activities in preparation for future ersodetug commercial activities, such as market research.

The $0.5 million increase in G&A cash compensation was primarily attributable to an increase in the average number of G&A employees from 16 for the three months ended March 31, 2024, to 20 employees for the three months ended March 31, 2025.

Interest and other income. Interest and other income amounted to $1.1 million for the three months ended March 31, 2025 and 2024. Interest and other income received is primarily from our investments in marketable debt securities.

Change in fair value of derivative liabilities. For the three months ended March 31, 2025, there were no warrant liabilities recognized. For the three months ended March 31, 2024, we recognized an expense of approximately $2.0 million, primarily due to the increase of $0.65 per share in our stock price, resulting in changes in the fair value of the warrant derivative liability related to the Exchange PFWs issued on March 8, 2024.

Income taxes. For the three months ended March 31, 2025 and 2024, 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 income tax assets.

Nine months ended March 31, 2025 and 2024

Research and development expenses. R&D expenses for the nine months ended March 31, 2025 and 2024 were as follows (in thousands, except percentages):

	March 31,		Increase	
	2025	2024	Amount	Percent
Total R&D expenses	$ 40,664	$ 36,654	$ 4,010	11 %

The increase in R&D expenses of $4.0 million for the nine months ended March 31, 2025 was primarily attributable to (i) an increase of $8.2 million related to ersodetug R&D costs and (ii) an increase of $1.5 million in other R&D costs. These increases amount to $9.7 million and were partially offset by a $5.7 million decrease in costs related to RZ402 program spend as there are no active RZ402 studies in the current period while we are actively seeking a partner to continue development of this program.

The net increase in ersodetug costs of $8.2 million was attributable to (i) $6.3 million of manufacturing related costs for process performance qualification batch production of drug product, which will also continue support both phase 3 studies and EAPs, (ii) $1.8 million of clinical related costs incurred for the tumor HI phase 3 study for which startup activities were initiated in August 2024 after clearance of our IND application and anticipating enrollment of the first patient in the study in the second quarter of calendar 2025 and (iii) $0.9 million of costs for the sunRIZE clinical trial which did not enroll its first patient until April 2024, and we are tracking to complete enrollment in the study in May 2025. These increases amount to $9.0 million and were partially offset by a $0.8 million decrease in preclinical, toxicology and other ersodetug costs that were no longer required to support our efforts to remove the partial clinical hold on the sunRIZE study, which was lifted by the FDA in September 2024.

Other R&D preclinical, toxicology and facilities costs increased by $1.5 million due to an increase in R&D employee compensation and employee related costs. The increase in R&D employee compensation and related costs was attributable to an increase in the average number of R&D employees from 42 for the nine months ended March 31, 2024 to 48 employees for the nine months ended March 31, 2025.

General and administrative expenses. G&A expenses for the nine months ended March 31, 2025 and 2024 were as follows (in thousands, except percentages):

	March 31,		Increase	
	2025	2024	Amount	Percent
Total G&A expenses	$ 13,380	$ 10,667	$ 2,713	25 %

The increase in G&A expenses of $2.7 million for the nine months ended March 31, 2025, was primarily attributable to (i) an increase in consulting expenses of $1.5 million related to business development, market planning activities for ersodetug and other professional service fees, and (ii) an increase of $1.2 million in compensation and benefits for our G&A workforce.

Cash-based compensation and benefits for our G&A workforce increased by approximately $1.9 million and was partially offset by a reduction of share-based compensation of $0.7 million. This $1.9 million increase in cash-based compensation was primarily attributable to an increase in the average number of G&A employees from 14 for the nine months ended March 31, 2024, to 18 employees for the nine months ended March 31, 2025. Share-based compensation for our G&A workforce decreased by $0.7 million from $3.1 million for the nine months ended March 31, 2024 to $2.4 million for the nine months ended March 31, 2025. This decrease in share-based compensation expense was primarily attributable to stock options that became fully vested during the fiscal year ended June 30, 2024.

Interest and other income. Interest and other income amounted to $4.0 million for the nine months ended March 31, 2025, compared to $3.8 million for the nine months ended March 31, 2024. This increase of $0.2 million was primarily due to an increase in the average

value of money market funds and investments in marketable debt securities from $79.1 million at March 31, 2024 to $85.0 million as of March 31, 2025. Investment balances were higher due to proceeds from the 2024 Underwritten Offering and 2024 Private Placement, offset by investment maturities that were utilized to fund operating activities. Investments in marketable debt securities are our primary source of liquidity to fund clinical expenditures and other operating expenses.

Change in fair value of derivative liabilities. For the nine months ended March 31, 2025, there were no warrant liabilities recognized. For the nine months ended March 31, 2024, we recognized an expense of approximately $2.0 million, primarily due to the increase of $0.65 per share in our stock price, resulting in changes in the fair value of the warrant derivative liability related to the Exchange PFWs issued on March 8, 2024.

Income taxes. For the nine months ended March 31, 2025 and 2024, 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 March 31, 2025, we had cash and cash equivalents of $14.6 million, short-term marketable debt securities of $72.3 million and working capital was approximately $78.2 million. We have incurred cumulative net losses of $379.5 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 placements and public offerings of our equity securities, as well as proceeds from the issuance of debt securities. For the nine months ended March 31, 2025, we received proceeds of $6.0 million related to a private placement of 1.5 million shares of common stock. Additionally, in April 2025 we completed the 2025 Underwritten Offering that resulted in net proceeds of $96.9 million from the issuance of 24.9 million shares of common stock and pre-funded warrants to purchase 6.9 million shares of common stock. For further information about the key terms and results of our recent equity financing activities please refer to the discussion above under the caption Recent Developments. The completion of equity financings between May 2022 and July 2024 is the primary source of our total cash, cash equivalents and short-term investments in marketable debt securities of $86.9 million as of March 31, 2025.

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 March 31, 2026 include approximately (i) $0.8 million under all of our operating lease agreements, (ii) a milestone payment to XOMA of $5.0 million due upon dosing of the last patient in any of our Phase 3 clinical trials for ersodetug. Due to uncertainties in the estimated timing associated with clinical trial activities, it is possible that the milestone payment due upon dosing of the last patient could be delayed beyond March 31, 2026.

Based on our cash and cash equivalents balance of $14.6 million and investments in short-term marketable debt securities balance of $72.3 million as of March 31, 2025, combined with the net proceeds of $96.9 million received in the 2025 Underwritten Offering, 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 $30.0 million payable to XOMA and additional milestone payments up to $25.0 million payable to ActiveSite. Of these amounts, we expect that $5.0 million will be payable to XOMA during the 12-month period ending March 31, 2026 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 ersodetug and RZ402 we will be obligated to pay additional milestone payments and alternative indication regulatory approval payments to XOMA and ActiveSite for an aggregate up to $202.5 million and royalties based on the net sales of the related products. 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 ersodetug or RZ402, in which case 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 of $0.8 million for each of the fiscal years ending June 30, 2026 and 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 into the second quarter of calendar year 2026.

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 given 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 shareholders.

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 March 31, 2025.

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 or RZ358, now ersodetug) 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 ersodetug 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. Milestone payments made to date include a $2.0 million payment in January 2022 for the enrollment of the last patient of the Phase 2 clinical study and $5.0 million paid in May 2024 related to the first patient enrollment in a Phase 3 study. We record a liability for milestone payments in our financial statements on the date that we achieve the milestone event. The next milestone payment of $5.0 million will be due upon the enrollment 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 ersodetug, 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 ersodetug exceed targets ranging from $100.0 million to $1.0 billion. Through March 31, 2025, 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 March 31, 2025, 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 nine months ended March 31, 2025 and 2024 (in thousands):

	2025	2024	Change
Net cash provided by (used in):			
Operating activities	$ (47,080)	$ (38,846)	$ (8,234)
Investing activities	(14,887)	29,036	(43,923)
Financing activities	6,167	(296)	6,463

Cash Used in Operating Activities

For the nine months ended March 31, 2025 and 2024, cash used in operating activities amounted to $47.1 million and $38.8 million, respectively. The key components in the calculation of our cash used in operating activities are as follows (in thousands):

	2025	2024	Change
Net loss	$ (50,022)	$ (45,483)	$ (4,539)
Non-cash expenses	5,183	8,008	(2,825)
Accretion of discounts and amortization of premiums on marketable debt securities, net	(2,059)	(2,100)	41
Changes in operating assets and liabilities, net	(182)	729	(911)
Total	$ (47,080)	$ (38,846)	$ (8,234)

For the nine months ended March 31, 2025, our net loss was $50.0 million compared to $45.5 million for the nine months ended March 31, 2024. For further discussion about changes in our operating results for the nine months ended March 31, 2025 and 2024, please refer to *Results of Operations* above.

For the nine months ended March 31, 2025 and 2024, our non-cash expenses of $5.2 million and $8.0 million, respectively, were primarily attributable to share-based compensation expense, loss in change of fair value of a warrant liabilities, and non-cash lease expense. For the nine months ended March 31, 2025 and 2024, accretion of discounts and amortization of premiums on marketable debt securities amounted to $2.1 million. For the nine months ended March 31, 2025, net changes in operating assets and liabilities decreased operating cash flow by $0.2 million, primarily driven by cash outflows resulting in a net increase in prepaid expense and other assets of $1.2 million. This amount was partially offset by a net increase of $1.0 million in accounts payable and other accrued liabilities. For the nine months ended March 31, 2024, net changes in operating assets and liabilities increased operating cash flow by $0.7 million, primarily driven by an increase of $1.3 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 $0.6 million.

Cash Provided by or Used in Investing Activities

For the nine months ended March 31, 2025, our net cash used in investing activities amounted to $14.9 million. For the nine months ended March 31, 2025, we received proceeds of $85.8 million upon the maturity of certain marketable debt securities. These cash proceeds from maturities, along with certain proceeds from the 2024 Underwritten Offering in June 2024 and the 2024 Private Placement in July 2024, were used to purchase a total of $100.7 million of marketable debt securities.

For the nine months ended March 31, 2024, our net cash provided by investing activities amounted to $29.0 million, primarily related to the maturity of marketable debt securities of $85.8 million partially offset by cash outflows of $56.7 million to reinvest in marketable debt securities.

Cash Provided by or Used in Financing Activities

For the nine months ended March 31, 2025, our net cash provided by financing activities was $6.2 million. Cash inflows amounted to $6.8 million consisting of proceeds of $6.0 million from the 2024 Private Placement and $0.8 million from the exercise of stock options. These amounts were partially offset by cash outflows related to the payment of offering costs of $0.6 million incurred in connection with the 2024 Underwritten Offering.

For the nine months ended March 31, 2024, 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.

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 Officer, 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 March 31, 2025.

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 Legacy Risk Factor Disclosures are set forth in (i) Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended June 30, 2024 filed with the Securities and Exchange Commission ("SEC") on September 19, 2024, and (ii) in Part II, Item 1A of our Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2024 filed with the SEC on February 12, 2025. As of the date of this Report, there have been no material changes with respect to the Legacy Risk Factor Disclosures except for the risk factor set forth below.

Clinical failure can occur at any stage of clinical development. Because the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we advance through clinical trials may not have favorable results in later clinical trials.

Clinical failure can occur at any stage of clinical development. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of pharmaceutical companies have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical testing.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including differences in trial protocols and design, the size and type of the patient population, adherence to the dosing regimen and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent and/or adequate efficacy and safety to obtain marketing approval for our product candidates.

On April 18, 2025, an independent data monitoring committee ("IDMC") conducted a non-binding, interim analysis of our sunRIZE study for the treatment of congenital HI and reported that the sunRIZE study should continue as planned without any adjustment to the sample size of the sunRIZE study. There can be no assurances that the observations made at the interim analysis will be consistent with the final study results for various reasons, including that the final study results based upon the full sample size may not be consistent with the results achieved by the limited sample size used to conduct the interim analysis and the current sample size of patients with active RMS patients for each trial may not be sufficiently large to demonstrate efficacy.

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
1.1	Underwriting Agreement, dated as of April 23, 2025, by and between the Company and Guggenheim Securities, LLC (incorporated by reference to Exhibit 1.1 of the Company's Form 8-K filed on April 23, 2025)
4.1	Form of Pre-funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K filed on April 23, 2025)
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: May 13, 2025

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: May 13, 2025

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 March 31, 2025, 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: May 13, 2025

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.