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

FORM 10-Q

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

For the quarterly period ended September 30, 2021
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 of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
201 Redwood Shores Parkway, Suite 315, Redwood City, California	**94065**
(Address of Principal Executive Offices)	(Zip Code)

(650) 206-4507
(Registrant's Telephone Number, including Area Code)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files.). ☒ Yes ☐ No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, and an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 17(a)(2)(B) of the Securities Act. ☐

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

The registrant had 15,440,250 shares of its $0.001 par value common stock outstanding as of November 10, 2021.

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:

- projected operating or financial results, including anticipated cash flows used in operations;
- expectations regarding capital expenditures, research and development expense and other payments;
- our expectation that the disruptive impact 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 or unknown risks, uncertainties and other factors including, but not limited to, the risks described in "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended June 30, 2021 (the "2021 Form 10-K"), filed with the Securities and Exchange Commission ("SEC") on September 15, 2021 and as amended on September 27, 2021.

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.

Special Note About COVID-19

We have been actively monitoring the COVID-19 situation and its impact. 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 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 fiscal quarter ended September 30, 2021 and the fiscal year ended June 30, 2021 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 variant, resurgences in number of rates of infections, 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, as well as our preclinical studies and clinical trial timeliness remains 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 consolidated financial position, results of operations and cash flows. We will continue to monitor the situation closely.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

Rezolute, Inc.

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

	September 30, 2021	June 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 37,292	$ 41,047
Prepaid expenses and other	1,053	946
Total current assets	38,345	41,993
Long-term assets:		
Right-of-use assets, net	317	396
Deferred offering costs and other	72	191
Property and equipment, net	26	29
Total assets	$ 38,760	$ 42,609
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,592	$ 1,035
Accrued liabilities:		
Compensation and benefits	—	77
Insurance premiums	121	242
Other	679	349
Current portion of operating lease liabilities	206	265
Total current liabilities	2,598	1,968
Long-term liabilities:		
Long term debt, net of discount	14,071	13,968
Embedded derivative liabilities	371	387
Operating lease liabilities, net of current portion	161	187
Total liabilities	17,201	16,510
Commitments and contingencies (Notes 4 and 8)		
Shareholders' equity:		
Preferred Stock, $0.001 par value; 400 shares shares authorized as of September 30, 2021 and June 30, 2021; no shares issued and outstanding	—	—
Common Stock, $0.001 par value, 40,000 shares authorized as of September 30, 2021 and June 30, 2021; 8,640 and 8,352 shares issued and outstanding as of September 30, 2021 and June 30, 2021, respectively	9	8
Additional paid-in capital	197,524	194,229
Accumulated deficit	(175,974)	(168,138)
Total shareholders' equity	21,559	26,099
Total liabilities and shareholders' equity	$ 38,760	$ 42,609

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,	
	2021	2020
Operating expenses:		
Research and development	$ 5,774	$ 2,344
General and administrative	1,866	1,279
Total operating expenses	7,640	3,623
Operating loss	(7,640)	(3,623)
Non-operating income (expense):		
Employee retention credit	231	—
Gain on change in fair value of embedded derivative liability	16	—
Interest expense, net	(443)	3
Total non-operating income (expense), net	(196)	3
Net loss	$ (7,836)	$ (3,620)
Net loss per common share - basic and diluted	$ (0.92)	$ (0.62)
Weighted average number of common shares outstanding - basic and diluted	8,513	5,867

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

Rezolute, Inc.

Unaudited Condensed Consolidated Statements of Shareholders' Equity
(in thousands, except per share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Three Months Ended September 30, 2021:					
Balances as of 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 as of September 30, 2021	8,640	$ 9	$ 197,524	$ (175,974)	$ 21,559
Three Months Ended September 30, 2020:					
Balances as of June 30, 2020	5,867	$ 6	$ 154,595	$ (147,236)	$ 7,365
Share-based compensation	—	—	634	—	634
Fair value of warrants issued to consultants for services	—	—	3	—	3
Net loss	—	—	—	(3,620)	(3,620)
Balances as of September 30, 2020	5,867	$ 6	$ 155,232	$ (150,856)	$ 4,382

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,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,836)	$ (3,620)
Share-based compensation expense	842	634
Accretion of debt discount and issuance costs	104	—
Non-cash lease expense	78	59
Depreciation and amortization expense	4	3
Fair value of warrants issued for services	—	3
Change in fair value of derivative liability	(16)	—
Changes in operating assets and liabilities:		
(Increase) Decrease in prepaid expenses and other assets	(96)	72
Increase (decrease) in accounts payable	555	(107)
Increase (decrease) in other accrued liabilities	24	(195)
Decrease in license fees payable to Xoma	—	(400)
Net Cash Used In Operating Activities	(6,341)	(3,551)
CASH FLOWS FROM INVESTING ACTIVITIES	—	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	2,690	—
Cash payments for debt discount and issuance costs	(104)	—
Net Cash Provided by Financing Activities	2,586	—
Net decrease in cash, cash equivalents and restricted cash	(3,755)	(3,551)
Cash, cash equivalents and restricted cash at beginning of period	41,047	9,955
Cash, cash equivalents and restricted cash at end of period	$ 37,292	$ 6,404
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	92	70
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of commitment shares for deferred offering costs subsequently charged to equity	$ 450	$ —
Increase in payables for deferred offering costs	24	—

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

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

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

Nature of Operations

Rezolute, Inc. (the "Company") is a clinical stage biopharmaceutical company developing transformative therapies for metabolic diseases related to chronic glucose imbalance.

Change in Domicile

In June 2021, the Company merged with and into its wholly owned subsidiary, Rezolute Nevada Merger Corporation, a Nevada corporation ("Merger Sub"), pursuant to an Agreement and Plan of Merger, dated as of June 18, 2021 (the "Reincorporation Merger Agreement"), between the Company and Merger Sub, with Merger Sub as the surviving corporation (the "Reincorporation Merger"). At the effective time of the Reincorporation Merger (the "Effective Time"), the Merger Sub was renamed "Rezolute, Inc." and succeeded to the assets, continued its business and assumed its rights and obligations by operation of law. The Reincorporation Merger Agreement was approved by the Company's shareholders at the 2021 annual meeting of its shareholders held on May 26, 2021.

Basis of Presentation

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

The condensed consolidated balance sheet as of June 30, 2021, 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 2021 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, 2021.

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 the 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, 2021 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, 2022.

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.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts in the 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, fair value of the embedded derivatives, 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 as discussed further in Note 2, and the future impact of COVID-19 as discussed in Note 8.

Significant Accounting Policies

The Company's significant accounting policies are described in Item 8 of the 2021 Form 10-K. For the three months ended September 30, 2021, the Company did not adopt any new accounting policies.

Recent Accounting Pronouncements

Standards Required to be Adopted in Future Years. The following accounting standards are 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 ASU 2016-13 will have a material impact on its consolidated financial statements as credit losses are not expected to be significant.

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 and is effective for smaller reporting companies for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years.

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.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 2 — LIQUIDITY

The Company is in the clinical stage and has not yet generated any revenues. For the three months ended September 30, 2021, the Company incurred a net loss of $7.8 million and net cash used in operating activities amounted to $6.3 million. For the fiscal year ended June 30, 2021, the Company incurred a net loss of $20.9 million and net cash used in operating activities amounted to $20.4 million. As of September 30, 2021, the Company had an accumulated deficit of $176.0 million, cash and cash equivalents of $37.3 million and total current liabilities of $2.6 million.

As discussed in Note 13, in October 2021 the Company completed an underwritten public offering for net proceeds of $46.7 million and a registered direct offering for net proceeds of $5.0 million, resulting in total net proceeds of approximately $51.7 million. If additional capital resources are required in the future, the Company has the ability to raise (i) additional debt financing proceeds up to $15.0 million if certain conditions are satisfied as discussed in Note 5, and additional equity financing proceeds as discussed in Note 6 under the captions *Equity Distribution Agreement* and *LPC Purchase Agreement*.

Management believes the Company's existing cash and cash equivalents balance of $37.3 million, combined with the net offering proceeds of $51.7 million received in October 2021 will be adequate to carry out currently planned activities into November 2022.

NOTE 3 — OPERATING LEASES

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

	September 30, 2021	June 30, 2021
Right-of-Use Assets, net	$ 317	$ 396
Operating Lease Liabilities:		
Current	$ 206	$ 265
Long-term	161	187
Total	$ 367	$ 452

For the three months ended September 30, 2021 and 2020, operating lease expense was as follows (in thousands):

	Three Months Ended September 30,	
	2021	2020
Research and development	$ 79	$ 49
General and administrative	23	24
Total	$ 102	$ 73

As of September 30, 2021, the weighted average remaining lease term under operating leases was 1.8 years, and the weighted average discount rate for operating lease liabilities was 7.1%. For the three months ended September 30, 2021 and 2020, cash paid for amounts included in the measurement of operating lease liabilities was $0.1 million. These cash payments were included in the determination of net cash used in operating activities in the condensed consolidated statements of cash flows.

Future payments under all operating lease agreements as of September 30, 2021 are as follows (in thousands):

Fiscal year ending June 30,		
Remainder of fiscal year 2022	$	192
2023		117
2024		79
Total lease payments		388
Less imputed interest		(21)
Present value of operating lease liabilities	$	367

NOTE 4 — LICENSE AGREEMENTS

Xoma License Agreement

In December 2017, the Company entered into a license agreement ("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 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.

Upon the achievement of certain clinical and regulatory events, the Company will be required to make up to $37.0 million in aggregate milestone payments to Xoma.

ActiveSite License Agreement

On August 4, 2017, the Company entered into a Development and 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 Development and License Agreement requires various milestone payments up to $46.5 million. 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 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 Development and License Agreement to date.

NOTE 5 — LOAN AND SECRUITY AGREEMENT

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) a $7.5 million term B loan to be funded upon request by the Company no later than January 25, 2022, and (iii) a $7.5 million term C loan to be funded upon request by the Company no later than September 25, 2022. Funding of the term B loan is subject to the Company's ability to obtain at least $35.0 million of equity or subordinated debt financing by January 2022 and the achievement of certain clinical milestones related to RZ358 and RZ402. Funding of the term C loan is subject to the Company's ability to (i) meet the conditions for funding the term B loan, and (ii) obtaining an additional $35.0 million of equity or subordinated debt financing, and the achievement of certain additional clinical milestones related to RZ358 and RZ402 by September 2022. Each term loan has a maturity date of April 1, 2026 (the "Maturity Date"). As discussed in Note 13, in October 2021 the Company completed an underwritten public offering for net proceeds of $46.7 million and a registered direct offering for net proceeds of $5.0 million, resulting in total net proceeds of approximately $51.7 million. As a result of the completion of these offerings, as well as equity issuances under the EDA and LPC Purchase Agreement during the three months ended September 30, 2021, we have met the financing threshold to qualify for the term B loan but will need to raise an additional $12.3 million to qualify for the term C loan. To date we have not achieved the clinical milestones to qualify for the term B and term C loans.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

In addition, the Company's cash and cash equivalents became subject to a blocked account control agreement ("BACA") in favor of the Lenders whereby a cash balance of at least $5.0 million must be maintained beginning on the earlier of (i) December 31, 2021, and (ii) the date the term B loan is funded. In the event of a default under the Loan Agreement, the BACA would enable the Lenders to prevent the release of funds from the Company's cash accounts.

Outstanding borrowings bear 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. ("IEBA") for a term of one month and (ii) 0.12% per annum. For the period from April 14, 2021 through September 30, 2021, the IEBA rate for a term of one month was approximately 0.12% per annum. Therefore, the contractual rate was 8.87% as of September 30, 2021 and June 30, 2021. The Company is permitted to make interest-only payments on each term loan through May 1, 2023. At the Company's request, the interest-only period can be extended until May 1, 2024, if the Company obtains at least $70.0 million of equity or subordinated debt financing by September 2022 and no event of default shall have occurred. The Company will be required to make monthly payments of principal and interest commencing at the end of the interest-only period.

The Company is obligated to pay the Lenders (i) a non-refundable facility fee in the amount of 1.00% of each term loan that is funded (the "Facility Fee"), and (ii) a final fee equal to 4.75% of the aggregate amount of the term loans funded (the "Final Fee"). As of September 30, 2021, the Company incurred debt discounts for an aggregate of $1.7 million that consisted of $0.5 million for financial advisory and legal fees, an aggregate of $0.8 million for the Facility Fee and the Final Fee, and an aggregate of $0.4 million as an exit fee as discussed below. The Final Fee is payable upon the earliest to occur of (i) the Maturity Date, (ii) the acceleration of the term loans, and (iii) the prepayment of the term loans. The total debt discount of $1.7 million related to the term A loan is being accreted to interest expense using the effective interest method which results in an overall current effective interest rate of 12.6% as of September 30, 2021 and June 30, 2021.

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 this embedded derivative for approximately $354,000. Fair value was determined 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 this embedded derivative is assessed at the end of each reporting period with changes in fair value recognized as a nonoperating gain or loss.

The Company has the option to prepay all, but not less than all, of the outstanding principal balance of the term loans. In the event of a voluntary or mandatory prepayment prior to the Maturity Date, the Company will incur a prepayment fee ranging from 1.00% to 3.00% of the outstanding principal balance.

The Company's obligations under the Loan Agreement are secured by a first-priority security interest in substantially all the Company's assets, including its intellectual property. This security interest will not be released until all obligations are repaid, including the requirement to pay an Exit Fee of $0.6 million for certain fundamental transactions that may occur through April 13, 2031. The Loan Agreement contains customary representations, warranties and covenants and also includes customary events of default, including payment defaults, breaches of covenants, and a default upon the occurrence of a material adverse change affecting the Company. Upon the occurrence of an event of default, a default interest rate of an additional 5.00% per annum may be applied to the outstanding loan balance, and the Lenders may declare all outstanding obligations immediately due and payable and exercise all their rights and remedies as set forth in the Loan Agreement.

As of September 30, 2021, the Company had outstanding contractual obligations under the Loan Agreement consisting of the principal balance of $15.0 million and the Final Fee of $0.7 million for a total of $15.7 million. After deducting the unaccreted discount of $1.6 million, the net carrying value was $14.1 million as of September 30, 2021. Future minimum principal payments and the net carrying value of the term A loan are as follows as of September 30, 2021 (in thousands):

Fiscal year ending June 30,	
2022	$ —
2023	833
2024	5,000
2025	5,000
2026	4,880
Total contractual payments	15,713
Less unaccreted debt discount	(1,642)
Net carrying value	$ 14,071

NOTE 6 — SHAREHOLDERS' EQUITY

Equity Distribution Agreement

On December 18, 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 is acting as sales agent and is required to use commercially reasonable efforts to sell all of the Placement Shares requested to be sold by the Company, consistent with the Agent's normal trading and sales practices, on mutually agreed terms between the Agent and the Company. The EDA will terminate when all of the Placement Shares have been sold, or earlier upon the election of either the Company or the Agent.

The Company has no obligation to sell any of the Placement Shares under the EDA. The Company intends to use the net proceeds, if any, from amounts sold under the EDA for general corporate purposes, including working capital. 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. Through 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. Accordingly, the maximum amount remaining for sale under the EDA amounts to approximately $48.5 million as of September 30, 2021.

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 of 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 can sell to LPC under the Purchase Agreement may not exceed 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 our common stock under the Purchase Agreement. Subject to the terms of the Purchase Agreement, the Company has 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"), which amounts may be increased under certain circumstances. LPC's committed obligation under any single Regular Purchase generally will not exceed $2.0 million. The Purchase Agreement provides for a purchase price per Purchase Shares 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.

In addition, on any date on which the Company submits a Regular Purchase Notice for the maximum amount allowed for such a Regular Purchase to LPC, the Company also has the right, in its sole discretion, to present LPC with an accelerated purchase notice (an "Accelerated Purchase Notice"), directing LPC to purchase an amount of Purchase Shares (an "Accelerated Purchase"), which number of Purchase Shares will not exceed the lesser of (i) 300% of the number of shares purchased pursuant to such Regular Purchase Notice and (ii) 30% of the total volume of shares of the common stock traded on the NCM during the Accelerated Purchase period. The Purchase Price per Purchase Share for each such Accelerated Purchase will be equal to the lesser of 97% of (i) the volume-weighted average price of the common stock on the NCM during the applicable Accelerated Purchase period on the applicable Accelerated Purchase date; and (ii) the closing sale price of the common stock on the NCM on the applicable Accelerated Purchase date.

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. Accordingly, LPC is obligated to purchase up to a maximum of $18.8 million under the Purchase Agreement as of September 30, 2021.

Pursuant to the RRA, the Company agreed to use its reasonable best efforts to maintain effectiveness of the registration statement and the related prospectus supplement within prescribed deadlines set forth in the RRA. In addition, the Company is required to use its reasonable best efforts to secure and maintain its listing of the Purchase Shares on the NCM. LPC has no obligation to purchase shares under the Purchase Agreement unless the Company complies with the terms of the RRA.

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, 2021 (in thousands):

Description	Termination Date	Number of Shares		
		Authorized	Outstanding	Available
2015 Plan	February 2020	50	50	—
2016 Plan	October 2021	313	313	—
2019 Plan	July 2029	200	200	—
2021 Plan	March 2030	1,200	766	434
Total		1,763	1,329	434

June 2021 Grants

On June 14, 2021, the Board of Directors granted stock options for an aggregate of approximately 0.7 million shares of common stock to certain officers, employees and independent directors at an exercise price of $12.28 per share (the "June 2021 Grants"). Stock options for an aggregate of approximately 0.5 million shares were granted to the Company's chief executive officer, independent directors and employees with less than one year of service that provide for vesting of 1/36th of the total award each month commencing on July 1, 2021, and stock options for approximately 0.2 million shares granted to employees with more than one year of service that provided for vesting of 25% of the award on grant date with the remainder of the award vesting for approximately 2.1% the total award each month until full vesting occurs. The aggregate fair value of the June 2021 Grants was $7.3 million, of which $0.6 million was recognized in June 2021, $0.6 million was recognized for the three months ended September 30, 2021, and the remaining $6.1 million will be recognized over the future vesting periods.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Stock Options Outstanding

The following table sets forth a summary of the stock option activity under all of the Company's stock option plans for the three months ended September 30, 2021 (shares in thousands):

	Shares	Price [1]	Term [2]
Outstanding, June 30, 2021	1,285	$ 16.35	8.7
Granted	75	8.96	
Forfeited	(31)	22.67	
Outstanding, September 30, 2021	1,329	15.78	8.5
Vested, September 30, 2021	507	21.07	7.2

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

For the three months ended September 30, 2021, the aggregate fair value of stock options granted for approximately 0.1 million shares of common stock that provide solely for time-based vesting, amounted to $0.5 million or approximately $6.73 per share as of the grant dates. There were no stock options granted in the three months ended September 30, 2020. Fair value was computed using the BSM option-pricing model and will result in the recognition of compensation cost ratably over the expected vesting period of the stock options. For the three months ended September 30, 2021, the fair value of stock options that provide for time-based vesting was estimated on the date of grant using the BSM option-pricing model, with the following weighted-average assumptions:

Market price of common stock on grant date	$ 8.96
Expected volatility	92 %
Risk free interest rate	0.97 %
Expected term (years)	6.0
Dividend yield	0 %

Share-based compensation expense for the three months ended September 30, 2021 and 2020 is included under the following captions in the unaudited condensed consolidated statements of operations (in thousands):

	2021	2020
Research and development	$ 309	$ 321
General and administrative	533	313
Total	$ 842	$ 634

Unrecognized share-based compensation expense is approximately $8.6 million as of September 30, 2021. This amount is expected to be recognized over a remaining weighted average period of 2.5 years.

Warrants

The Company has issued warrants in conjunction with various debt and equity financings and for services. The following table sets forth a summary of the warrant activity for the three months ended September 30, 2021 (shares in thousands):

	Shares	Price[1]	Term[2]
Outstanding, June 30, 2021	1,252	$ 28.91	4.8
Warrants expired	(28)	82.50	
Outstanding, September 30, 2021	1,224	27.66	4.6

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

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 8 — COMMITMENTS AND CONTINGENCIES

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.

COVID-19

The current COVID-19 pandemic, which is impacting worldwide economic activity, poses risks that the Company or its employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. The extent to which COVID-19 impacts the Company's business, including its clinical trials and financial condition, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. As COVID-19 continues to spread around the globe, including the spread of more contagious and virulent variants, we could experience disruptions, including delays or difficulties in enrolling patients in our clinical trials, delays or difficulties in clinical site initiation, interruption of key clinical trial activities, delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials and delays in necessary interactions with local regulatory authorities. COVID-19 may also impact the Company's ability to raise additional capital on a timely basis or at all, which could negatively impact short-term and long-term liquidity.

Registration Rights Agreement

In connection with the Purchase Agreement further discussed in Note 6, the Company entered into a Registration Rights Agreement whereby it agreed to register all the shares issuable under the facility. The Company filed a prospectus supplement to meet this obligation in August 2021 and is required to maintain the effectiveness of the prospectus supplement on a reasonable best-efforts basis.

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, 2021, 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 or not 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

On September 15, 2020, the Company entered into an exclusive license agreement with Handok, Inc. (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 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.

NOTE 10 — INCOME TAXES

Income tax expense during interim periods is based on applying an estimated annual effective income tax rate to year-to-date operating results, plus any significant unusual or infrequently occurring items which are recorded in the interim period. The computation of the

annual estimated effective tax rate at 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, 2021 and 2020, 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 months ended September 30, 2021 and 2020.

NOTE 11 — NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to common shareholders by the weighted average number of common shares outstanding during the period. For the three months ended September 30, 2021 and 2020, basic and diluted net loss per share were the same since all common stock equivalents were anti-dilutive. As of September 30, 2021 and 2020, 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):

	2021	2020
Stock options	1,329	944
Warrants	1,224	618
Total	2,553	1,562

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 embedded derivative liabilities discussed in Note 5 were classified under Level 3 and were required to be measured and recorded at fair value on a recurring basis beginning on April 14, 2021. Fair value was determined based on management's assessment of the probability and timing of occurrence for the events that give rise to embedded derivatives using a discounted rate equal to the effective interest rate for the term A loan.

The following tables set forth a summary of changes in the fair value of the Company's embedded derivative liability for which fair value was determined by Level 3 inputs (in thousands):

	Embedded Derivatives
Balance, June 30, 2021	$ 387
Changes in fair value of embedded derivative liabilities	(16)
Balance, September 30, 2021	$ 371

Except for the embedded derivative liability, the Company did not have any other assets or liabilities measured at fair value on a recurring basis as of September 30, 2021 and June 30, 2021.

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, 2021 and June 30, 2021. 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, 2021 and 2010, 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, 2021, cash deposits have exceeded the amount of federal insurance provided on such deposits. As of September 30, 2021 and June 30, 2021, the Company had cash and cash equivalents with a single financial institution with an aggregate balance of $37.3 million and $41.0 million, respectively. The Company has never experienced any losses related to its investments in cash and cash equivalents.

NOTE 13 — SUBSEQUENT EVENTS

Underwritten Public Offering

On October 12, 2021, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Oppenheimer & Co., Inc., as representative of the underwriters listed therein (the "Underwriters") for the planned issuance and sale of equity securities in an underwritten public offering (the "Underwritten Offering"). On October 15, 2021, closing occurred for the 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 $6.49 per the Pre-Funded Warrants for gross proceeds of $10.8 million. The aggregate gross proceeds from the Underwritten Offering amounted to $50.0 million before deductions for underwriting discounts and 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 Underwritten Offering amounted to approximately $46.7 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 Underwritten Offering at a public offering price of $6.50 per share, less underwriting discounts and commissions (the "Underwriters' Option").

In connection with the Underwritten Offering, certain of the Company's officers and directors agreed not to sell or otherwise dispose of any common stock held by them through January 10, 2022 (the "Lock-Up Period"). In addition, the Company is prohibited from selling any shares of its common stock under the LPC Purchase Agreement or the EDA discussed in Note 6.

The Pre-Funded Warrants have an exercise price of $0.01 per share, which is subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. Each Pre-Funded Warrant is exercisable at any time and from time to time after issuance. In the event of certain corporate transactions, the holders of the Pre-Funded Warrants will be entitled to receive, upon exercise of the Pre-Funded Warrants, the kind and amount of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such transaction.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

The Pre-Funded Warrants do not entitle the holders thereof to any voting rights or any of the other rights or privileges to which holders of Common Stock are entitled.

Registered Direct Offering

Concurrently with the Underwritten Offering, a large shareholder (the "Purchaser") entered into a subscription agreement for a registered direct offering, pursuant to which the Company agreed to sell to the Purchaser an aggregate of 769,231 shares of the Company's common stock at a purchase price of $6.50 per share. The closing for the registered direct offering occurred on October 27, 2021 whereby the Company received gross proceeds of $5.0 million.

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.

Recent Developments

Lincoln Park Capital

In August 2021, we entered into the Purchase Agreement with LPC, which provides that we may sell to LPC up to $20.0 million of Purchase Shares. The aggregate number of shares that we can sell to LPC under the Purchase Agreement may not exceed 1,669,620 shares of our common stock, subject to certain exceptions set forth in the Purchase Agreement. Through September 30, 2021, we have issued an aggregate of 149,507 shares under the Purchase Agreement and have received gross proceeds of approximately $1.2 million.

Equity Offerings

On October 12, 2021, we entered into the Underwriting Agreement with the Underwriters for the planned issuance and sale of equity securities in the Underwritten Offering. On October 15, 2021, closing occurred for the 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 $6.49 per the Pre-Funded Warrants for gross proceeds of $10.8 million. The aggregate gross proceeds from the Underwritten Offering amounted to $50.0 million. We paid underwriting discounts and commissions of 6.0% of the gross proceeds or a total of approximately $3.0 million and other offering costs amount to $0.3 million. After deduction of all offering costs, the net proceeds of the Underwritten Offering amounted to approximately $46.7 million.

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

Please refer to our discussion under *Liquidity and Capital Resources* below and in Notes 6 and 13 to our unaudited condensed consolidated financial statements for further discussion of the LPC Purchase Agreement and the Underwritten Offering.

Special Note About COVID-19

We have been actively monitoring the COVID-19 situation and its impact. 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 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, 2021 and the fiscal year ended June 30, 2021 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 variant, resurgences in number of rates of infections, 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, as well as our preclinical studies and clinical trial timeliness remains 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 consolidated financial position, results of operations and cash flows. We will continue to monitor the situation closely.

Summary of Clinical Assets

Our lead clinical asset, RZ358, is an antibody therapy in Phase 2b development as a potential treatment for congenital hyperinsulinism ("**HI**"), an ultra-rare pediatric genetic disorder. In February 2020, we announced the initiation of the RZ358-606 Phase 2b study ("**RIZE**") globally at multiple study centers. Prior to COVID-19, we had planned to complete the RIZE study by the middle of calendar year 2021. In March 2020, we paused the RIZE study as a result of the COVID-19 pandemic. As the COVID-19 pandemic began to abate in different regions, we resumed clinical activities including trial site initiations and patient enrollment. Subject to COVID-19 conditions, we are expecting to report top-line results in the first quarter of calendar year 2022.

In addition, in the first half of calendar year 2020, we had positive interactions with the U.S. Food and Drug Administration ("**FDA**"). In June 2020, we announced that FDA granted us Rare Pediatric Disease ("**RPD**") designation for RZ358, which qualifies us to receive a priority review voucher ("**PRV**") upon marketing approval of the drug in congenital HI. Such a voucher could be redeemed to receive a priority review of a subsequent marketing application for any drug candidate in any disease indication. Further, we submitted the RIZE protocol to FDA which allows us to expand the study to clinical sites in the United States.

Our second clinical asset, RZ402, is a selective and potent plasma kallikrein inhibitor ("**PKI**") being developed as a potential oral therapy for the chronic treatment of diabetic macular edema ("**DME**"). RZ402 is currently in Phase 1 development. In January 2021, we dosed the first subject in the Phase 1a study, and in May 2021, we announced positive topline results whereby single dose oral administration of RZ402 resulted in plasma concentrations that substantially exceeded target pharmacologically-active drug levels, demonstrating the potential for once daily dosing. RZ402 was generally safe and well-tolerated at all doses tested, without dose-limiting toxicities. In August 2021, we announced the initiation in the Phase 1b multiple-ascending dose ("**MAD**") study and planned to be completed by the first quarter of calendar year 2022. If favorable results are also obtained in the Phase 1b study, we expect to advance developmental activities toward a Phase 2a proof-of-concept study during the second half of calendar year 2022.

RZ358

Congenital HI is an ultra-rare pediatric genetic disorder characterized by excessive production of insulin by the pancreas. If untreated, the elevated insulin levels in these patients 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 congenital HI and the current standard of care treatments are suboptimal. In some cases, pancreatic surgery is a treatment option, but this approach is invasive and may require repeat surgeries.

Our lead candidate, RZ358, is an intravenously administered human monoclonal antibody that binds to a unique site (allosteric) on the insulin receptor throughout the body, 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. 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 the hyperinsulinism and low blood sugar characteristic of diseases such as congenital HI. 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.

RZ358 received Pediatric Rare Disease Designation in the U.S. as well as Orphan Drug Designation in the U.S. and European Union. RZ358 is currently in Phase 2b development (the RIZE study, RZ358-606). The RIZE study is a multi-center, open-label, repeat-dose Phase 2b study of RZ358 in four sequential dosing cohorts of patients with congenital HI who are at least two years old and have residual low blood sugar (<70 mg/dL) that is inadequately controlled on existing therapies. In addition to safety and pharmacokinetic evaluations, continuous glucose monitoring ("**CGM**") and self-monitored blood glucose will be utilized to evaluate several glycemic efficacy endpoints. The primary endpoint is the time within a glucose target range of 70-180 mg/dL by CGM after week 8 of treatment compared to baseline.

RZ402

DME is a vascular complication of diabetes and a leading cause of blindness in the U.S. 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 left untreated, blindness.

Currently available treatments for DME involve frequent burdensome anti-vascular growth factor (anti-VEGF) injections into the eye or invasive laser surgery. RZ402 is designed to be a once daily oral therapy for the treatment of DME. Unlike the anti-VEGF therapies, RZ402 targets the Kallikrein–Kinin System in order 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 patients to initiate therapy sooner, adhere to prescribed treatment guidelines, and improve overall outcomes.

Factors Impacting our Results of Operations

We have not generated any revenues since our inception in March 2010. Since inception, we have engaged in organizational activities, conducted private placements to raise additional capital, built out a manufacturing suite and produced material for our lead product candidate under good laboratory practices ("**GLP**"), conducted studies using the GLP material, subsequently changed our strategy to a licensing model that resulted in disposal of our manufacturing assets, 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 any of our product candidates, we anticipate it will be some time before we generate substantial revenues, if ever. We expect to generate operating losses for the foreseeable future; therefore, we expect to continue efforts to raise additional capital to maintain our current operating plans beyond the next year. 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 consultants 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.

Gain on changes in fair value of derivative liability. We recognized liabilities for embedded derivatives in our debt agreements. Derivative liabilities are adjusted to fair value at the end of each reporting period until the derivative liability contracts are settled, expire, or 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. Any gains or losses reflected prior to the deficiency was cured will not be reversed.

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 2021 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.

Change in Fair Value of Derivative Liability

We recognize liabilities for embedded derivatives in our debt agreements. The determination of the fair value of the embedded derivatives includes subjective assumptions that can materially affect the fair value estimates. Derivative liabilities are adjusted to fair value at the end of each reporting period with changes in fair value reflected as a gain or loss in our unaudited condensed consolidated statements of operations.

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 granted which 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.

We have granted stock options with vesting that is dependent on achieving certain market, performance and service conditions ("**Hybrid Options**"). For purposes of recognizing compensation cost, we determine the requisite service period as the longest of the derived, implicit and explicit vesting periods for each of the market, performance and service conditions, respectively. Due to achievement of the performance condition, we began recognizing compensation cost using the grant date fair value in November 2020 and continuing through the end of the requisite service period. Determination of the requisite service period of the Hybrid Options was based on the date that the performance condition was achieved. If the Hybrid Options do not ultimately become exercisable due to the option holders' failure to achieve the requisite service period, any previously recognized compensation cost will be reversed. However, if the Hybrid Options do not ultimately become exercisable due to the failure to achieve the market condition, previously recognized compensation cost will not be reversed.

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, 2021 and 2020

Revenue. As a clinical stage company, we did not generate any revenue for the three months ended September 30, 2021 and 2020. We are at an early stage of development as a proprietary product specialty pharmaceutical company, and we 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 market any of our product candidates for several years.

Research and development expenses. R&D expenses for each of the three months ended September 30, 2021 and 2020 were as follows (in thousands, except percentages):

	Three Months Ended September 30,	
	2021	2020
Research and development expenses	$ 5,774	$ 2,344
Dollar increase	$ 3,430	
Precentage increase	146 %	

The increase in research and development expenses of $3.4 million for the three months ended September 30, 2021 was primarily attributable to an increase in clinical trial costs associated with RZ402 of approximately $1.3 million and RZ358 of approximately $0.9 million. The $1.3 million of costs for RZ402 was primarily attributable to the MAD study that was initiated in August 2021, as discussed above under the caption *Summary of Clinical Assets*. No clinical trial costs related to RZ402 were incurred for the three months ended September 30, 2020. Aside from clinical trial costs, we had an increase of approximately $0.6 million in compensation and benefits for our R&D workforce that was primarily attributable to increased headcount.

General and administrative expenses. G&A expenses for each of the three months ended September 30, 2021 and 2020 were as follows (in thousands, except percentages):

	Three Months Ended September 30,	
	2021	2020
General and Administrative expenses	$ 1,866	$ 1,279
Dollar increase	$ 587	
Precentage increase	46 %	

The increase in general and administrative expenses of $0.6 million for the three months ended September 30, 2021 was primarily attributable to an increase in professional fees associated with corporate development activities, consulting services, and strategic financial advisory services. In addition, there was an increase in share-based compensation expense primarily due to a grant of stock options to G&A employees and directors in June 2021.

Employee Retention Credit. Employee retention credit income was $0.2 million for the three months ended September 30, 2021. This income is a result of of the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act benefits we qualified for during the fiscal quarter. We did not qualify for any employee retention credits in the same period in 2020

Interest Expense. Interest expense was approximately $0.4 million for the three months ended September 30, 2021, whereas we did not incur any interest expense for the same period in 2020. Interest expense for the three months ended September 30, 2021 was solely attributable to the Loan Agreement entered into in April 2021 and consisted of (i) interest expense of $0.3 million based on the contractual rate of 8.87%, and (ii) accretion of discount of $0.1 million.

Income Taxes

For the three months ended September 30, 2021 and 2020, we did not recognize any income tax benefit due to our net losses and our determination that a full valuation allowance was required for our deferred tax assets.

Liquidity and Capital Resources

As of September 30, 2021, we had cash and cash equivalents totaling approximately $37.3 million and working capital was approximately $35.7 million. We have incurred cumulative net losses of $176.0 million since our inception, and as a clinical stage company we have not generated any revenue to date.

As discussed above under the caption *Recent Developments,* in August 2021 we entered into the Purchase Agreement with LPC that provides for issuances of common stock up to an aggregate of $20.0 million. The aggregate number of shares that we can sell to LPC under the Purchase Agreement may not exceed 1,669,620 shares of our common stock, subject to certain exceptions set forth in the Purchase Agreement. Through September 30, 2021, we have issued an aggregate of 149,507 shares under the Purchase Agreement and have received gross proceeds of approximately $1.2 million.

In December 2020, we entered into the EDA with Oppenheimer & Co. Inc. as sales agent that provides for an "at the market offering" for the sale of up to $50.0 million in Placement Shares. For the period from July 1, 2021 through September 30, 2021, we sold 138,388 shares of our common stock for which aggregate net proceeds of approximately $1.5 million were received. Accordingly, we may sell up to an additional $48.5 million under the EDA.

In April 2021, we 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) a $7.5 million term B loan to be funded upon our request no later than January 25, 2022, and (iii) a $7.5 million term C loan to be funded upon our request no later than September 25, 2022. Funding of the term B loan was subject to our ability to obtain at least $35 million of equity or subordinated debt financing by January 2022 and the achievement of certain clinical milestones related to RZ358 and RZ402. Funding of the term C loan is subject to our ability to meet the conditions for funding the term B loan, plus obtaining an additional $35 million of equity or subordinated debt financing by September 2022 and the achievement of certain additional clinical milestones related to RZ358 and RZ402. Each term loan has a maturity date of April 1, 2026 (the "Maturity Date"). We are permitted to make interest-only payments on each term loan at least through May 1, 2023.

As a result of the completion of the Underwritten Offering and the registered direct offering in October 2021 for gross proceeds of $55.0 million, as well as equity issuances under the EDA and LPC Purchase Agreement during the three months ended September 30, 2021, we have met the financing threshold to qualify for the term B loan but will need to raise an additional $12.3 million to qualify for the term C loan. To date we have not achieved the clinical milestones to qualify for the term B and term C loans. No assurance can be provided that we will meet the requirements to qualify for the term B and term C loans and, even if we do qualify for this funding, no assurance can be provided that we would elect to request it.

As a condition of the Loan Agreement, our cash and cash equivalents became subject to a blocked account control agreement ("BACA") in favor of the Lenders whereby a cash balance of at least $5.0 million must be maintained beginning on the earlier of (i) December 31, 2021, and (ii) the date the term B loan is funded. In the event of a default under the Loan Agreement, the BACA would enable the Lenders to prevent the release of funds from our cash accounts until the default is cure or waived. For additional information about the Loan Agreement, please refer to Note 5 to the financial statements included in Part I, Item 1 of this Report.

We believe our existing cash and cash equivalents balance of $37.3 million as of September 30, 2021, combined with the public offering and registered direct offering net proceeds of $51.7 million received in October 2021 will be adequate to carry out currently planned activities into November 2022.

Cash Flows Summary

Presented below is a summary of our operating, investing and financing cash flows for the three months ended September 30, 2021 and 2020 (in thousands):

	2021	2020	Change
Net cash provided by (used in):			
Operating activities	$ (6,341)	$ (3,551)	$ (2,790)
Investing activities	—	—	—
Financing activities	2,586	—	2,586

Cash Flows Used in Operating Activities

For the three months ended September 30, 2021 and 2020, cash flows used in operating activities amounted to $6.3 million and $3.6 million, respectively. The key components in the calculation of our cash used in operating activities are as follows (in thousands):

	2021	2020	Change
Net loss	$ (7,836)	$ (3,620)	$ (4,216)
Non-cash expenses	1,028	699	329
Non-cash gains	(16)	—	(16)
Changes in operating assets and liabilities, net	483	(630)	1,113
Total	$ (6,341)	$ (3,551)	$ (2,790)

For the three months ended September 30, 2021, our net loss was $7.8 million compared to $3.6 million for the three months ended September 30, 2020. For further discussion about changes in our operating results for the three months ended September 30, 2021 and 2020, please refer to *Results of Operations* above.

For the three months ended September 30, 2021 and 2020, our non-cash expenses of $1.0 million and $0.7 million, respectively, were primarily attributable to share-based compensation expense. 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. For the three months ended September 30, 2020, net changes in operating assets and liabilities decreased operating cash flow by $0.6 million, primarily driven by a reduction in accrued liabilities of $0.6 million.

Cash Flows Provided by Investing Activities

We did not have any cash flows from investing activities for the three months ended September 30, 2021 and 2020.

Cash Flows Provided by Financing Activities

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.

We did not have any cash flows from financing activities for the three months ended September 30, 2020.

Recent Accounting Pronouncements

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

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 required for smaller reporting companies.

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, as of June 30, 2021, our internal control over financial reporting was not effective due to two material weaknesses 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 first material weakness identified by management is 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 our fiscal year ended June 30, 2021, we hired a VP of Finance and we implemented additional procedures to improve our segregation of duties. However, without hiring additional personnel we have been unable to fully remediate this material weakness. We cannot provide assurance that these or other measures will eventually result in the elimination of the material weakness described above.

In March 2021, we identified a second material weakness that resulted from ineffective treasury controls over review of outstanding authorized shares and requirements for all securities and contracts to issue common shares to ensure adequate authorized shares exist. This material weakness occurred in February 2021 when we decided to file a Charter Revision that changed our authorized shares of capital stock in the same 50 shares for one share ratio that applied to our issued shares of common stock, stock options and warrants pursuant to a reverse stock split that was effected in October 2020. The impact of this adjustment caused an immediate reduction in our authorized shares of common stock from 500,000,000 shares to 10,000,000 shares. Accordingly, after the Charter Revision we did not have a sufficient number of authorized shares of common stock in the event that all of our outstanding stock options and warrants are subsequently exercised.

On May 26, 2021, our shareholders voted to approve motions to reincorporate from the state of Delaware to the state of Nevada and to increase our authorized shares of common stock from 10,000,000 shares to 40,000,000 shares. Accordingly, the authorized share deficiency that occurred in February 2021 was cured on May 26, 2021, such that we have an adequate number of shares of common stock whereby all outstanding stock options and warrants may be exercised in exchange for shares of common stock. In addition to the shareholder approvals to reincorporate and increase our authorized shares, we are implementing procedures to ensure that our Board of Directors provides explicit approval for all future charter amendments, and all future issuances of shares of our common stock and any warrants and stock options that are not subject to a plan approved by our shareholders. We cannot provide assurance that these or other measures will eventually result in the elimination of this material weakness.

Changes in internal controls over financial reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2021 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.

Certain factors exist which may affect the Company's business and could cause actual results to differ materially from those expressed in any forward-looking statements. Factors that could cause our actual results to differ materially from those in this Report are any of the risks described in Item 1.A. *Risk Factors* of our 2021 Form 10-K, and the risk factor discussed below. Any of these factors could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations.

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

There were no reportable issuances of unregistered shares of the Company's equity securities for the period covered by this Report.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description of Exhibits
10.1	Purchase Agreement, dated as of August 2, 2021 by and between the Company and Lincoln Park Capital Fund, LLC *(incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filing on August 4, 2021)*
10.2	Registration Rights Agreement, dated as of August 2, 2021 by and between the Company and Lincoln Park Capital Fund, LLC *(incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filing on August 4, 2021)*
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 (Embedded within the Inline XBRL document and included in Exhibit)

* 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 12, 2021

By: /s/ Nevan Elam
Nevan 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 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 12, 2021

By: /s/ Nevan Elam
Nevan 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, 2021, 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 12, 2021

By: /s/ Nevan Elam
Nevan 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.