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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 September 30, 2026

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 96,728,913 shares of its $0.001 par value common stock outstanding as of November 2, 2026.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2026 (this "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 a favorable path forward with the U.S. Food and Drug Administration ("FDA" or the "Agency") for ersodetug in the potential treatment of tumor or congenital hyperinsulinism;
- our ability to obtain regulatory approvals for our therapeutics in development;
- our expectations regarding clinical development and the timeline to complete clinical studies;
- 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 Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended June 30, 2026 (the "2026 Form 10-K"), filed with the Securities and Exchange Commission ("SEC") on September 24, 2026.

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 Number of Shares and Par Value)

	September 30, 2026	June 30, 2026
Assets		
Current assets:		
Cash and cash equivalents	$ 8,150	$ 10,615
Investments in marketable debt securities	81,849	97,186
Prepaid expenses and other	3,834	2,710
Total current assets	93,833	110,511
Long-term assets:		
Deposits and other	1,528	1,528
Right-of-use assets	616	769
Property and equipment, net	33	41
Total assets	$ 96,010	$ 112,849
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,181	$ 5,026
Accrued liabilities:		
Accrued clinical and other	3,523	3,697
Compensation and benefits	3,116	2,037
Current portion of operating lease liabilities	643	658
Total current liabilities	9,463	11,418
Long-term liabilities:		
Embedded derivative liability	488	468
Operating lease liabilities, net of current portion	111	276
Total liabilities	10,062	12,162
Commitments and contingencies (Notes 5, 9 and 10)		
Shareholders' equity:		
Preferred stock, $0.001 par value per share; 400,000 shares authorized; no shares issued	—	—
Common stock, $0.001 par value per share; 165,000,000 shares authorized; issued and outstanding 96,722,333 and 96,405,982 shares as of September 30, 2026 and June 30, 2026, respectively	97	96
Additional paid-in capital	585,952	582,152
Accumulated other comprehensive loss	(172)	(119)
Accumulated deficit	(499,929)	(481,442)
Total shareholders' equity	85,948	100,687
Total liabilities and shareholders' equity	$ 96,010	$ 112,849

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 September 30,	
	2026	**2025**
Operating expenses:		
Research and development	$ 12,807	$ 13,149
General and administrative	6,578	6,668
Total operating expenses	19,385	19,817
Operating loss	(19,385)	(19,817)
Non-operating income (expense):		
Interest and other income, net	918	1,682
Loss from change in fair value of embedded derivative liability	(20)	(15)
Total non-operating income, net	898	1,667
Net loss	(18,487)	(18,150)
Other comprehensive income (loss):		
Net unrealized gain (loss) on marketable debt securities	(53)	56
Comprehensive loss	$ (18,540)	$ (18,094)
Net loss per common share:		
Basic and diluted	$ (0.18)	$ (0.18)
Weighted average shares outstanding:		
Basic and diluted	104,777,511	103,422,647

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

Rezolute, Inc.

Unaudited Condensed Consolidated Statements of Shareholders' Equity
Three Months Ended September 30, 2026 and 2025
(In Thousands, Except Number of Shares)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Three Months Ended September 30, 2026:						
Balances, June 30, 2026	96,405,982	$ 96	$ 582,152	$ (119)	$ (481,442)	$ 100,687
Issuance of common stock upon exercise of stock options	174,846	1	526	—	—	527
Issuance of common stock upon vesting of restricted stock units	141,505	—	—	—	—	—
Share-based compensation	—	—	3,274	—	—	3,274
Other comprehensive loss	—	—	—	(53)	—	(53)
Net loss	—	—	—	—	(18,487)	(18,487)
Balances, September 30, 2026	96,722,333	$ 97	$ 585,952	$ (172)	$ (499,929)	$ 85,948
Three Months Ended September 30, 2025:						
Balances, June 30, 2025	86,995,985	$ 87	$ 565,903	$ (7)	$ (403,856)	$ 162,127
Issuance of common stock upon exercise of stock options	255,907	—	604	—	—	604
Share-based compensation	—	—	2,531	—	—	2,531
Cashless exercise of pre-funded warrants	3,784,808	4	(4)	—	—	—
Other comprehensive income	—	—	—	56	—	56
Net loss	—	—	—	—	(18,150)	(18,150)
Balances, September 30, 2025	91,036,700	$ 91	$ 569,034	$ 49	$ (422,006)	$ 147,168

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

Rezolute, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows
(In Thousands)

	Three Months Ended September 30,	
	2026	**2025**
Cash Flows From Operating Activities:		
Net loss	$ (18,487)	$ (18,150)
Share-based compensation expense	3,274	2,531
Non-cash lease expense	153	140
Loss from change in fair value of embedded derivative liability	20	15
Depreciation expense	8	8
Accretion of discounts and amortization of premiums on marketable debt securities, net	(483)	(799)
Changes in operating assets and liabilities:		
Prepaid expenses, deposits, and other assets	(1,148)	673
Accounts payable	(2,845)	(2,515)
Accrued liabilities	725	667
Net cash used in operating activities	(18,783)	(17,430)
Cash Flows From Investing Activities:		
Purchase of marketable debt securities	(20,131)	(88,890)
Proceeds from maturities of marketable debt securities	35,897	20,400
Net cash provided by (used in) investing activities	15,766	(68,490)
Cash Flows From Financing Activities:		
Proceeds from exercise of stock options	552	946
Payment of offering costs	—	(35)
Net cash provided by financing activities	552	911
Net change in cash and cash equivalents	(2,465)	(85,009)
Cash and cash equivalents at beginning of period	10,615	94,107
Cash and cash equivalents at end of period	$ 8,150	$ 9,098
Supplementary Cash Flow Information:		
Cash paid for amounts included in the measurement of operating lease liabilities	$ 195	$ 189
Cash paid for interest	—	—
Cash paid for income taxes	—	—
Non-Cash Financing Activities:		
Receivable from exercise of stock options	$ —	$ 161

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 developing therapies that treat refractory and debilitating hypoglycemia associated with various forms of hyperinsulinism ("HI"). The Company believes that its primary clinical asset, ersodetug, is a potential treatment for refractory hypoglycemia caused by multiple forms of hyperinsulinism, including congenital HI and tumor HI. The Company is fully enrolled in a Phase 3 clinical trial for a tumor HI indication ("upLIFT") and topline data is expected in mid-December 2026. As announced on October 5, 2026, following a preliminary review of detailed data from the Phase 3 clinical trial of ersodetug for the treatment of hypoglycemia due to congenital HI ("sunRIZE"), the FDA recommended a pre-biologics license application meeting with the Company as a precursor to submitting a biologics license application ("BLA"). The Company expects to request a pre-BLA meeting with the Agency to take place during the first half of calendar year 2027.

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, 2026, has been derived from the Company's audited consolidated financial statements. The unaudited interim financial statements should be read in conjunction with the 2026 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, 2026.

The Company's Chief Executive Officer also serves as the Company's chief operating decision maker ("CODM") for purposes of allocating resources and assessing performance based on financial information of the Company. Since its inception, the Company has determined that its activities as a clinical stage biopharmaceutical company are classified as a single reportable operating segment.

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 months ended September 30, 2026, 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, 2027.

Consolidation

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

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

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, the 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.

Significant Accounting Policies

The Company's significant accounting policies are described in Note 1 to the financial statements in Item 8 of the 2026 Form 10-K.

Recently Adopted Accounting Standard

In September 2025, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2025-07, *Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606)* ("ASU 2025-07"). This update provides a derivative scope refinement and scope clarification for share-based noncash consideration from a customer in a revenue contract. Entities may apply the amendments prospectively to new contracts or retrospectively with a cumulative-effect adjustment. ASU 2025-07 is effective for annual periods beginning after December 15, 2026, with early adoption permitted. The Company early adopted the guidance in ASU 2025-07 effective July 1, 2026, and applied the guidance on a prospective basis. The adoption of ASU 2025-07 did not have a material impact on the unaudited condensed consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). ASU 2024-03 is intended to enhance disclosures by requiring public entities to disclose specified information about certain costs and expenses. The Company is required to adopt ASU 2024-03 in its annual financial statements for the fiscal year ending June 30, 2028, and for interim periods thereafter. The Company does not expect the adoption of ASU 2024-03 will have a material impact on its consolidated financial statements as the ASU only requires more detailed disclosures in the footnotes to the Company's consolidated financial statements.

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 consolidated financial statements upon adoption.

Note 2 — Liquidity

The Company is in the clinical stage and has not yet generated any revenues. For the three months ended September 30, 2026, the Company incurred a net loss of $18.5 million and net cash used in operating activities amounted to $18.8 million. For the fiscal year ended June 30, 2026, the Company incurred a net loss of $77.6 million and net cash used in operating activities amounted to $64.6 million. As of September 30, 2026, the Company had an accumulated deficit of $499.9 million, and the Company's capital resources consist of cash and cash equivalents of $8.2 million and short-term investments in marketable debt securities of $81.8 million.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

As of September 30, 2026, the Company has total liabilities of $10.1 million, including current liabilities of $9.5 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 Ersodetug License Agreement (as defined below), a $25.0 million milestone payment will be due upon regulatory approval of ersodetug by any regulatory authority. Due to uncertainties in the timing associated with regulatory approvals, the timing of the commitment to pay the $25.0 million for regulatory approval of ersodetug remains unknown.

Management believes the Company's cash and cash equivalents and investments in marketable debt securities will be adequate to meet the Company's contractual obligations and fund operations for at least 12 months from the issuance date of the unaudited condensed consolidated financial statements as of September 30, 2026.

Note 3 — Investments in Marketable Debt Securities

Investments in marketable debt securities are accounted for as available-for-sale investments at fair value. 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 September 30, 2026, investments in marketable debt securities with an aggregate fair value of $81.8 million are scheduled to mature during the 12-month period ending September 30, 2027. As of September 30, 2026, the Company did not hold any long-term investments in marketable debt securities.

During the three months ended September 30, 2026, marketable debt securities for $35.9 million matured and approximately $20.1 million was invested in additional marketable debt securities. The Company did not sell any marketable debt securities prior to the scheduled maturity dates for the three months ended September 30, 2026.

Accrued interest receivable on all marketable debt securities amounted to $0.3 million and $0.5 million as of September 30, 2026 and June 30, 2026, respectively. Accrued interest receivable is included in other current assets in the accompanying unaudited condensed consolidated balance sheets.

For the three months ended September 30, 2026, the Company did not recognize any allowance for credit losses or 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 September 30, 2026 and June 30, 2026 (in thousands):

	September 30, 2026			
		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
Corporate commercial paper	$ 43,077	$ —	$ (94)	$ 42,983
Corporate notes and bonds	36,691	—	(76)	36,615
U.S. Treasury obligations	2,253	—	(2)	2,251
Total	$ 82,021	$ —	$ (172)	$ 81,849

	June 30, 2026			
		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
Corporate commercial paper	$ 41,935	$ —	$ (57)	$ 41,878
Corporate notes and bonds	51,362	—	(60)	51,302
U.S. Treasury obligations	4,008	—	(2)	4,006
Total	$ 97,305	$ —	$ (119)	$ 97,186

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):

	September 30, 2026	June 30, 2026
Right-of-use assets	$ 616	$ 769
Operating lease liabilities:		
Current	$ 643	$ 658
Long-term	111	276
Total	$ 754	$ 934

For the three months ended September 30, 2026 and 2025, operating lease expense is included under the following captions in the accompanying unaudited condensed consolidated statements of operations and comprehensive loss (in thousands):

	2026	2025
Research and development	$ 118	$ 120
General and administrative	49	47
Total	$ 167	$ 167

As of September 30, 2026, the weighted average remaining lease term under operating leases was 1.0 years, and the weighted average discount rate used to determine the operating lease liabilities was 7.0%. Future cash payments under all operating lease agreements as of September 30, 2026 are as follows (in thousands):

Fiscal year ending June 30,	
2027	$ 555
2028	224
Total lease payments	779
Less imputed interest	(25)
Present value of operating lease liabilities	$ 754

Note 5 — License Agreements

Ersodetug License Agreement

In December 2017, the Company entered into a license agreement that has been subsequently amended ("Ersodetug License Agreement") with a wholly-owned subsidiary of XOMA Corporation ("XOMA"), pursuant to which XOMA granted an exclusive global license to the Company to develop and commercialize ersodetug for all indications. On July 14, 2026, XOMA was acquired by Ligand Pharmaceuticals Incorporated ("Ligand").

To date the Company has paid a total of $12.0 million in milestone payments pursuant to the Ersodetug License Agreement. The most recent milestone payment of $5.0 million became due in May 2025 upon dosing of the last patient in the Company's Phase 3 clinical trial for ersodetug and was paid in June 2025. The next milestone payment of $25.0 million will be due upon regulatory approval for ersodetug by any regulatory authority. After the final regulatory milestone, the Company will be required, upon the future commercialization of ersodetug, to pay royalties to Ligand based on the net sales of the related products and additional milestone payments up to $185.0 million related to annual net sales amounts. There have been no events that would result in any royalty payments

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

owed under the Ersodetug License Agreement to date. The Company records a liability for milestone payments under license agreements in the period that the milestone event is achieved.

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 initially focused on the development of RZ402 as a therapy for diabetic macular edema ("DME"). Following the completion of a Phase 2 clinical study for RZ402, the Company decided to pause the program to focus its resources on ersodetug. The Company is currently exploring the use of the PKI Portfolio to develop therapies for different indications. To date the Company has paid a total of $4.0 million in milestone payments to ActiveSite. The most recent milestone payment of $3.0 million was 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. Upon the achievement of certain clinical and regulatory events and various sales-based milestones and alternative indication regulatory approvals under the ActiveSite License Agreement the Company will be required to make up to $42.5 million in additional milestone payments to ActiveSite. The Company is also required to pay royalties equal to 2.0% of any net 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, 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 September 30, 2026 and June 30, 2026. 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.

Note 7 — Shareholders' Equity

Pre-Funded Warrants

Between October 2021 and April 2025, the Company issued fully vested pre-funded warrants ("PFWs"). As of September 30, 2026, 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.

The PFWs are exercisable at any time, subject to the then effective ownership blocker percentage ("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.

For the three months ended September 30, 2026, no PFWs were issued or exercised. As of September 30, 2026 and June 30, 2026, the Company had an aggregate of 8,174,438 PFWs that were outstanding as follows:

	2021 PFWs	2022 PFWs	2024 PFWs	2025 PFWs	Total
PFWs outstanding	123,000 (1)	3,421,053 (2)	1,875,000 (3)	2,755,385 (4)	8,174,438

(1) Issued in connection with an underwritten offering in October 2021 at an issuance price of $6.49 per share (the "2021 PFWs"). The exercise price of the 2021 PFWs is $0.01 per share.

(2) Issued in connection with a registered direct offering in May 2022 at an issuance price of $3.799 per warrant (the "2022 PFWs"). The exercise price of the 2022 PFWs is $0.001 per share.

(3) Issued in connection with an underwritten offering in June 2024 at an issuance price of $3.999 a share (the "2024 PFWs"). The exercise price of the 2024 PFWs is $0.001 per share.

(4) Issued in connection with an underwritten offering in April 2025 at an issuance price of $3.249 a share (the "2025 PFWs"). The exercise price of the 2025 PFWs is $0.001 per share.

Note 8 — Share-Based Compensation and Warrants

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 September 30, 2026:

	Number of Shares		
Description	Authorized	Outstanding	Available
2015 Plan	14,000	14,000	—
2016 Plan	115,200	115,200	—
2019 Plan	200,000	200,000	—
2021 Plan	19,877,201	13,454,574	6,422,627
Inducement Awards	1,500,000	705,000	795,000
Total	21,706,401	14,488,774 (1)	7,217,627

(1) Consists of approximately 12.5 million shares outstanding under stock option agreements and 2.0 million shares under restricted stock units.

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Notes to Unaudited Condensed Consolidated Financial Statements

The Company currently has one active stock option plan approved by shareholders which is the 2021 Plan. The 2021 Plan terminates on March 31, 2030. Pursuant to the 2021 Plan, no awards may be granted under the three legacy stock option 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. Stock options outstanding under the plans presented above expire pursuant to their contractual provisions on various dates through 2036.

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 stock option plans. Through September 30, 2026, the Board of Directors has authorized a total of 1,500,000 shares for inducement awards. The Board of Directors has discretion to issue 795,000 shares for future inducement awards as of September 30, 2026.

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 September 30, 2026.

Stock Options Outstanding

For the three months ended September 30, 2026, the following table summarizes the combined stock option activity under the Company's equity incentive plans and Inducement Awards:

	Shares	Price [1]	Term [2]
Outstanding, beginning of period	12,468,431	$ 4.73	6.9
Granted	210,000	4.59	
Exercised	(174,846)[3]	3.01	
Expired	(2,055)	10.16	
Forfeited	(39,336)	5.69	
Outstanding, end of period	12,462,194 [4]	4.74	6.7
Vested, end of period	9,484,599 [5]	4.42	6.1

(1) Represents the weighted average exercise price per share.
(2) Represents the weighted average remaining contractual term 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 three months ended September 30, 2026, was $0.3 million.
(4) As of September 30, 2026, the intrinsic value of outstanding stock options was approximately $9.6 million.
(5) As of September 30, 2026, the intrinsic value of vested stock options was approximately $8.3 million.

For the three months ended September 30, 2026, the aggregate fair value of stock options granted for approximately 0.2 million shares of common stock amounted to $0.7 million or approximately $3.52 per share as of the grant dates. Fair value of stock options was computed using the BSM option-pricing model and will result in the recognition of compensation expense ratably over the expected vesting period of the stock options. Unrecognized share-based compensation expense related to outstanding stock options is approximately $11.6 million as of September 30, 2026. This amount is expected to be recognized over a weighted average period of 2.1 years.

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Notes to Unaudited Condensed Consolidated Financial Statements

For the three months ended September 30, 2026, 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	$ 4.59
Expected volatility	90 %
Risk free interest rate	4.6 %
Expected term (years)	6.1
Dividend yield	0 %

Restricted Stock Units ("RSUs")

For the three months ended September 30, 2026, the following table summarizes the combined RSU activity under the Company's 2021 Plan:

	Shares	Price [1]
Unvested, beginning of period	2,230,335	$ 8.46
Granted	—	—
Vested	(141,505)[2]	4.52
Forfeited	(62,250)	7.16
Unvested, end of period	2,026,580	8.78

(1) Represents the weighted average fair value per share based on the closing market price of the Company's common stock on the grant date of the respective RSUs.

(2) Based on the closing market price of the Company's common stock on the respective vesting dates, the aggregate fair value for the RSUs that vested during the three months ended September 30, 2026, amounts to $0.7 million or approximately $4.87 per share.

There were no grants of RSUs during the three months ended September 30, 2026. RSUs vest over a period of one to four years. Fair value is based on the closing market price on the date of grant and will result in the recognition of compensation cost on a straight-line basis over the vesting period of the RSUs. Unrecognized share-based compensation expense related to RSUs is approximately $12.3 million as of September 30, 2026. This amount is expected to be recognized over a weighted average period of 1.9 years.

Share-Based Compensation Expense

Share-based compensation expense for the three months ended September 30, 2026 and 2025 is included under the following captions in the unaudited condensed consolidated statements of operations and comprehensive loss (in thousands):

	2026	2025
Research and development	$ 1,468	$ 1,167
General and administrative	1,806	1,364
Total	$ 3,274	$ 2,531

The aggregate unrecognized share-based compensation expense related to stock options and RSUs was approximately $23.9 million as of September 30, 2026. This amount is expected to be recognized over a weighted average period of 2.0 years.

Pre-Funded Warrants

PFWs are outstanding for a total of approximately 8.2 million shares as of September 30, 2026. Please refer to Note 7 for additional information about outstanding PFWs.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Legacy Warrants

In connection with an equity financing in October 2020, the Company issued warrants entitling the holders to purchase 820,001 shares of common stock. These 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 September 30, 2026, all of the warrants were vested. The Participating Warrants and other warrants are collectively referred to as the "Legacy Warrants."

For the three months ended September 30, 2026, no Legacy Warrants were granted, expired or exercised. As of September 30, 2026, Legacy Warrants were outstanding for an aggregate of 849,782 shares with a weighted average exercise price of $19.86 per share. The weighted average remaining contractual term for the Legacy Warrants was 1.0 year as of September 30, 2026.

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 Ligand 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 or a potential range of loss is probable and reasonably estimable under ASC 450, *Contingencies*. As of September 30, 2026, there have been no pending or threatened lawsuits against the Company 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, Inc. ("Handok"), whose CEO serves on the Company's board of directors, 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 the PKI Portfolio. 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 regulatory approval 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.

Note 11 — Income Taxes

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

For the three months ended September 30, 2026 and 2025, the Company did not recognize any income tax benefit due to a full valuation allowance on its deferred income tax assets. The Company did not have any material changes to its conclusions regarding valuation allowances for deferred income tax assets or uncertain tax positions for the three months ended September 30, 2026 and 2025.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Note 12 — Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of outstanding shares of common stock and PFWs. 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 because 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 for the three months ended September 30, 2026 and 2025 consists of the following:

	2026	2025
Common Stock	96,603,073	89,625,732
2021 PFWs	123,000	123,000
2022 PFWs	3,421,053	4,113,943
2024 PFWs	1,875,000	3,198,883
2025 PFWs	2,755,385	6,361,089
Total	104,777,511	103,422,647

For the three months ended September 30, 2026 and 2025, basic and diluted net loss per share are the same since all other common stock equivalents were anti-dilutive. As of September 30, 2026 and 2025, the following potential common stock equivalents were excluded from the computation of diluted net loss per share since the impact of inclusion was anti-dilutive:

	2026	2025
Stock options	12,462,194	13,395,587
RSUs	2,026,580	1,081,500
Legacy Warrants	849,782	850,262
Total	15,338,556	15,327,349

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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Notes to Unaudited Condensed Consolidated Financial Statements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the fair value hierarchy classification as of September 30, 2026 and June 30, 2026 (in thousands):

	Fair Value Measurement of Assets as of September 30, 2026			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents:				
Money market funds	$ 4,413	$ 4,413	$ —	$ —
Marketable debt securities:				
Corporate commercial paper	42,983	—	42,983	—
Corporate notes and bonds	36,615	—	36,615	—
U.S. Treasury securities	2,251	—	2,251	—
Total	$ 86,262	$ 4,413	$ 81,849	$ —

	Fair Value Measurement of Assets as of June 30, 2026			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents:				
Money market funds	$ 6,102	$ 6,102	$ —	$ —
Marketable debt securities:				
Corporate commercial paper	41,878	—	41,878	—
Corporate notes and bonds	51,302	—	51,302	—
U.S. Treasury securities	4,006	—	4,006	—
Total	$ 103,288	$ 6,102	$ 97,186	$ —

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 tables above, the Company did not have any other assets measured at fair value on a recurring basis as of September 30, 2026 and June 30, 2026.

The 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 historical effective interest rate under the Loan Agreement.

The following table sets forth changes in the fair value of the embedded derivative liability for which fair value was determined on a recurring basis for the three months ended September 30, 2026 and 2025 (in thousands):

	2026	2025
Fair value, beginning of period	$ 468	$ 468
Changes in fair value	20	15
Fair value, end of period	$ 488	$ 483

Except for the embedded derivative liability, the Company did not have any other liabilities measured at fair value on a recurring basis as of September 30, 2026 and June 30, 2026.

Due to the relatively short maturity of the respective instruments, the fair value of cash, accounts payable, and accrued liabilities approximated their carrying values as of September 30, 2026 and June 30, 2026.

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Notes to Unaudited Condensed Consolidated Financial Statements

The Company's policy is to recognize asset or liability transfers among Level 1, Level 2 and Level 3 as of the actual date of the events or change in circumstances that caused the transfer. During the three months ended September 30, 2026 and 2025, 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 three months ended September 30, 2026 and 2025, cash deposits have exceeded the amount of insurance provided on such deposits by the Federal Deposit Insurance Corporation.

As of September 30, 2026, the Company had an aggregate of $49.0 million invested in marketable 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 — Segment Disclosures

The Company has determined that it operates as a single reportable segment which includes all of its activities as a clinical stage biopharmaceutical company. The CODM uses consolidated net loss as reported in the unaudited condensed consolidated statements of operations and comprehensive loss to assess performance, analyze budget to actual results, forecast future operating results and cash requirements, and allocate resources for its single reportable segment. The significant segment expenses regularly reviewed by the CODM consist of clinical and manufacturing costs of ersodetug, personnel expenses, and other segment expenses. The measure of the operating segment assets is reported on the unaudited condensed consolidated balance sheets as total assets and all of the Company's tangible assets are located in the United States.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

The following table presents consolidated net loss summarized by the significant segment expenses regularly reviewed by the CODM for the three months ended September 30, 2026, and 2025 (in thousands):

	2026	2025
Research and development:		
Ersodetug	$ 5,519	$ 5,610
Compensation and benefits	5,573	5,588
Other research and development segment expenses [1]	1,715	1,951
Total research and development	12,807	13,149
General and administrative:		
Compensation and benefits	3,692	3,350
Other general and administrative segment expenses [2]	2,886	3,318
Total general and administrative	6,578	6,668
Operating loss	(19,385)	(19,817)
Total non-operating income, net	898	1,667
Net loss	$ (18,487)	$ (18,150)

(1) Other research and development segment expenses primarily include quality, regulatory, and other pipeline development costs; employee travel and other employee expenses; and other facility and information technology costs.

(2) Other general and administrative segment expenses primarily include consulting expenses related to business development and market planning activities, insurance expense, public company costs, employee travel and expense, and other facility and information technology costs.

Note 15 — Subsequent Events

Consulting Agreement

On October 1, 2026, the Company entered into a consulting agreement under which it will receive professional services on an hourly basis and pay a one-time success fee of $1.0 million (the “Success Fee”) upon regulatory approval for ersodetug for either congenital HI or tumor HI, provided that no additional clinical study is required for the approved indication. The Company would also become obligated to pay the Success Fee upon entering into a definitive agreement providing for a merger, acquisition, change of control, sale of all or substantially all of the Company’s assets, or other similar strategic transaction before regulatory approval of ersodetug. Payment of the Success Fee is due upon, and is a condition to, the closing of such transactions. The Company records a liability for contingent payments in the period that the event becomes probable.

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.

We are a late-stage rare disease company focused on developing therapies that treat refractory and debilitating hypoglycemia associated with various forms of hyperinsulinism ("HI").

Our priorities for the remainder of 2026 and first half of 2027 are to: (i) announce topline data for the registrational Phase 3 upLIFT study in tumor HI, (ii) complete a pre-Biologics License Application meeting with the U.S. Food and Drug Administration (the "FDA" or the "Agency"), and (iii) submit a Biologics License Application ("BLA") to the FDA for ersodetug for one or both programs in mid-2027.

Ersodetug

Our lead clinical asset, ersodetug, is a potential treatment for refractory hypoglycemia caused by multiple forms of hyperinsulinism.

Ersodetug is an intravenously administered human monoclonal antibody that binds to a unique site (allosteric) on the insulin receptor in insulin target tissues, such as in the liver, fat, and muscle. The antibody modulates insulin receptor activity, thereby helping to restore glucose to a more normalized range in conditions associated with elevated insulin or insulin-like substances (e.g. IGF-2 variants). Ersodetug shows dose dependent pharmacokinetics with a half-life greater than 2 weeks, which has the potential for monthly dosing. Therefore, we believe that ersodetug is ideally suited as a potential therapy for conditions characterized by HI, and it is being developed to treat any form of HI. As ersodetug acts downstream from the cause of disease and source of HI (insulin or IGF-2 production), it has the potential to be universally effective at treating hypoglycemia related to HI, whether genetic or acquired.

Ersodetug for Congenital HI

sunRIZE Phase 3 Study

On December 11, 2025, we announced that the sunRIZE study did not meet its primary endpoint (hypoglycemia events by finger stick self-monitored blood glucose "SMBG") or its key secondary endpoint (time in hypoglycemia by continuous glucose monitoring "CGM") at the defined Week 24 evaluable window. Although statistical significance for the secondary endpoint was not achieved at the Week 24/End of Treatment evaluation window, larger and often nominally statistically significant reductions in hypoglycemia compared to placebo were consistently observed throughout the maintenance dosing phase of the study, across time and numerous pre-specified and post-hoc CGM-based endpoints. There was evidence of pharmacologic activity, as target therapeutic drug concentrations were achieved in both treatment groups (5 mg/kg and 10 mg/kg) with highly sensitive biomarker responses (increases in circulating insulin) in the active treatment groups that are directly indicative of reduced insulin activity at its receptor, which biologically implies reduced cellular glucose transport and an increase in blood glucose.

We met with the FDA on March 17, 2026, under our Breakthrough Therapy Designation to discuss next steps for this indication. During the meeting, we presented summary results from sunRIZE including: (i) information to support our belief that the primary endpoint was confounded as a result of behavioral factors; (ii) evidence of pharmacologic activity; (iii) consistent improvements compared to placebo in time in hypoglycemia and a variety of other CGM-based glycemic endpoints, as discussed above; and (iv) preliminary favorable observations from the ongoing open-label extension ("OLE"). At the meeting the Agency acknowledged the challenges posed by behavioral factors in clinical trials in this patient population, including limitations associated with SMBG based measures of hypoglycemia. The Agency requested that the Company provide the continuous CGM data for its independent review. In June 2026, the Company submitted source and analysis datasets, and summary results from a substantial number of pre-specified, post-hoc, and sensitivity analyses.

The Agency has reviewed the data and, despite the trial's failure to meet the prespecified primary and key secondary endpoints, as a next step, encouraged the Company to request a Type B pre-BLA meeting as a precursor to submitting a BLA for congenital HI. The Agency explicitly did not opine on the approvability of ersodetug for congenital HI and noted that any such determination would only be made as a part of an in-depth evaluation of the supporting data during a formal BLA review, as is customary during a BLA process.

The OLE phase of the study is ongoing, with a continued high retention rate, equating to an ersodetug treatment duration in sunRIZE ranging from approximately nine months to well over two years. This, along with continued glycemic control and a notable reduction in the use of background standard of care therapies, potentially indicate continued glycemic and clinical benefit with ersodetug in longer-term use.

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 where individuals have diffuse disease, a near-total pancreatectomy may 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 treatments used by physicians today include glucagon, diazoxide, somatostatin analogues and pancreatectomy. We estimate that in the U.S. alone, the initial addressable pediatric market for congenital HI is more than 2,000 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 BLA submission. Based on the multinational Phase 2b (RIZE) 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 Breakthrough Therapy Designation by the FDA in the U.S.

Ersodetug for Tumor HI

upLIFT Phase 3 Study

In mid-2025 we initiated the Phase 3 registrational study ("upLIFT") of ersodetug for the treatment of hypoglycemia due to tumor HI. The study is now fully enrolled and topline data is expected in mid-December 2026.

At a meeting held with FDA on August 19, 2025, the Agency agreed to modifications to the design of the upLIFT study including removing the need to conduct a randomized, double-blind, placebo-controlled trial with hypoglycemia events as the endpoint. The streamlined upLIFT study is a Phase 3, registrational, single-arm, open-label, pivotal trial in approximately 16 participants with insulinoma or paraneoplastic non-islet cell tumors, who require continuous parenteral dextrose because of refractory hypoglycemia. Eligible participants requiring continuous parenteral dextrose will receive ersodetug 9 mg/kg per week for 8 weeks, as an add-on to standard of care. Following this 8-week pivotal treatment period, all participants may receive ersodetug in long-term extension, with the discretion to decrease the dosing frequency to every 2 to 4 weeks. The primary endpoint is the proportion of participants able to achieve at least a 50 percent reduction from baseline in the rate of continuous parenteral dextrose (glucose infusion rate; "GIR"), where statistical significance would be achieved if the lower bound of the 95% confidence interval of the point estimate exceeds 30% (equating to a responder rate of ~9 of 16 participants). Additional endpoints include the time to discontinuation of glucose infusion, time to discharge from the hospital, extent of hypoglycemia events and hypoglycemia time in the outpatient setting by SMBG and CGM, respectively, and patient reported quality of life.

Earlier this year, the Company announced that 7 of the 8 participants enrolled in the first half of the study met the responder criterion for the study's primary endpoint. Furthermore, each of these participants also achieved complete discontinuation of intravenous glucose with the administration of ersodetug. Ersodetug has been well-tolerated in the study thus far, with no drug-related safety findings reported. The eighth participant in the first half of the study elected to pursue hospice care at home shortly after enrollment, where they died one week later due to cancer progression. The Company considers this participant as a non-responder, for purposes of the primary endpoint. On October 14, 2026, we announced the completion of enrollment in upLIFT.

Based on historical precedent, supportive data from the sunRIZE study (i.e., safety and drug activity), the recent liberalization of the tumor HI study and differentiation between study endpoints, and the experience that we have reported in the historical Expanded Access Program, we remain cautiously optimistic regarding the probability of success in this indication.

Tumor HI may be caused by two distinct types of solid 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 types of tumors.

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 diazoxide and 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 incidence market for the combined indications causing tumor HI is estimated to be approximately 4,000 patients in the U.S. alone per year. We believe 60% of these patients are managed at the National Cancer Institutes and academic medical centers, which will be our primary focus at launch.

Expanded Access Program

We maintain an expanded access program ("EAP") for a variety of HI indications for the purpose of making ersodetug available on a compassionate use basis when patients have refractory hypoglycemia and cannot access a clinical trial. 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 numerous inbound physician inquiries regarding the use of ersodetug in patients with tumor HI caused by metastatic insulinomas or non-islet cell tumors, which led to compassionate use treatment in an expanded access program in more than a dozen patients. In the U.S., these requests have all been individually approved by the FDA's Office of Cardiology, Hematology, Endocrinology and Nephrology — Division of Diabetes, Lipid Disorders, and Obesity. The tumor HI patients that have received ersodetug have been refractory to SOC therapies for chronic management of hypoglycemia. These patients have generally required continuous parenteral dextrose 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 debilitating hypoglycemia.

Generally, dosing for tumor HI patients in the EAP has been either 6 mg/kg or 9 mg/kg every 1-4 weeks. Nearly universally, ersodetug has led to substantial reductions in GIR (equating to an improvement in hypoglycemia) and has been well tolerated. After initiation of

ersodetug, GIR 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 2 years in some instances, in this subset of tumor HI patients with significantly advanced and metastatic tumor burden.

Presented in a table filed on January 7, 2026, on Form 8-K with the SEC are cumulative data from the initial 9 participants in the EAP, including patient characteristics, ersodetug dosing and observed outcomes. This same data cohort was provided to FDA last year in support of our request for Breakthrough Therapy Designation and subsequently informed the discussion with FDA that led to revision of the upLIFT study in tumor HI to a single arm, open-label study. In summary, 75% of the patients receiving IV dextrose/total parenteral nutrition ("TPN") in the EAP achieved a complete discontinuation of IV dextrose/TPN.

We also maintain an EAP for patients with congenital and other forms of hyperinsulinism, which has served to provide access on a compassionate use basis, to patients who do not qualify or otherwise cannot participate in a clinical trial of ersodetug. This includes several congenital HI participants who were refractory to usual therapies and one infant where off-label or surgical (pancreatectomy) intervention was being considered as the only remaining option, but was averted by use of ersodetug in the EAP. The duration of treatment in these participants ranges from more than a year to more than 4 years, with ongoing benefit.

Recent Developments

Consulting Agreement

On October 1, 2026, the Company entered into a consulting agreement under which it will receive professional services on an hourly basis and pay a one-time success fee of $1.0 million (the "Success Fee") upon regulatory approval for ersodetug for either congenital HI or tumor HI, provided that no additional clinical study is required for the approved indication. The Company would also become obligated to pay the Success Fee upon entering into a definitive agreement providing for a merger, acquisition, change of control, sale of all or substantially all of the Company's assets, or other similar strategic transaction before regulatory approval of ersodetug. Payment of the Success Fee is due upon, and is a condition to, the closing of such transactions.

Factors Impacting our Results of Operations

We have not generated any meaningful revenue 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.

We do not expect to generate revenue from any of our product candidates until we obtain regulatory approval and commercialize our approved product candidates. 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 cash and share-based compensation and employee benefits related to personnel engaged in R&D activities, clinical trial costs, licensing costs, and consulting and outside services engaged in the design and development of our product candidates and other scientific research projects. Our R&D costs also include an allocable portion of our facilities and overhead costs based on personnel and other resources devoted to R&D activities.

General and administrative expenses. General and administrative ("G&A") expenses consist primarily of cash and share-based compensation and employee benefits related to personnel engaged in our administrative, finance, accounting and executive functions. Our G&A expenses also include professional fees for business development, legal, auditing, consulting, investor relations, other costs

primarily related to our status as a public company, and an allocable portion of our facilities and overhead costs based on personnel and other resources devoted to G&A activities.

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

Loss from change in fair value of embedded derivative liabilities. We recognize liabilities for financial instruments that are required to be accounted for as derivatives, including 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 unaudited condensed 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 the 2026 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.

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 research and development 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.

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 stock options with time-based vesting using the Black-Scholes Merton (“BSM”) option-pricing model and recognize the cost of the equity awards over the period that services are provided to earn the award. For stock option 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. Fair value of RSUs is based on the closing market price on the date of grant whereby compensation costs are recognized on a straight-line basis over the vesting period of the RSUs.

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.

Results of Operations

Revenue. As a late-stage rare disease company, we did not generate any revenue for the three months ended September 30, 2026 and 2025. 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 until we obtain regulatory approval and commercialize our approved product candidates.

Three months ended September 30, 2026 and 2025

Research and development expenses. R&D expenses for the three months ended September 30, 2026 and 2025 were as follows (in thousands, except percentages):

	September 30,		Decrease	
	2026	2025	Amount	Percent
Total R&D expenses	$ 12,807	$ 13,149	$ (342)	(3)%

The decrease in R&D expenses of $0.3 million for the three months ended September 30, 2026 was attributable to a decrease of $0.2 million in other R&D costs related to preclinical and other patient affairs costs, and a decrease of $0.1 million related to ersodetug program costs.

The $0.1 million decrease in ersodetug R&D costs was driven by (i) a decrease of $0.4 million due to the timing of drug substance and drug product manufacturing, including decreases in activity surrounding process performance qualification batch productions, (ii) a decrease of $0.1 million in clinical trial costs for the Phase 3 clinical sunRIZE study, which had 56 participants continuing on the open-label extension as of September 30, 2026. These decreases were offset by an increase of $0.4 million in clinical costs for the Phase 3 upLIFT study. For the three months ended September 30, 2025, there were lower clinical costs incurred for startup activities, such as site activations, for the tumor HI related Phase 3 upLIFT study and clinical costs for the Phase 3 sunRIZE study were higher due to patients' participation in the study compared to exclusively OLE participation in the three months ended September 30, 2026.

R&D compensation and benefits remained consistent over the period as an increase of $0.3 million in share-based compensation was offset by a $0.3 million decrease in cash compensation and benefits due to a decrease in the average number of R&D employees, from 54 for the three months ended September 30, 2025 to 45 employees for the three months ended September 30, 2026.

General and administrative expenses. G&A expenses for the three months ended September 30, 2026 and 2025 were as follows (in thousands, except percentages):

	September 30,		Decrease	
	2026	2025	Amount	Percent
Total G&A expenses	$ 6,578	$ 6,668	$ (90)	(1)%

The decrease in G&A expenses of $0.1 million for the three months ended September 30, 2026 was attributable to a decrease of $0.4 million in other G&A costs, partially offset by an increase of $0.3 million in G&A compensation and benefits.

The decrease of $0.4 million in other G&A costs was primarily due to a $0.3 million decrease related to the deferred financing costs for the open market sales agreement with Jefferies that was terminated in the prior fiscal year and expensed in the three months ended September 30, 2025, and a $0.1 million decrease in certain business development, market research and planning activities in preparation for future ersodetug commercial activities for the three months ended September 30, 2026 when compared to the three months ended September 30, 2025.

The $0.3 million increase in G&A compensation and benefits was attributable to an increase of $0.4 million in share-based compensation offset by a decrease of $0.1 million in cash-based compensation and benefits due to a decrease in the average number of G&A employees, from 21 for the three months ended September 30, 2025 to 18 employees for the three months ended September 30, 2026.

Interest and other income. Interest and other income amounted to $0.9 million for the three months ended September 30, 2026, compared to $1.7 million for the three months ended September 30, 2025. This decrease of $0.8 million was primarily due to the lower average balance of investments in marketable debt securities for the three months ended September 30, 2026 compared to the three months ended September 30, 2025.

Income taxes. For the three months ended September 30, 2026 and 2025, we did not recognize any income tax benefit attributable to our net loss because a valuation allowance was required for our deferred income tax assets.

Liquidity and Capital Resources

Short-term Liquidity Requirements

As of September 30, 2026, our capital resources consist of cash and cash equivalents of $8.2 million and short-term marketable debt securities of $81.8 million. Working capital amounted to approximately $84.4 million as of September 30, 2026. We have incurred cumulative net losses of $499.9 million since our inception and as a clinical stage company we have not generated any meaningful revenue to date.

Our primary source of liquidity has historically been from the completion of private placements and public offerings of our equity securities. The completion of equity financings between April 2025 and June 2025 is the primary source of our cash, cash equivalents and short-term investments in marketable debt securities totaling $90.0 million as of September 30, 2026.

Expected cash payments related to existing contractual obligations for the 12-month period ending September 30, 2027 include approximately $0.7 million under our operating lease agreements.

Based on our cash, cash equivalents and investments in marketable debt securities totaling $90.0 million as of September 30, 2026, we believe we have adequate capital resources to meet our contractual obligations and carry out ongoing clinical trials and other planned activities for at least 12 months from the issuance date of the unaudited condensed consolidated financial statements as of September 30, 2026.

Long-term Liquidity Requirements

Our most significant long-term contractual obligations consist of the regulatory milestone payment of $25.0 million payable to Ligand and additional clinical and regulatory milestone payments up to $25.0 million payable to ActiveSite. Due to uncertainties in the timing associated with clinical trial activities and regulatory approvals, there is even greater uncertainty in forecasting the timing of our long-term future clinical and regulatory milestone payments to Ligand and ActiveSite.

In addition to the clinical and regulatory milestone payments discussed above, upon the future commercialization of ersodetug and compounds from our PKI Portfolio (as defined below) we will be obligated to pay additional milestone payments and alternative indication regulatory approval payments to Ligand 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 Ligand 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 compounds from our PKI Portfolio, in which case none of these future payments may ever be required.

In addition to our licensing obligations, we may be required to pay a $1.0 million Success Fee from our consulting agreement discussed above and have approximately $0.1 million of long-term contractual obligations under existing operating lease agreements that expire by October 2027.

Based on our current forecast, we expect that our existing capital resources will be sufficient to fund our short-term liquidity requirements. However, we will need to obtain additional equity or debt financing in order to fund all of our long-term liquidity requirements.

Presented below is further discussion about the ongoing requirements pursuant to our license agreements with Ligand and ActiveSite, along with additional information about our cash flow activity that impacted our liquidity and capital resources through September 30, 2026.

Ersodetug License Agreement

In December 2017, we entered into a license agreement (the "Ersodetug License Agreement") with XOMA through its wholly-owned subsidiary, XOMA (U.S.) LLC, pursuant to which XOMA granted an exclusive global license to develop and commercialize ersodetug for all indications. On July 14, 2026, XOMA was acquired by Ligand Pharmaceuticals Incorporated ("Ligand").

To date we have paid a total of $12.0 million in milestone payments pursuant to the Ersodetug License Agreement. The most recent milestone payment of $5.0 million became due in May 2025 upon dosing of the last patient in our Phase 3 clinical trial for ersodetug and was paid in June 2025. The next milestone payment of $25.0 million will be due upon regulatory approval for ersodetug by any regulatory authority. We record a liability for milestone payments in our financial statements on the date that we achieve the milestone event. Additionally, upon the future commercialization of ersodetug, we will be required to pay royalties to Ligand based on the net sales of the related products, and milestone payments up to an additional $185.0 million if future net sales related to ersodetug exceed annual targets ranging from $100.0 million to $1.0 billion. Through September 30, 2026, no events have occurred that would result in a requirement to make additional milestone payments, and no royalties have been incurred to date.

ActiveSite License Agreement

In August 2017, we entered into a Development and License Agreement (the "ActiveSite License Agreement") with ActiveSite Pharmaceuticals, Inc. ("ActiveSite") pursuant to which we acquired the rights to ActiveSite's Plasma Kallikrein Inhibitor program ("PKI Portfolio"). We initially focused on the development of RZ402 as a therapy for diabetic macular edema ("DME"). Following the completion of a Phase 2 clinical study for RZ402, we decided to pause the program to focus our resources on ersodetug. We are currently exploring the use of the PKI Portfolio to develop therapies for different indications. To date we have paid a total of $4.0 million in milestone payments to ActiveSite. The most recent milestone payment of $3.0 million was in February 2023 after dosing 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. 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 net sales of products that use the PKI Portfolio. Through September 30, 2026, no events have occurred that would result in the requirement to make additional milestone payments, and no royalties have been incurred to date.

Cash Flows Summary

Presented below is a summary of our operating, investing, and financing cash flows for the three months ended September 30, 2026 and 2025 (in thousands):

	2026	2025	Change
Net cash provided by (used in):			
Operating activities	$ (18,783)	$ (17,430)	$ (1,353)
Investing activities	15,766	(68,490)	84,256
Financing activities	552	911	(359)

Cash Used in Operating Activities

For the three months ended September 30, 2026 and 2025, cash used in operating activities amounted to $18.8 million and $17.4 million, respectively. The key components in the calculation of our cash used in operating activities are as follows (in thousands):

	2026	2025	Change
Net loss	$ (18,487)	$ (18,150)	$ (337)
Non-cash expenses	3,455	2,694	761
Accretion of discounts and amortization of premiums on marketable debt securities, net	(483)	(799)	316
Changes in operating assets and liabilities, net	(3,268)	(1,175)	(2,093)
Total	$ (18,783)	$ (17,430)	$ (1,353)

For the three months ended September 30, 2026, our net loss was $18.5 million compared to $18.2 million for the three months ended September 30, 2025. For further discussion about changes in our operating results for the three months ended September 30, 2026 and 2025, please refer to *Results of Operations* above.

For the three months ended September 30, 2026 and 2025, our non-cash expenses of $3.5 million and $2.7 million, respectively, were primarily attributable to share-based compensation expense and non-cash lease expense. For the three months ended September 30, 2026 and 2025, the net impact of accretion of discounts and amortization of premiums on marketable debt securities reduced operating cash flows by $0.5 million and $0.8 million, respectively. For the three months ended September 30, 2026, net changes in operating assets and liabilities decreased operating cash flow by $3.3 million, primarily driven by cash outflows that resulted in a net decrease in accounts payable and other accrued liabilities of $2.1 million and a net increase of $1.2 million in prepaid expenses and other assets. For the three months ended September 30, 2025, net changes in operating assets and liabilities decreased operating cash flow by $1.2 million, primarily driven by cash outflows resulting in a net decrease in accounts payable and other accrued liabilities of $1.8 million. This amount was partially offset by a net decrease of $0.7 million in prepaid expenses and other assets.

Cash Provided by (Used in) Investing Activities

For the three months ended September 30, 2026, our net cash provided by investing activities amounted to $15.8 million. For the three months ended September 30, 2026, we received proceeds of $35.9 million upon the maturity of certain marketable debt securities. These cash proceeds from maturities were used to purchase a total of $20.1 million of marketable debt securities.

For the three months ended September 30, 2025, our net cash used in investing activities amounted to $68.5 million. For the three months ended September 30, 2025, we received proceeds of $20.4 million upon the maturity of certain marketable debt securities. These cash proceeds from maturities, along with certain proceeds from the 2025 Underwritten Offering in April 2025 and the 2025 Private Placement in June 2025, were used to purchase a total of $88.9 million of marketable debt securities.

Cash Provided by Financing Activities

For the three months ended September 30, 2026 and 2025, our net cash provided by financing activities of $0.6 million and $0.9 million, respectively, were primarily attributable to cash receipts from the exercise of employee stock options.

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 expected 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 Report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief 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 evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2026.

Changes in Internal Controls over Financial Reporting

During the quarter ended September 30, 2026, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

Our Risk Factor disclosures are set forth in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended June 30, 2026 filed with the Securities and Exchange Commission ("SEC") on September 24, 2026. The risk factors included in the 2026 Form 10-K have not materially changed, except as reflected in the following new risk factors:

Risks Related to Our Product Development and Commercialization

Although the FDA has recommended a pre-Biologics License Application meeting as a precursor to a Biologics License Application ("BLA") submission there can be no guarantee that the FDA will agree with the Company that the totality of evidence from the sunRIZE program demonstrates a clinically meaningful benefit or is sufficient to support the approval for ersodetug in congenital HI.

On October 5, 2026, we announced that the FDA recommended a pre-BLA meeting as a precursor to a BLA submission as it relates to ersodetug for congenital HI. Although we believe this is a positive development, the FDA has not opined on the approvability of ersodetug for congenital HI, and its recommendation that we proceed to a pre-BLA meeting does not mean that the FDA has determined that the existing data is sufficient to support the submission or approval of a BLA. Accordingly, there can be no guarantee that the FDA will agree with us that the totality of evidence from the sunRIZE program and the supplemental information that we have provided to the FDA or that we will provide as part of the pre-BLA meeting will be sufficient to support the approval of ersodetug for congenital HI. The FDA may require us to provide additional information or conduct additional clinical studies, including another study similar to sunRIZE, which could delay the submission or approval of a BLA, increase our costs and require changes to our operating plans.

The upLIFT trial may fail to produce results sufficient to support regulatory approval of ersodetug for tumor HI.

We have completed enrollment in the Phase 3 upLIFT study and expect to report topline results in December 2026. Although interim results from the initial participants enrolled in the study were encouraging, such results may not be predictive of final results, and there can be no guarantee that the final results will be consistent with the interim results or that the study will meet its primary or secondary endpoints. Even if the study meets its endpoints, there can be no guarantee that the FDA will determine that the results are sufficient to support regulatory approval of ersodetug for tumor HI.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Number	Description of Exhibits
31.1*	Certification of Principal Executive Officer as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
31.2*	Certification of Principal Financial Officer as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1*	Certification of Principal Executive Officer as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
32.2*	Certification of 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

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REZOLUTE, INC.

Date: November 5, 2026

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

Date: November 5, 2026

By: /s/ Daron Evans
Daron Evans
Chief Financial and Business Officer
(Principal Financial Officer)

EXHIBIT 31.1

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

I, Nevan Charles Elam, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Rezolute, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report.

4. As the Registrant's certifying officer, I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. As the Registrant's certifying officer, I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: November 5, 2026

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

EXHIBIT 31.2

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

I, Daron Evans, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Rezolute, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report.

4. As the Registrant's certifying officer, I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. As the Registrant's certifying officer, I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: November 5, 2026

By: /s/ Daron Evans
Daron Evans
Chief Financial and Business Officer
(Principal Financial Officer)

EXHIBIT 32.1

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

In connection with the quarterly report of Rezolute, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026, 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: November 5, 2026

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

EXHIBIT 32.2

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

In connection with the quarterly report of Rezolute, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daron Evans, Chief Financial and Business 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: November 5, 2026

By: /s/ Daron Evans
Daron Evans
Chief Financial and Business Officer
(Principal 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.