Table of Contents

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

FORM 10-Q

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

For the quarterly period ended September 30, 2022

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)

201 Redwood Shores Parkway, Suite 315, Redwood City, California 94065
(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 36,827,567 shares of its $0.001 par value common stock outstanding as of November 7, 2022.

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

- our projected operating or financial results, including anticipated cash flows used in operations;
- our expectations regarding capital expenditures, research and development expenses and other payments;
- our expectation about the extent and duration of the COVID-19 pandemic ("COVID-19") on our business;
- our beliefs and assumptions relating to our liquidity position, including our ability to obtain additional financing;
- our ability to obtain regulatory approvals for our pharmaceutical drugs and diagnostics; and
- our future dependence on third party manufacturers or strategic partners to manufacture any of our pharmaceutical drugs and diagnostics that receive regulatory approval, and our ability to identify strategic partners and enter into license, co-development, collaboration or similar arrangements.

Any or all of our forward-looking statements may turn out to be wrong. They can be affected by inaccurate assumptions or by known and unknown risks, uncertainties and other factors including, but not limited to, the risks described in Part II, Item 1.A Risk factors, as well as "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended June 30, 2022 (the "2022 Form 10-K"), filed with the Securities and Exchange Commission ("SEC") on September 15, 2022.

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

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

Rezolute, Inc.

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

	September 30, 2022	June 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 154,322	$ 150,410
Prepaid expenses and other	1,305	1,694
Total current assets	155,627	152,104
Long-term assets:		
Deposits and other	148	148
Right-of-use assets	130	152
Property and equipment, net	83	16
Total assets	$ 155,988	$ 152,420
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,110	$ 1,132
Accrued liabilities:		
Insurance premiums	122	243
Accrued clinical and other	1,085	979
Current portion of operating lease liabilities	112	108
Total current liabilities	2,429	2,462
Long term liabilities:		
Operating lease liabilities, net of current portion	49	80
Embedded derivative liabilities	420	407
Total liabilities	2,898	2,949
Commitments and contingencies (Notes 3, 4, 8 and 9)		
Shareholders' equity:		
Preferred stock, $0.001 par value; 400 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 100,000 shares authorized; issued and outstanding 36,827 and 33,582 shares as of September 30, 2022 and June 30, 2022, respectively	37	34
Additional paid-in capital	372,082	358,635
Accumulated deficit	(219,029)	(209,198)
Total shareholders' equity	153,090	149,471
Total liabilities and shareholders' equity	$ 155,988	$ 152,420

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

Rezolute, Inc.

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

	Three Months Ended September 30,	
	2022	**2021**
Operating expenses:		
Research and development	$ 7,704	$ 5,774
General and administrative	2,514	1,866
Total operating expenses	10,218	7,640
Operating loss	(10,218)	(7,640)
Non-operating income (expense):		
Interest and other income	400	—
Gain (loss) from change in fair value of derivative liabilities, net	(13)	16
Employee retention credit	—	231
Interest expense	—	(443)
Total non-operating income (expense), net	387	(196)
Net loss	$ (9,831)	$ (7,836)
Net loss per common share:		
Basic and diluted	$ (0.19)	$ (0.92)
Weighted average number of common shares outstanding:		
Basic and diluted	50,528	8,513

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, 2022 and 2021
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Three Months Ended September 30, 2022:					
Balances, June 30, 2022	33,582	$ 34	$ 358,635	$ (209,198)	$ 149,471
Gross proceeds from issuance of common stock for cash:					
In 2022 Private Placement	3,245	3	12,327	—	12,330
Underwriting commissions and other equity offering costs	—	—	(759)	—	(759)
Share-based compensation	—	—	1,879	—	1,879
Net loss	—	—	—	(9,831)	(9,831)
Balances, September 30, 2022	36,827	$ 37	$ 372,082	$ (219,029)	$ 153,090
Three Months Ended September 30, 2021:					
Balances, June 30, 2021	8,352	$ 8	$ 194,229	$ (168,138)	$ 26,099
Share-based compensation	—	—	842	—	842
Issuance of common stock for cash	254	1	2,689	—	2,690
Advisory fees and other offering costs	—	—	(686)	—	(686)
Issuance of commitment shares	34	—	450	—	450
Net loss	—	—	—	(7,836)	(7,836)
Balances, September 30, 2021	8,640	$ 9	$ 197,524	$ (175,974)	$ 21,559

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,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (9,831)	$ (7,836)
Share-based compensation expense	1,879	842
Non-cash lease expense	23	78
Loss (Gain) from change in fair value of derivative liabilities, net	13	(16)
Depreciation and amortization expense	3	4
Accretion of debt discount and issuance costs	—	104
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other assets	388	(96)
Increase (decrease) in accounts payable	(22)	555
Increase (decrease) in other accrued liabilities	(42)	24
Net Cash Used in Operating Activities	(7,589)	(6,341)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(70)	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Gross proceeds from issuance of common stock for cash:		
2022 Private Placement	12,330	—
Under Equity Distribution Agreement	—	1,519
Under LPC Purchase Agreement	—	1,171
Payment of commissions and other deferred offering costs	(759)	—
Payment of debt discount and issuance costs	—	(104)
Net Cash Provided by Financing Activities	11,571	2,586
Net increase (decrease) in cash, cash equivalents and restricted cash	3,912	(3,755)
Cash, cash equivalents and restricted cash at beginning of period	150,410	41,047
Cash, cash equivalents and restricted cash at end of period	$ 154,322	$ 37,292
SUPPLEMENTARY CASH FLOW INFORMATION:		
Cash paid for interest	$ —	$ 340
Cash paid for income taxes	—	—
Cash paid for amounts included in the measurement of operating lease liabilities	29	92
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of commitment shares for deferred offering costs subsequently charged to additional paid-in capital	$ —	$ 450
Payables for deferred offering costs subsequently charged to additional paid-in capital	—	24

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

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

Nature of Operations

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

Basis of Presentation

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

The condensed consolidated balance sheet as of June 30, 2022, has been derived from the Company's audited consolidated financial statements. The unaudited interim financial statements should be read in conjunction with the Company's 2022 Form 10-K, which contains the Company's audited financial statements and notes thereto, together with the Management's Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended June 30, 2022.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted, pursuant to the rules and regulations of the SEC for interim financial reporting. Accordingly, they do not include all information and footnote disclosures necessary for a comprehensive presentation of financial position, results of operations, and cash flows. It is management's opinion, however, that all material adjustments (consisting of normal recurring adjustments) that are necessary for a fair financial statement presentation have been made. The interim results for the three months ended September 30, 2022 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, 2023.

Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts in the unaudited condensed consolidated financial statements and the accompanying notes. The Company bases its estimates and assumptions on current facts, historical experience, and various other factors that it believes are reasonable under the circumstances, to determine the carrying values of assets and liabilities that are not readily apparent from other sources. The Company's significant accounting estimates include, but are not necessarily limited to, the fair value of derivative liabilities, fair value of share-based payments, management's assessment of going concern, and 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, and the future impact of COVID-19.

Significant Accounting Policies

The Company's significant accounting policies are described in Note 1 to the financial statements in Item 8 of the 2022 Form 10-K.

Recent Accounting Pronouncements

Recently Adopted Standard. The following standard was adopted during the three months ended September 30, 2022:

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity).* ASU 2020-06 reduces the number of accounting models for convertible debt instruments and convertible preferred stock, which results in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Additionally, ASU 2020-06 affects the diluted earnings per share calculation for instruments that may be settled in cash or shares and for convertible instruments and requires enhanced disclosures about the terms of convertible instruments and contracts in an entity's own equity. ASU 2020-06 allows entities to use a modified or full retrospective transition method. The Company adopted this standard using the full retrospective transition method effective July 1, 2022. The adoption did not have any impact on the Company's financial statements.

Standard Required to be Adopted in Future Periods. The following accounting standard is not yet effective; management has not completed its evaluation to determine the impact that adoption of this standard will have on the Company's consolidated financial statements.

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.* ASU 2016-13 amends the guidance on the impairment of financial instruments. This update adds an impairment model (known as the current expected credit losses model) that is based on expected losses rather than incurred losses. Under the new guidance, an entity recognizes, as an allowance, its estimate of expected credit losses. In November 2019, ASU 2016-13 was amended by ASU 2019-10, *Financial Instruments- Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)* whereby the effective date for ASU 2016-13 for smaller reporting companies is now required for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company does not expect the adoption of ASU 2016-13 will have a material impact on its 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 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, 2022, the Company incurred a net loss of $9.8 million and net cash used in operating activities amounted to $7.6 million. For the fiscal year ended June 30, 2022, the Company incurred a net loss of $41.1 million and net cash used in operating activities amounted to $39.6 million. As of September 30, 2022, the Company had an accumulated deficit of $219.0 million, cash and cash equivalents of $154.3 million, and total current liabilities of $2.4 million.

As discussed in Note 4, the Company is subject to license agreements that provide for future contractual payments upon achievement of various milestone events. Pursuant to the ActiveSite License Agreement (as defined below), a $3.0 million milestone payment will be due upon dosing of the first patient in a Phase 2 clinical trial for RZ402. Additionally, pursuant to the XOMA License Agreement (as defined below), a $5.0 million milestone payment will be due upon dosing of the first patient in a Phase 3 clinical trial for RZ358. First patient dosing milestones for the RZ402 Phase 2 clinical trial and RZ358 Phase 3 clinical trial are expected to occur within the next 12 months.

Management believes the Company's cash and cash equivalents balance of $154.3 million as of September 30, 2022, will be adequate to meet the Company's contractual obligations and carry out ongoing clinical trials and other planned activities at least through November 2023.

NOTE 3 — OPERATING LEASES

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

	September 30, 2022	June 30, 2022
Right-of-use assets	$ 130	$ 152
Operating lease liabilities:		
Current	$ 112	$ 108
Long-term	49	80
Total	$ 161	$ 188

For the three months ended September 30, 2022 and 2021, operating lease expense is included under the following captions in the accompanying condensed consolidated statements of operations (in thousands):

	2022	2021
Research and development	$ 77	$ 79
General and administrative	23	23
Total	$ 100	$ 102

As of September 30, 2022, the weighted average remaining lease term under operating leases was 1.4 years, and the weighted average discount rate for operating lease liabilities was 6.0%. Future payments under all operating lease agreements that had commenced as of September 30, 2022 are as follows (in thousands):

Fiscal year ending June 30,	
Remainder of fiscal year 2023	$ 88
2024	79
Total lease payments	167
Less imputed interest	(6)
Present value of operating lease liabilities	$ 161

Headquarters Lease

In April 2022, the Company entered into a lease agreement for a new corporate headquarters in Redwood City, California. The space consists of approximately 9,300 square feet and provides for total base rent payments of approximately $2.9 million through the expected expiration of the lease in November 2027. The landlord was required to make improvements to the facility before the Company could occupy the space, which were completed in October 2022, triggering the commencement of the lease. The lease provides for a six-month rent abatement period beginning upon commencement of the lease term which occurred on October 18, 2022. In addition, the lease provides an allowance of approximately $0.1 million that may be utilized by the Company for the purchase of furniture and equipment. The average base rent payable in cash over the 60-month lease term is approximately $48,000 per month. Upon commencement of the lease, the Company expects to recognize a right-of-use asset and a related operating lease liability for approximately $2.3 million.

The future payments under this operating lease agreement are as follows (in thousands):

Fiscal year ending June 30,		
Remainder of fiscal year 2023	$	50
2024		609
2025		627
2026		646
2027		666
Thereafter		224
Total lease payments	$	2,822

NOTE 4 — LICENSE AGREEMENTS

XOMA License Agreement

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

In January 2022, the Company was required to make a milestone payment under the XOMA License Agreement of $2.0 million that became due upon the dosing of the last patient in the Company's ongoing Phase 2b Clinical Trial for RZ358. Upon the achievement of certain clinical and regulatory events under the XOMA License Agreement, the Company will be required to make additional milestone payments to XOMA up to $35.0 million. After the clinical and regulatory milestones, the Company will be required, upon the future commercialization of RZ358, to pay royalties to XOMA based on the net sales of the related products and additional milestone payments to XOMA up to $185.0 million related to annual net sales amounts. The next milestone payment of $5.0 million will be due upon dosing of the first patient in a Phase 3 clinical trial for RZ358.

ActiveSite License Agreement

On August 4, 2017, the Company entered into a Development and License Agreement (the "ActiveSite License Agreement") with ActiveSite Pharmaceuticals, Inc. ("ActiveSite") pursuant to which the Company acquired the rights to ActiveSite's Plasma Kallikrein Inhibitor program ("PKI Portfolio"). The Company is initially using the PKI Portfolio to develop an oral PKI therapeutic for diabetic macular edema (RZ402) and may use the PKI Portfolio to develop other therapeutics for different indications. The ActiveSite License Agreement requires various milestone payments up to $46.5 million, if all milestones are achieved. The first milestone payment for $1.0 million was paid in December 2020 after clearance was received for an Initial Drug Application, or IND, filed with the U.S. Food and Drug Administration ("FDA"). The next milestone payment of $3.0 million will be due upon dosing of the first patient in a Phase 2 clinical trial for RZ402. The company is also required to pay royalties equal to 2.0% of any sales of products that use the PKI Portfolio. There have been no events that would result in any royalty payments owed under the ActiveSite License Agreement to date.

NOTE 5 — EMBEDDED DERIVATIVE LIABILTY

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 (the "Lenders"). The Lenders agreed to loan up to $30.0 million in three tranches consisting of (i) a $15.0 million term A loan that was funded on April 14, 2021, (ii) term B and term C loans for an aggregate of $15.0 million, which were subject to the Company's ability to obtain prescribed amounts of financing and the achievement of certain clinical milestones. The Company did not achieve the initial clinical milestones by January 2022 and, accordingly, the term B and term C loans were no longer a source of liquidity. The term A loan had a maturity date of April 1, 2026 (the "Maturity Date"), but was repaid in full 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 of each term loan in the event certain transactions (defined as "Exit Events") occur prior to April 13, 2031. Exit Events include, but are not limited to, sales of substantially all assets, certain mergers, change of control transactions, and issuances of common stock that result in new investors owning more than 35% of the Company's shares. As of April 14, 2021, the Company allocated a portion of the proceeds from the term A loan to recognize a liability for the fair value of embedded derivatives. Fair value was determined primarily based on the Company's strategic corporate development plans and management has performed a detailed evaluation of the different types of Exit Events that could occur and using a discounted rate equivalent to the effective rate for the term A loan. Fair value of embedded derivatives is assessed at the end of each reporting period with changes in fair value recognized as a nonoperating gain or loss.

NOTE 6 — SHAREHOLDERS' EQUITY

July 2022 Financing

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

Equity Distribution Agreement

In December 2020, the Company and Oppenheimer & Co. Inc. (the "Agent") entered into an Equity Distribution Agreement (the "EDA") that provides for an "at the market offering" for the sale of up to $50.0 million in shares of the Company's common stock (the "Placement Shares") through the Agent. The Agent was acting as sales agent and was required to use commercially reasonable efforts to sell all of the Placement Shares requested to be sold by the Company, consistent with the Agent's normal trading and sales practices, on mutually agreed terms between the Agent and the Company. The EDA was scheduled to terminate when all of the Placement Shares had been sold, or earlier upon the election of either the Company or the Agent. In May 2022, the Company provided the Agent with notice of termination of the EDA and no further shares will be issued under this agreement.

Under the terms of the EDA, the Company agreed to pay the Agent a commission equal to 3.0% of the gross sales price of the Placement Shares plus certain expenses incurred by the Agent in connection with the offering. For the three months ended September 30, 2021, the Company sold 138,388 shares of its common stock pursuant to the EDA for net proceeds of approximately $1.5 million.

LPC Purchase Agreement

In August 2021, the Company entered into a purchase agreement (the "Purchase Agreement") and a registration rights agreement (the "RRA") with Lincoln Park Capital Fund, LLC ("LPC"), which provides that the Company may sell to LPC up to an aggregate of $20.0 million shares (the "Purchase Shares") of its common stock. The Company concurrently filed a prospectus supplement with the SEC to register the shares issuable under the Purchase Agreement. The aggregate number of shares that the Company could sell to LPC under the Purchase Agreement was 1,669,620 shares of common stock, subject to certain exceptions set forth in the Purchase Agreement.

LPC's initial purchase consisted of 95,708 Purchase Shares at a purchase price of approximately $10.45 per share for a total purchase price of $1.0 million. Concurrently, the Company issued 33,799 shares of common stock to LPC as an initial fee for its commitment to purchase shares of common stock under the Purchase Agreement. Subject to the terms of the Purchase Agreement, the Company had the right, in its sole discretion, to present LPC with a purchase notice (a "Regular Purchase Notice"), directing LPC to purchase up to 25,000 Purchase Shares (a "Regular Purchase"). LPC's committed obligation under any single Regular Purchase generally could not exceed $2.0 million. The Purchase Agreement provided for a purchase price per share for each Regular Purchase (the "Purchase Price") equal to the lesser of (i) the lowest sale price of the common stock on the Nasdaq Capital Market ("NCM") on the purchase date of such shares; and (ii) the average of the three lowest closing sale prices for the common stock traded on the NCM during the ten consecutive business days ending on the business day immediately preceding the purchase date of such shares.

On September 17, 2021, the Company submitted a Regular Purchase Notice, resulting in the sale of 20,000 Purchase Shares to LPC for net proceeds of approximately $0.2 million. In May 2022, the Company provided LPC with notice of termination of the Purchase Agreement whereby no further shares are issuable under this agreement.

NOTE 7 — SHARE-BASED COMPENSATION AND WARRANTS

Stock Option Plans

Presented below is a summary of the number of shares authorized, outstanding, and available for future grants under each of the Company's stock option plans as of September 30, 2022 (in thousands):

Description	Plan Termination Date	Number of Shares		
		Authorized	Outstanding	Available
2015 Plan	February 2020	35	35	—
2016 Plan	October 2021	250	250	—
2019 Plan	July 2029	200	200	—
2021 Plan	March 2031	10,700	7,998	2,702
Total		11,185	8,483	2,702

2022 Employee Stock Purchase Plan

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

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

Stock Options Outstanding

The following table sets forth a summary of the activity under all of the Company's stock option plans for the three months ended September 30, 2022 (shares in thousands):

	Shares	Price [1]	Term [2]
Outstanding, June 30, 2022	8,506	$ 5.24	9.7
Grants to employees	85	2.99	
Forfeited	(108)	4.87	
Outstanding, September 30, 2022	8,483	5.22	9.4
Vested, September 30, 2022	794	17.31	7.45

(1) Represents the weighted average exercise price.

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

For the three months ended September 30, 2022, the aggregate fair value of stock options granted for approximately 0.1 million shares of common stock, amounted to $0.2 million or approximately $2.28 per share as of the grant dates. Fair value was computed using the Black-Scholes-Merton ("BSM") option-pricing model and will result in the recognition of compensation cost ratably over the expected vesting period of the stock options.

For the three months ended September 30, 2022, the fair value of stock options was estimated on the date of grant, with the following weighted-average assumptions:

	2022
Market price of common stock on grant date	$ 2.99
Expected volatility	91 %
Risk free interest rate	3.2 %
Expected term (years)	6.1
Dividend yield	0 %

Share-based compensation expense for the three months ended September 30, 2022 and 2021 is included under the following captions in the unaudited condensed consolidated statements of operations (in thousands):

	2022	2021
Research and development	$ 870	$ 309
General and administrative	1,009	533
Total	$ 1,879	$ 842

Unrecognized share-based compensation expense is approximately $22.2 million as of September 30, 2022. This amount is expected to be recognized over a weighted average period of 3.5 years.

Warrants

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

In connection with a registered direct offering in May 2022, the Company issued 1,973,684 Class A PFWs and 10,947,371 Class B PFWs to purchase an aggregate of 12,921,055 shares of common stock at an issuance price of $3.799 per warrant (collectively, the "2022 PFWs"). As of September 30, 2022 all of the 2022 PFWs may be exercised at any time by paying the exercise price of $0.001 per share, subject to certain ownership restrictions.

In addition, the Company has issued warrants in conjunction with various debt and equity financings and for services. As of September 30, 2022, all of the warrants were vested.

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

	Shares	Price [1]	Term [2]
Outstanding, June 30, 2022	1,150	$ 22.83	4.2
Warrants granted	—	—	
Warrant expirations	—	—	
Outstanding, September 30, 2022	1,150	22.83	3.9

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

NOTE 8 — COMMITMENTS AND CONTINGENCIES

Licensing Commitments

Please refer to Note 4 for further discussion of commitments to make milestone payments and to pay royalties under license agreements with XOMA and ActiveSite.

Legal Matters

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of September 30, 2022, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the Company's results of operations. At each reporting period, the Company evaluates known claims to determine whether a potential loss amount or a potential range of loss is probable and reasonably estimable under ASC 450, *Contingencies*. Legal fees are expensed as incurred.

NOTE 9 — RELATED PARTY TRANSACTIONS

Related Party Licensing Agreement

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

Investors in 2022 Private Placement

Handok and certain of its affiliates were the sole investors in the 2022 Private Placement discussed in Note 6.

NOTE 10 — 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 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, 2022 and 2021, the Company did not record any income tax benefit due to a full valuation allowance on its deferred 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 September 30, 2022 and 2021.

NOTE 11 — NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares, 2021 PFWs and 2022 PFWs outstanding during the period, without consideration for potentially dilutive securities. PFWs are included in the computation of basic and diluted net loss per share since the exercise price is negligible and all of the PFWs are fully vested and exercisable. Accordingly, the weighted average number of shares outstanding is computed as follows for the three months ended September 30, 2022 and 2021 (in thousands):

	2022	2021
Common Stock	35,946	7,445
2021 PFWs	1,661	—
Class A PFWs	1,974	—
Class B PFWs	10,947	—
Total	50,528	7,445

For the three ended September 30, 2022 and 2021, basic and diluted net loss per share were the same since all other common stock equivalents were anti-dilutive.

As of September 30, 2022 and 2021, the following outstanding potential common stock equivalents were excluded from the computation of diluted net loss per share since the impact of inclusion was anti-dilutive (in thousands):

	2022	2021
Stock options	8,482	1,329
Warrants	1,150	1,224
Total	9,632	2,553

NOTE 12 — 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.

The Company's embedded derivative liabilities are classified under Level 3 of the hierarchy and are 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 5 using a discount rate equal to the effective interest rate for the term A loan. The following table sets forth changes in the fair value of the embedded derivative liabilities for the three months ended September 30, 2022 and 2021 (in thousands):

	2022	2021
Fair value, beginning of period	$ 407	$ 387
Loss from change in fair value	13	(16)
Fair value, end of period	$ 420	$ 371

Except for the embedded derivative liabilities, the Company did not have any other assets or liabilities measured at fair value on a recurring basis as of September 30, 2022 and June 30, 2022.

Due to the relatively short maturity of the respective instruments, the fair value of cash and cash equivalents, accounts payable, and accrued liabilities approximated their carrying values as of September 30, 2022 and June 30, 2022.

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, 2022 and 2021, 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 and cash equivalents. The Company maintains its cash and cash equivalents at high-quality financial institutions. For the three months ended September 30, 2022, cash deposits have exceeded the amount of federal insurance provided on such deposits. As of September 30, 2022 and June 30, 2022, the Company had cash and cash equivalents with a single financial institution with an aggregate balance of $154.3 million and $150.4 million, respectively. The Company has never experienced any losses related to its investments in cash and cash equivalents.

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.

Special Note About COVID-19

We have been actively monitoring the COVID-19 pandemic and its impact on our business activities. Our primary objectives have remained the same throughout the pandemic: to support the safety of our team members and their families and continue to support our preclinical studies and clinical trials. Currently, with respect to the operation of our facilities, we are closely adhering to applicable guidelines and orders. Essential operations in research and maintenance that occur within our facilities are continuing in accordance with the permissions granted under government ordinances. Across all of our locations, we have instituted a temporary work from home policy for all office personnel who do not need to work on site to maintain productivity. We have recently allowed these employees to voluntarily return to work on site with appropriate health and safety measures.

While our financial results for the three months ended September 30, 2022 and the fiscal year ended June 30, 2022 were not significantly impacted by COVID-19, we cannot predict the impact of the progression of the COVID-19 pandemic on future results due to a variety of factors, including the ongoing challenges associated with the pandemic, including the emergence of new variants of the coronavirus, such as the Delta and Omicron variants, resurgences in the number and rates of infection, the continued good health of our employees, the ability of us to maintain operations, access to healthcare facilities and patient willingness to participate in our clinical trials, any further government and/or public actions taken in response to the pandemic, and ultimately the length of the pandemic. The ultimate impact of the COVID-19 pandemic on our business operations, our ability to raise capital, our preclinical studies and clinical trial timeliness remain uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. Any prolonged material disruption of our employees, suppliers, or manufacturing may negatively impact our financial position, results of operations, and cash flows. We will continue to monitor the situation closely.

Recent Developments

Financing Activities

In July 2022, we entered into amended securities purchase agreements with Handok, Inc. ("Handok") and certain of its affiliates (the "2022 Private Placement"), resulting in gross proceeds of $12.3 million in exchange for the issuance of approximately 3.2 million shares of common stock. We incurred approximately $0.8 million for underwriting commissions and other offering costs, resulting in net proceeds of $11.5 million.

Termination of Loan Agreement

On April 14, 2021, we entered into a $30.0 million Loan and Security Agreement (the "Loan Agreement") with Solar Investment Corp. ("SLR") as collateral agent, and the parties signing the Loan Agreement from time to time as lenders, including SLR in its capacity as a lender. The scheduled maturity date of the Loan Agreement was on April 1, 2026. In April 2021, we borrowed $15.0 million under the Loan Agreement. On June 30, 2022, we paid off the outstanding loan amount of $15.0 million in full and terminated the Loan Agreement in accordance with its terms.

Please refer to our discussion under the caption *Liquidity and Capital Resources* for further discussion of our recent financing activities.

Summary of Clinical Assets

RZ358

Our lead clinical asset, RZ358, is a potential treatment for congenital hyperinsulinism ("HI"), an ultra-rare pediatric genetic disorder characterized by excessive production of insulin by the pancreas. If untreated, the elevated insulin levels in patients suffering with congenital HI can induce extreme hypoglycemia (low blood sugar) events, increasing the risk of neurological and developmental complications, including persistent feeding problems, learning disabilities, recurrent seizures, brain damage or even death. There are no FDA approved therapies for all forms of congenital HI and the current standard of care treatments are suboptimal. The current treatments used by physicians include glucagon, diazoxide, somatostatin analogues and pancreatectomy.

RZ358 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 modifies insulin's binding and signaling to maintain glucose levels in a normal range which counteracts the effects of elevated insulin in the body. RZ358 shows dose dependent pharmacokinetics with a half-life greater than two weeks which has the potential for semi-monthly dosing. Therefore, we believe that RZ358 is ideally suited as a potential therapy for conditions characterized by excessive insulin levels, and it is being developed to treat hyperinsulinism and low blood sugar. As RZ358 acts downstream from the beta cells, it has the potential to be universally effective at treating congenital HI caused by any of the underlying genetic defects.

A summary of the completed clinical studies for RZ358 is as follows.

A Phase 1 pharmacokinetic ("PK") study of single intravenous doses of RZ358 at 0.1 to 9 mg/kg in healthy volunteers revealed dose-dependent pharmacokinetics with a half-life of 15 days, supporting the biweekly dosing approach. In healthy volunteers, RZ358 prevented hypoglycemia induced by insulin administration, without producing hyperglycemia. This effect showed a PK-pharmacodynamic (dose—response) correlation, with the hypoglycemia blunting effects of RZ358 lasting for two weeks.

The clinical proof-of-concept of RZ358 in congenital HI was evaluated in a Phase 2a study in a total of 14 patients with congenital HI. The study investigated the PK, pharmacodynamics ("PD"), safety and preliminary efficacy of RZ358. RZ358 was well-tolerated in adult and pediatric patients with congenital HI who received single intravenous doses in the Phase 2a study and the PK results from the Phase 2a studies were consistent with those in healthy volunteers. There was a durable normalization of blood sugar in patients with hypoglycemia, with an approximate 50% improvement and near normalization of glucose control, which was sustained for more than two weeks after dosing. RZ358 did not increase blood sugar levels in patients with normal blood sugar levels at baseline.

In calendar year 2022 we completed the RZ358-606 Phase 2b global clinical study for RZ358 ("RIZE"). The RIZE study was conducted in a repeat-dose fashion to evaluate the safety, pharmacokinetics, dose-exposure response relationship and to assess the glycemic efficacy across a range of continuous glucose monitoring ("CGM") and blood glucose monitoring-based principle glycemic endpoints to inform Phase 3. In the study, eligible patients received RZ358 in open-label fashion in one of 4, sequentially conducted dosing cohorts of up to 8 participants per cohort. RZ358 was administered as a 30-minute intravenous infusion every other week for eight weeks. The first three cohorts were fixed dosing levels of RZ358 and the fourth cohort was designed to explore whether there were any advantages of a fixed titration approach.

The RIZE study enrolled 23 patients, primarily in a young pediatric population, averaging approximately 6.5 years of age, in a diverse group across gender and genetic cause of congenital HI. A key entry criterion was for patients to have continued hypoglycemia despite available therapies to be eligible for enrollment. We observed that patients enrolled on stable background therapies had clinically significant, and in many cases, substantial residual hypoglycemia as well as some hyperglycemia (> 180 mg/dL) at baseline.

Outcomes from the RIZE study were presented at the Pediatric Endocrine Society meeting on May 1, 2022. The results from the study showed that target and expected RZ358 concentrations were achieved and dose-exposure dependent responses were also observed. RZ358 was generally safe and well-tolerated and there were no adverse drug reactions, adverse events leading to study discontinuations, or dose-limiting toxicities. Importantly, RZ358 demonstrated an approximately 50% improvement in hypoglycemia across all doses and cohorts and an approximately 75% improvement in hypoglycemia at the 6 mg/kg and 9 mg/kg cohorts. Time in range by CGM improved 8% across all doses, 16% at the top dose, and more significantly (>25%) in patients without baseline hyperglycemia on SOC.

We believe that the positive results from the RIZE study will be Phase 3 enabling and accordingly we have initiated interactions with regulatory authorities in the US and Europe. Our objective is to complete the regulatory dialogue prior to the end of the first quarter of calendar year 2023, which would facilitate initiation of a Phase 3 study in the first half of calendar year 2023.

RZ402

Our second clinical asset, RZ402, is an oral plasma kallikrein inhibitor ("PKI") being developed as a potential therapy for the chronic treatment of diabetic macular edema ("DME"). DME is a vascular complication of diabetes and a leading cause of blindness in the US and elsewhere. Chronic exposure to high blood sugar levels can lead to inflammation, cell damage, and the breakdown of blood vessel walls. Specifically, in DME, blood vessels behind the back of the eye become porous and permeable leading to the unwanted infiltration of fluid into the macula. This fluid leakage creates distorted vision, and if left untreated, blindness.

Currently available treatments for DME include anti-vascular growth factor (anti-VEGF) injections into the eye or laser surgery. RZ402 is designed to be a once daily oral therapy for the treatment of DME and unlike the anti-VEGF therapies, RZ402 targets the Kallikrein-Kinin System to address inflammation and vascular leakage. We believe that systemic exposure through oral delivery is critical to target the microvasculature behind the back of the eye. Further, as an oral therapy, RZ402 has the potential to substantially change the therapeutic paradigm for patients suffering with DME by providing a convenient, self-administered treatment option to encourage earlier initiation of therapy, adherence to prescribed treatment guidelines, and improved overall outcomes.

Results from our single ascending dose ("SAD") Phase 1a Study ("RZ402-101") were reported in May 2021. RZ402-101 was a first-in-human single-center, randomized, double-blind, placebo-controlled SAD study in healthy adult volunteers. The study objectives were to characterize the safety profile and pharmacokinetics of RZ402 administered as single oral doses. The study enrolled 30 individuals in three planned sequential dose- level cohorts of 25 mg, 100 mg, and 250 mg. Within each ten-subject dose cohort, volunteers were randomized 8:2 to receive either RZ402 oral solution or matched placebo. After receiving single doses, participants remained in the clinic for seven days for serial PK and safety assessments, before completing two outpatient follow-up visits at study days 14 and 30. Dose advancement proceeded following blinded reviews of safety and PK data from the preceding cohort(s).

Single doses of RZ402 resulted in dose-dependent increases in systemic exposure. Plasma concentrations of RZ402 significantly exceeded the 3.5 ng/mL target concentration that was pharmacologically active in animal models of DME for a 24-hour period after receipt of RZ402. Across the dose and exposure range, there were no serious adverse events, adverse drug reactions, or discontinuations due to adverse events, and no imbalance of adverse events between the treatment and placebo control groups. Similarly, regular laboratory, hemodynamic, cardiac, and ophthalmologic safety examinations were unremarkable.

Following the success of the SAD study, we undertook a follow-on multiple ascending dose ("MAD") study ("RZ402-102"). Results from the MAD Study were reported in February 2022. RZ402-102 was a single center, randomized, double-blind, placebo-controlled, in healthy adult volunteers. The objectives of the study were to characterize the repeat dose safety profile (including maximum tolerated dose) and PK of RZ402 administered as daily oral doses for two weeks. The study was conducted in 40 volunteers in sequential ascending dose cohorts with 10 individuals per cohort. Within each cohort, participants were randomized in an 8:2 ratio to receive either RZ402 as an oral solution or a placebo. Participants remained in the clinic throughout the two-week dosing period for serial PK and safety assessments, before completing an outpatient follow-up visit at study day 28. Blood biomarkers of target engagement (kallikrein activity) were explored as a systemic surrogate for DME, using a precedent from studies of kallikrein inhibitors in a systemic vascular leakage syndrome (hereditary angioedema). Dose advancement proceeded in staggered fashion every three weeks as appropriate, following blinded reviews of data from the preceding cohort(s).

The MAD study showed dose-dependent increases in systemic exposures, with repeat-dosing to steady-state resulting in the highest concentrations of RZ402 explored to date, exceeding 200 ng/mL and 50 ng/mL at peak and 24-hour trough, respectively. Following the precedent established in hereditary angioedema, steady-state plasma kallikrein activity in human plasma was measured on Day 14 as a biomarker of RZ402 target engagement. Daily dosing with RZ402 inhibited plasma kallikrein in a dose and concentration-dependent manner ($r=0.74$; $p < 0.001$). Given that the in-vivo EC90 for RZ402 in animal models of DME is ~6 ng/mL, the results at both peak and 24-hour trough substantially exceeded target concentrations based on a combination of in-vitro and in-vivo profiling. RZ402 was generally safe and well-tolerated, including at higher doses than previously tested in the SAD study. There were no serious adverse events, adverse drug reactions or identified risks.

We are advancing developmental activities toward a Phase 2a proof-of-concept study, which we plan to initiate during the fourth quarter of calendar year 2022. Dosing of the first patient in a Phase 2 study will trigger a developmental milestone payment of $3.0 million due to ActiveSite Pharmaceuticals.

Factors Impacting our Results of Operations

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

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

Key Components of Consolidated Statements of Operations

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

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

Interest and other income. Interest and other income consist primarily of interest income earned on temporary cash investments.

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

Employee retention credit. In response to the COVID-19 pandemic, the United States government has designed programs to assist businesses in dealing with the financial hardships caused by the pandemic. We recognize the right to receive governmental assistance payments in the period in which the related conditions on which they depend are substantially met.

Interest expense. The components of interest expense include the amount of interest payable in cash at the stated interest rate, and accretion of debt discounts and issuance costs ("DDIC") using the effective interest method. DDIC arises from the issuance of debt instruments and other related contracts or agreements which possess certain terms and conditions resulting in additional financing costs arising from origination, exit and final fees, and other incremental and direct costs incurred to consummate the financing.

Critical Accounting Policies and Significant Judgments and Estimates

Overview

The discussion herein is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

With respect to our significant accounting policies that are described in Note 1 to our consolidated financial statements included in Item 8 of our 2022 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.

Accounting for Complex Financings

In order to account for complex financing transactions, we are required to make judgments, assumptions, and estimates to determine the appropriate amounts reported in our consolidated financial statements. These financing transactions typically involve entering into several distinct legal agreements, whereby we are required to identify and account for each freestanding financial instrument separately. The freestanding financial instruments may be classified as debt, temporary equity or permanent equity instruments depending on the results of our evaluation. In addition, we evaluate if any of the financial instruments contain embedded features that are required to be accounted for as derivatives at fair value. Each freestanding financial instrument is required to be recognized at fair value on the closing date of the financing. The fair value of warrants is generally determined using the Black-Scholes-Merton ("BSM") valuation model and the fair value of common stock is based on the trading price of our shares on the closing date.

For financial instruments classified as debt, a discount is recognized if the stated principal balance exceeds the initial allocation of fair value as of the closing date. This discount is accreted to interest expense using the interest method that results in recognition of interest expense at a fixed rate through the expected maturity date.

Share-Based Compensation Expense

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

Research and Development

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

Clinical Trial Accruals

Clinical trial costs are a component of R&D expenses. We accrue and recognize expenses for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements

established with clinical research organizations and clinical trial sites. We determine the estimates through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. Nonrefundable advance payments for goods and services that will be used or rendered in future R&D activities, are deferred and recognized as expense in the period that the related goods are delivered, or services are performed.

Results of Operations

Three months ended September 30, 2022 and 2021

Revenue. As a clinical stage company, we did not generate any revenue for the three months ended September 30, 2022 and 2021. We are at an early stage of development and do not currently have any commercial products. Our existing product candidates will require extensive additional clinical evaluation, regulatory review, significant marketing efforts and substantial investment before they generate any revenues. We do not expect to be able to generate revenue from any of our product candidates for several years.

Research and development expenses. R&D expenses for the three months ended September 30, 2022 and 2021 were as follows (in thousands, except percentages):

			Increase	
	2022	2021	Amount	Percent
Total R&D expenses	$ 7,704	$ 5,774	$ 1,930	33 %

The increase in R&D expenses of $1.9 million for the three months ended September 30, 2022 was primarily attributable to compensation and benefits for our R&D workforce that increased by approximately $1.3 million. Approximately $0.6 million of this increase was attributable to an increase in share-based compensation related to stock options granted in June 2022. In addition, cash-based compensation and benefits increased by approximately $0.7 million that was primarily attributable to an increase in the average number of R&D employees from 23 for the three months ended September 30, 2021 to 33 for the three months ended September 30, 2022. In addition to the increases in compensation and benefits cost, an increase of $0.5 million was due to higher spending for RZ358 program related costs, primarily for Phase 3 readiness manufacturing costs.

General and administrative expenses. G&A expenses for the three months ended September 30, 2022 and 2021 were as follows (in thousands, except percentages):

			Increase	
	2022	2021	Amount	Percent
Total G&A expenses	$ 2,514	$ 1,866	$ 648	35 %

The increase in G&A expenses of $0.6 million for the three months ended September 30, 2022 was primarily attributable to an increase in share-based compensation expense of $0.5 million due to stock options granted to certain executives and employees in June 2022. An additional $0.1 million increase in other G&A was due to facilities and travel expenses as COVID related travel restrictions have diminished.

Interest and Other Income. Interest and other income amounted to $0.4 million for the three months ended September 30, 2022, whereas we did not earn any interest income for the three months ended September 30, 2021. The increase in interest income for the three months ended September 30, 2022 was primarily due to (i) an increase in excess of $100 million in cash balances held in interest bearing accounts, and (ii) an increase in interest rates for such temporary cash investments. The large increase in cash balances was attributable to the completion of equity financings between October 2021 and July 2022.

Employee Retention Credit. We did not generate any employee retention credit income for the three months ended September 30, 2022, compared to $0.2 million for the three months ended September 30, 2021. The income in the prior year was a result of CARES Act benefits. For the three months ended September 30, 2022, governmental assistance was not available under the CARES Act.

Interest Expense. We did not incur any interest expense for the three months ended September 30, 2022 due to the repayment of the Loan Agreement on June 30, 2022, whereas we incurred $0.4 million of interest expense for the three months ended September 30, 2021. Interest expense for the three months ended September 30, 2021 was solely attributable to the Loan Agreement and consisted of (i) interest expense of $0.3 million based on the weighted average contractual rate of 9.0%, and (ii) accretion of discount of $0.1 million.

Income Taxes. For the three months ended September 30, 2022 and 2021, we did not recognize any income tax benefit due to our net losses, and our determination that a valuation allowance was required for all of our deferred tax assets.

Liquidity and Capital Resources

Short-term Liquidity Requirements

As of September 30, 2022, we had cash and cash equivalents of $154.3 million and working capital was approximately $153.2 million. We have incurred cumulative net losses of $219.0 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, as well as proceeds from the issuance of debt securities. For the three months ended September 30, 2022, as discussed above under the caption *Recent Developments,* we issued common stock in the 2022 Private Placement that resulted in net proceeds of $11.6 million. For the fiscal year ended June 30, 2022, we received net proceeds from the issuance of equity securities of $165.2 million. The completion of these equity financings is the primary factor that resulted in our cash and cash equivalents balance of $154.3 million as of September 30, 2022. For further information about the key terms and results of our debt and equity financing activities, please refer to the discussion below under the captions *2022 Registered Direct Offering*, *2021 Underwritten Public Offering* and *2021 Registered Direct Offering*.

Our most significant contractual obligations consist of milestone payments pursuant to licensing agreements with XOMA Corporation ("XOMA") and ActiveSite Pharmaceuticals, Inc. ("ActiveSite") discussed below. Based on our expectations for the dates when certain clinical and regulatory milestones will be achieved, we anticipate that $5.0 million will be payable to XOMA and $3.0 million will be payable to ActiveSite within the next twelve months.

Based on our cash and cash equivalents balance of $154.3 million as of September 30, 2022, we believe we have adequate capital resources to meet all of our contractual obligations and conduct all planned activities to advance our clinical trials during through the fiscal quarter ending September 30, 2023.

Long-term Liquidity Requirements

Our most significant long-term contractual obligations consist of clinical and regulatory milestone payments up to $35.0 million payable to XOMA and up to $45.5 million in milestones payable to ActiveSite, for a total of $80.5 million. As discussed above, we expect that $5.0 million will be payable to XOMA and $3.0 million will be payable to ActiveSite during the next twelve months. Accordingly, the remainder of $72.5 million is considered a long-term liquidity requirement. Our current expectations are that we will incur additional milestone payments of $5.0 million payable to XOMA for the fiscal year ending June 30, 2024. Due to uncertainties in the timing associated with clinical trial activities and regulatory approvals, there is even greater uncertainty in forecasting the milestone payments to XOMA and ActiveSite during the fiscal year ending June 30, 2024 and thereafter.

Our long-term contractual obligations also include (i) operating lease payments up to approximately $0.7 million per year through calendar year 2027, and (ii) an exit fee of $0.6 million if we enter into certain transactions (defined as "Exit Events") prior to April 13, 2031. Exit Events include, but are not limited to, sales of substantially all assets, certain mergers, change of control transactions, and issuances of common stock that result in new investors owning more than 35% of the Company's shares. As discussed above under the caption *Recent Developments*, on June 30, 2022 we terminated the Loan Agreement with SLR. However, we remain contingently obligated to pay the $0.6 million exit fee.

The following discussion provides additional information about the ongoing requirements pursuant to our license agreements with XOMA and ActiveSite, along with additional information about our recent financing activities that impacted our liquidity and capital resources through September 30, 2022.

XOMA License Agreement

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

Upon the achievement of certain clinical and regulatory events, we will be required to make up to $35.0 million in aggregate milestone payments to XOMA. The first such milestone payment of $2.0 million was triggered upon enrollment of the last patient in our ongoing phase 2 clinical study in January 2022. The next milestone payment of $3.0 million will be due upon the enrollment of the first patient in a Phase 3 study, which we believe will occur in the next twelve months. Additionally, upon the future commercialization of RZ358, we will be required to pay royalties to XOMA based on the net sales of the related products, and milestone payments up to an additional $185.0 million if future annual sales related to RZ358 exceed targets ranging from $100.0 million to $1.0 billion. Through September 30, 2022, no events have occurred that would result in the requirement to make additional milestone payments and no royalties have been incurred.

ActiveSite License Agreement

In August 2017, we entered into a Development and License Agreement with ActiveSite ("ActiveSite License Agreement") pursuant to which we acquired the rights to ActiveSite's plasma kallikrein inhibitor portfolio (the "PKI Program"). We are planning to use the PKI Program to develop, file, manufacture, market and sell products for diabetic macular edema and other therapeutic indications. The ActiveSite License Agreement requires various milestone payments ranging from $1.0 million to $10.0 million when milestone events occur, up to an aggregate of $46.5 million of aggregate milestone payments. The first milestone payment for $1.0 million paid in December 2020 after completion of the preclinical work and submission of an IND to the FDA for RZ402. The next milestone payment for $5.0 million will be due upon enrollment of the first patient in a Phase 2 study, which we expect to occur within the next 12 months. We will also be required to pay royalties equal to 2.0% of any sales of products that use the PKI Program. Through September 30, 2022, no events have occurred that would result in the requirement to make additional milestone payments and no royalties have been incurred.

2022 Registered Direct Offering

On May 1, 2022, we entered into an underwriting agreement with Jefferies LLC, as representative of the underwriters listed therein, relating to the issuance and sale of equity securities in an underwritten registered direct offering (the "2022 RDO"). The 2022 RDO resulted in the issuance of (i) approximately 18.0 million shares of our common stock at a public offering price of $3.80 per share, (ii) Class A pre-funded warrants (the "Class A PFWs") to purchase up to 2.0 million shares of common stock at a public offering price of $3.799 per Class A PFW, and (iii) Class B pre-funded warrants (the "Class B PFWs") to purchase up to 10.9 million shares of common stock at a public offering price of $3.799 per Class B PFW. On May 4, 2022, the 2022 RDO closed resulting in net proceeds of approximately $110.1 million. The gross amount of the 2022 RDO was $117.6 million, before deduction of an aggregate of $7.1 million for underwriting discounts and approximately $0.4 million for professional fees and other offering expenses payable by us. We believe the additional funding from the 2022 RDO along with the funding received in July 2022 from the 2022 Private Placement provides us with sufficient cash to fund a Phase 3 clinical program for RZ358, as well as a Phase 2 proof of concept study for RZ402.

2021 Underwritten Public Offering and Registered Direct Offering

In October 2021, we entered into an underwriting agreement with Oppenheimer & Co., Inc., as representative of the underwriters listed therein (the "2021 Underwriters") for the planned issuance and sale of equity securities in an underwritten public offering (the "2021 Underwritten Offering"). On October 15, 2021, closing occurred for the 2021 Underwritten Offering resulting in the issuance of (i) 6,030,847 shares of common stock at $6.50 per share for gross proceeds of $39.2 million, and (ii) 1,661,461 pre-funded warrants to purchase 1,661,461 shares of common stock at an issuance price of $6.49 per warrant (the "2021 PFWs") for gross proceeds of $10.8 million. The Company granted the Underwriters a 30-day option to purchase up to an additional 1,153,845 shares of its common stock in the 2021 Underwritten Offering at a public offering price of $6.50 per share, less underwriting discounts and commissions (the "Underwriters' Option"). In November 2021, the Underwriters' Option was partially exercised for 116,266 shares resulting in gross proceeds of approximately $0.8 million. The aggregate gross proceeds from the 2021 Underwritten Offering amounted to $50.7 million, excluding the Underwriters' Option, and before deductions for underwriting commissions of 6.0% of the gross proceeds and other offering costs of approximately $0.3 million. After deducting total offering costs of $3.3 million, the net proceeds of the 2021 Underwritten Offering amounted to approximately $47.2 million.

Concurrently with the 2021 Underwritten Offering, Handok, an entity affiliated with a member of the Board of Directors, entered into a subscription agreement for a registered direct offering (the "2021 RDO") pursuant to which we agreed to sell to the Handok an aggregate of 769,231 shares of our common stock at a purchase price of $6.50 per share. The closing for the 2021 RDO occurred on October 27, 2021, whereby we received gross proceeds of $5.0 million.

EDA and LPC Financings

In December 2020, we entered into an Equity Distribution Agreement (the "EDA") with Oppenheimer & Co. Inc. as sales agent that provided for an "at the market offering" for the sale of up to $50.0 million in shares of our common stock (the "Placement Shares"). For the three months ended September 30, 2021, we sold 138,388 Placement Shares for which aggregate net proceeds of approximately $1.5 million were received. In August 2021, we entered into a purchase agreement (the "LPC Purchase Agreement") with Lincoln Park Capital Fund, LLC ("LPC"), that provided for issuances up to an aggregate of $20.0 million of shares of our common stock (the "Purchase Shares"). For the three months ended September 30, 2021, LPC purchased 115,708 shares of our common stock and we received net proceeds of $1.2 million. In May 2022, we terminated the EDA and the LPC Purchase Agreement whereby no further equity securities are issuable under these agreements.

Loan Agreement

In April 2021, we borrowed $15.0 million under the Loan Agreement discussed above under the caption Recent Developments. Outstanding borrowings under the Loan Agreement provided for interest at a floating rate equal to (a) 8.75% per annum plus (b) the greater of (i) the rate per annum published by the Intercontinental Exchange Benchmark Administration Ltd. for a term of one month and (ii) 0.12% per annum. On June 30, 2022, we paid off the outstanding loan amount of $15.0 million and terminated the Loan Agreement in accordance with its terms. In addition to the repayment of principal and accrued interest, we paid (i) a prepayment fee equal to 2.00% of the outstanding principal balance for a total of $300,000, and (ii) a final fee equal to 4.75% of the aggregate amount of the term loans funded for a total of $712,500. The terminated Loan Agreement was secured by substantially all of our assets. The security interests and liens granted in connection with the terminated Loan Agreement were released on June 30, 2022.

Cash Flows Summary

Presented below is a summary of our operating, investing, and financing cash flows for the three months ended September 30, 2022 and 2021 (in thousands):

	2022	2021	Change
Net cash provided by (used in):			
Operating activities	$ (7,589)	$ (6,341)	$ (1,248)
Investing activities	(70)	—	(70)
Financing activities	11,571	2,586	8,985

Cash Used in Operating Activities

For the three months ended September 30, 2022 and 2021, cash used in operating activities amounted to $7.6 million and $6.3 million, respectively. The key components in the calculation of our cash used in operating activities are as follows (in thousands):

	2022	2021	Change
Net loss	$ (9,831)	$ (7,836)	$ (1,995)
Non-cash expenses	1,918	1,028	890
Non-cash gains, net	—	(16)	16
Changes in operating assets and liabilities, net	324	483	(159)
Total	$ (7,589)	$ (6,341)	$ (1,248)

For the three months ended September 30, 2022, our net loss was $9.8 million compared to $7.8 million for the three months ended September 30, 2021. For further discussion about changes in our operating results for the three months ended September 30, 2022 and 2021, please refer to *Results of Operations* above.

For the three months ended September 30, 2022 and 2021, our non-cash expenses of $1.9 million and $1.0 million, respectively, were primarily attributable to share-based compensation expense, accretion of debt discount and issuance costs, and non-cash lease expense. For the three months ended September 30, 2022, net changes in operating assets and liabilities decreased operating cash flow by $0.3 million, primarily driven by an increase in prepaid expenses and other assets of $0.4 million, offset by a net decrease of $0.1 million in accounts payable and other accrued liabilities. For the three months ended September 30, 2021, net changes in operating assets and liabilities increased operating cash flow by $0.5 million, primarily driven by increased in accounts payable by $0.6 million, partially offset by an increase in prepaid expenses and other assets of $0.1 million.

Cash Provided by Investing Activities

For the three months ended September 30, 2022, our net cash utilized in investing activities amounted to $70,000, related to the purchase of furniture and equipment. We did not have any cash flows from investing activities for the three months ended September 30, 2021.

Cash Provided by Financing Activities

Net cash provided by financing activities for the three months ended September 30, 2022 amounted to $11.6 million. This amount consisted of proceeds of $12.3 million from the 2022 Private Placement. The total proceeds from the 2022 Private Placement of $12.3 million were partially offset by payments of $0.8 million for underwriting commissions and other costs related to this offering.

Net cash provided by financing activities for the three months ended September 30, 2021 amounted to $2.6 million. This amount included (i) $1.5 million of gross proceeds from the EDA and (ii) $1.2 million of gross proceeds from LPC purchase agreement. The total proceeds from equity financing activities amounted to $2.7 million and were partially offset by payments of $0.1 million related to financial advisory fees and other costs of equity financings.

Recent Accounting Pronouncements

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

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive and financial officer), of the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended ("Exchange Act"). Based on that assessment under those criteria, our management has determined that our internal control over financial reporting was not effective due to a material weakness in the system of internal control. A material weakness is a deficiency, or combination of deficiencies, that creates a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected in a timely manner.

The material weakness identified by management is primarily that due to our limited number of employees, we have not adequately segregated certain duties to prevent employees from overriding the internal control system. During the fiscal year ended June 30, 2022, we implemented a more robust accounting software that is expected to result in stronger controls. In October 2022, we hired additional personnel, which will enable us to better segregate many functions. We cannot provide assurance that these or other measures will eventually result in the elimination of the material weakness described above.

Changes in internal controls over financial reporting

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

None

Item 1A. Risk Factors.

Our risk factors are set forth under "Item 1A. Risk Factors" in our 2022 Form 10-K (referred to as our "Legacy Risk Factor Disclosures"). As of the date of this Report, there have been no material changes with respect to Legacy Risk Factor Disclosures.

You should carefully consider the Legacy Risk Factor Disclosures in addition to the other information set forth in this Report and in our 2022 Form 10-K, including the *Management's Discussion and Analysis of Financial Condition and Results of Operations* sections and the consolidated financial statements and related notes. These risks, some of which have occurred and any of which may occur in the future, can have a material adverse effect on our business, financial condition, results of operations or the prices of our publicly traded securities. The Legacy Risk Factor Disclosures are not the only risks we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, may occur or become material in the future and adversely affect our business, reputation, financial condition, results of operations or the prices of our publicly traded securities. Therefore, historical operating results, financial and business performance, events and trends are often not a reliable indicator of future operating results, financial and business performance, events or trends.

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

On May 1, 2022, we entered into a placement agency agreement with Jefferies LLC, that provided for a private placement of equity securities (the "Private Placement") with Handok, Inc. and certain of its affiliates. The closing for the Private Placement occurred on July 22 and July 26, 2022, whereby we received gross proceeds of approximately $12.3 million in exchange for the issuance of approximately 3.2 million shares of common stock at a purchase price of $3.80 per share. The net proceeds from the Private Placement amounted to approximately $11.6 million after deduction of $0.7 million for underwriting commissions. The securities that were sold in the Private Placement were offered and sold pursuant to an exemption from the registration requirements under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Number	Description of Exhibits
10.1	Form of Amended and Restated Securities Purchase Agreement, dated as of July 22, 2022 (*incorporated by reference to Exhibit 10.22 of the Company's Form 10-K filing on September 15, 2022*)
31.1*	Certification of Chief Executive and Principal Financial Officer as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1*	Certification of Chief Executive and Principal Financial Officer as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS*	Inline XBRL Instance Document
101.SC*	Inline XBRL Taxonomy Extension Schema
101.CA*	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase
101.LA*	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File, formatted in Inline XBRL (included as Exhibit 101)

* Filed herewith.

SIGNATURES

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

REZOLUTE, INC.

Date: November 9, 2022

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

EXHIBIT 31.1

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

I, Nevan Charles Elam, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2022

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

EXHIBIT 32.1

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

In connection with the quarterly report of Rezolute, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022, 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 9, 2022

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

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