

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

FORM 10-Q

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

For the quarterly period ended March 31, 2022

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-39683

**REZOLUTE, INC.**

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or other jurisdiction of incorporation or organization)

27-3440894

(I.R.S. Employer Identification No.)

201 Redwood Shores Parkway, Suite 315, Redwood City, California

(Address of principal executive offices)

94065

(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 33,582,831 shares of its \$0.001 par value common stock outstanding as of May 6, 2022.

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## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

- our projected operating or financial results, including anticipated cash flows used in operations;
- our expectation that our shareholders will approve an increase in our authorized shares of common stock;
- our expectations that closing will occur in May 2022 under a securities purchase agreement entered into on May 4, 2022 with Handok, Inc. and certain of its affiliates;
- our expectations regarding capital expenditures, research and development expenses and other payments;
- our expectation about the extent and duration of the COVID-19 pandemic on our business;
- our beliefs and assumptions relating to our liquidity position, including our ability to obtain additional financing;
- our ability to obtain regulatory approvals for our pharmaceutical drugs and diagnostics; and
- our future dependence on third party manufacturers or strategic partners to manufacture any of our pharmaceutical drugs and diagnostics that receive regulatory approval, and our ability to identify strategic partners and enter into license, co-development, collaboration or similar arrangements.

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

**PART I - FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS.****Rezolute, Inc.****Unaudited Condensed Consolidated Balance Sheets  
(In thousands, except per share amounts)**

	<u>March 31,</u> <u>2022</u>	<u>June 30,</u> <u>2021</u>
<b><u>Assets</u></b>		
Current assets:		
Cash and cash equivalents	\$ 63,416	\$ 41,047
Prepaid expenses and other	915	946
Total current assets	<u>64,331</u>	<u>41,993</u>
Long-term assets:		
Restricted cash	5,000	—
Right-of-use assets, net	175	396
Deferred offering costs and other	48	191
Property and equipment, net	19	29
Total assets	<u>\$ 69,573</u>	<u>\$ 42,609</u>
<b><u>Liabilities and Shareholders' Equity</u></b>		
Current liabilities:		
Accounts payable	\$ 1,557	\$ 1,035
Accrued liabilities:		
Insurance premiums	—	242
Compensation and benefits	450	77
Other	764	349
Current portion of operating lease liabilities	107	265
Total current liabilities	<u>2,878</u>	<u>1,968</u>
Long term liabilities:		
Long term debt, net of discount	14,286	13,968
Operating lease liabilities, net of current portion	107	187
Embedded derivative liabilities	395	387
Total liabilities	<u>17,666</u>	<u>16,510</u>
Commitments and contingencies (Notes 4 and 8)		
Shareholders' equity:		
Preferred Stock, \$0.001 par value; 400 shares authorized; no shares issued and outstanding	—	—
Common Stock, \$0.001 par value, 40,000 shares authorized; 15,556 and 8,352 shares issued and outstanding as of March 31, 2022 and June 30, 2021, respectively	16	8
Additional paid-in capital	251,666	194,229
Accumulated deficit	<u>(199,775)</u>	<u>(168,138)</u>
Total shareholders' equity	<u>51,907</u>	<u>26,099</u>
Total liabilities and shareholders' equity	<u>\$ 69,573</u>	<u>\$ 42,609</u>

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)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>March 31,</b>		<b>March 31,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
Operating expenses:				
Research and development	\$ 8,686	\$ 3,758	\$ 23,912	\$ 10,598
General and administrative	2,068	1,725	6,632	5,660
Total operating expenses	10,754	5,483	30,544	16,258
Operating loss	(10,754)	(5,483)	(30,544)	(16,258)
Non-operating income (expense):				
Interest expense	(442)	—	(1,329)	—
Gain (loss) from change in fair value of derivative liabilities	(12)	1,784	(8)	1,784
Employee retention credit	—	—	231	—
Interest and other income	—	4	13	62
Total non-operating income (expense), net	(454)	1,788	(1,093)	1,846
Net loss	\$ (11,208)	\$ (3,695)	\$ (31,637)	\$ (14,412)
Net loss per common share - basic and diluted	\$ (0.65)	\$ (0.44)	\$ (2.30)	\$ (1.94)
Weighted average number of common shares outstanding - basic and diluted	17,218	8,352	13,748	7,445

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

Rezolute, Inc.

Unaudited Condensed Consolidated Statements of Shareholders' Equity  
 Nine Months Ended March 31, 2022 and 2021  
 (In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
<b>Nine Months Ended March 31, 2022:</b>					
Balances, June 30, 2021	8,352	\$ 8	\$ 194,229	\$ (168,138)	\$ 26,099
Gross proceeds from issuance of equity securities for cash in Underwritten Public Offering:					
Common Stock	6,147	6	39,950	—	39,956
2021 pre-funded warrants	—	—	10,783	—	10,783
Gross proceeds from issuance of common stock for cash:					
In 2021 registered direct offering	769	1	4,999	—	5,000
Under Equity Distribution Agreement	138	1	1,518	—	1,519
Under LPC Purchase Agreement	116	—	1,172	—	1,172
Underwriting discounts and other equity offering costs	—	—	(4,136)	—	(4,136)
Share-based compensation	—	—	2,701	—	2,701
Commitment shares issued under LPC Purchase Agreement	34	—	450	—	450
Net loss	—	—	—	(31,637)	(31,637)
Balances, March 31, 2022	<u>15,556</u>	<u>\$ 16</u>	<u>\$ 251,666</u>	<u>\$ (199,775)</u>	<u>\$ 51,907</u>
<b>Nine Months Ended March 31, 2021:</b>					
Balances, June 30, 2020	5,867	\$ 6	\$ 154,595	\$ (147,236)	\$ 7,365
Share-based compensation	—	—	2,305	—	2,305
Fair value of warrants issued to consultants for services	—	—	8	—	8
Issuance of common stock for cash	2,485	2	40,998	—	41,000
Advisory fees and other offering costs related to issuance of Units	—	—	(3,550)	—	(3,550)
Issuance of common stock for services	—	—	7	—	7
Reclassification of derivative liability for authorized share deficiency	—	—	(3,591)	—	(3,591)
Net loss	—	—	—	(14,412)	(14,412)
Balances, March 31, 2021	<u>8,352</u>	<u>\$ 8</u>	<u>\$ 190,772</u>	<u>\$ (161,648)</u>	<u>\$ 29,132</u>

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

**Rezolute, Inc.**  
**Unaudited Condensed Consolidated Statements of Cash Flows**  
**(In thousands)**

	Nine Months Ended	
	March 31,	
	2022	2021
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (31,637)	\$ (14,412)
Share-based compensation expense	2,701	2,305
Accretion of debt discount and issuance costs	319	—
Non-cash lease expense	221	214
Depreciation and amortization expense	10	10
Loss (gain) from change in fair value of derivative liabilities	8	(1,784)
Fair value of warrants issued for services	—	8
Fair value of shares of common stock issued for services	—	7
Changes in operating assets and liabilities:		
Decrease in prepaid expenses and other assets	17	376
Increase (decrease) in accounts payable	548	(81)
Increase (decrease) in other accrued liabilities	307	(45)
Decrease in license fees payable to Xoma	—	(1,809)
<b>Net Cash Used in Operating Activities</b>	<b>(27,506)</b>	<b>(15,211)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
	—	—
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from 2021 Underwritten Public Offering	50,738	—
Proceeds from 2021 Registered Direct Offering	5,000	—
Proceeds from issuance of Units	—	41,000
Payment of commissions and other deferred offering costs	(3,449)	(3,680)
Payment for debt discount and issuance costs	(104)	(75)
Proceeds from issuances of common stock	2,690	—
<b>Net Cash Provided by Financing Activities</b>	<b>54,875</b>	<b>37,245</b>
Net increase in cash, cash equivalents and restricted cash	\$ 27,369	\$ 22,034
Cash, cash equivalents and restricted cash at beginning of period	41,047	9,955
Cash, cash equivalents and restricted cash at end of period	<b>\$ 68,416</b>	<b>\$ 31,989</b>
<b>CASH, CASH EQUIVALENTS AND RESTRICTED CASH:</b>		
Cash and cash equivalents, end of period	63,416	31,989
Restricted cash, end of period	5,000	—
<b>Total cash, cash equivalents and restricted cash, end of period</b>	<b>\$ 68,416</b>	<b>\$ 31,989</b>
<b>SUPPLEMENTARY CASH FLOW INFORMATION:</b>		
Cash paid for interest	\$ 1,011	\$ —
Cash paid for income taxes	—	—
Right-of-use assets acquired in exchange for operating lease liabilities	—	302
Cash paid for amounts included in the measurement of operating lease liabilities	254	275
<b>NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Issuance of commitment shares for deferred offering costs subsequently charged to additional paid-in capital	\$ 450	\$ —
Reclassification of warrants and stock options from equity to derivative liability due to authorized share deficiency	—	3,591
Increase in payables for debt issuance costs	—	16
Furniture and equipment received as inducement under operating lease	—	10

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

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

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

***Nature of Operations***

Rezolute, Inc. (the “Company”) is a 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”), 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”), the rules and regulations of the SEC for interim financial information, and the instructions to Form 10-Q and Article 8 of Regulation S-X.

The condensed consolidated balance sheet as of June 30, 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 information and footnote disclosures necessary for a comprehensive presentation of financial position, results of operations, and cash flows. It is management’s opinion, however, that all material adjustments (consisting of normal recurring adjustments) that are necessary for a fair financial statement presentation have been made. The interim results for the three and nine months ended March 31, 2022 are not necessarily indicative of the financial condition and results of operations that may be expected for any future interim period or for the fiscal year ending June 30, 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 unaudited condensed consolidated financial statements and the accompanying notes. The Company bases its estimates and assumptions on current facts, historical experience, and various other factors that it believes are reasonable under the circumstances, to determine the carrying values of assets and liabilities that are not readily apparent from other sources. The Company's significant accounting estimates include, but are not necessarily limited to, the fair value of derivative liabilities, fair value of share-based payments, management's assessment of going concern, and clinical trial accrued liabilities. Actual results could differ from those estimates.

***Risks and Uncertainties***

The Company's operations may be subject to significant risks and uncertainties including financial, operational, regulatory and other risks associated with a clinical stage company, including the potential risk of business failure, and the future impact of COVID-19 as discussed in Note 8.

***Significant Accounting Policies***

The Company's significant accounting policies are described in Note 1 to the financial statements in Item 8 of the 2021 Form 10-K.

***Recent Accounting Pronouncements***

*Standard Required to be Adopted in Future Periods.* 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 the adoption of ASU 2016-13 will have a material impact on its consolidated financial statements.

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. The Company plans to early adopt this standard using the full retrospective transition method effective July 1, 2022. The Company does not expect the impact of adoption will have a material effect on the Company's financial statements.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not currently expected to have a material impact on the Company's financial statements upon adoption.

**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 nine months ended March 31, 2022, the Company incurred a net loss of \$31.6 million and net cash used in operating activities amounted to \$27.5 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 March 31, 2022, the Company had an accumulated deficit of \$199.8 million, unrestricted cash and cash equivalents of \$63.4 million, and total current liabilities of \$2.9 million.

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

As discussed in Note 6, in October and November 2021 the Company completed an underwritten public offering for net proceeds of \$47.3 million and a registered direct offering for net proceeds of \$5.0 million, resulting in aggregate net proceeds of approximately \$52.3 million. In addition, for the nine months ended March 31, 2022, the Company received net proceeds of approximately \$2.7 million from equity issuances under the Equity Distribution Agreement and the LPC Purchase Agreement discussed in Note 6.

As discussed in Note 13, the Company received gross proceeds of approximately \$117.6 million upon closing of a registered direct offering on May 4, 2022. This amount consists of \$41.6 million related to the issuance of 10.9 million Class B pre-funded warrants where exercise is subject to shareholder approval of an increase in our authorized shares, and the remainder relates to unrestricted issuances of equity securities. Underwriting discounts and commissions amounted to \$7.1 million related to the registered direct offering. In addition, the Company entered into a securities purchase agreement on May 1, 2022, to sell Class C pre-funded warrants exercisable for 3.3 million shares whereby exercisability is also subject to shareholder approval and which is expected to result in net proceeds of \$11.4 million upon closing of the securities purchase agreement. Management expects shareholders will approve the necessary increase in authorized shares to eliminate the restrictions on the Class B and Class C pre-funded warrants. However, no assurance can be provided that such approval will be obtained.

Management believes the Company's cash and cash equivalents balance of \$63.4 million as of March 31, 2022, combined with the unrestricted net proceeds received from the registered direct offering in May 2022 will be adequate to meet the Company's contractual obligations and carry out ongoing clinical trials and other planned activities at least through May 2023.

**NOTE 3 — OPERATING LEASES**

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

	March 31, 2022	June 30, 2021
<b>Right-of-use assets, net</b>	<u>\$ 175</u>	<u>\$ 396</u>
<b>Operating lease liabilities:</b>		
Current	\$ 107	\$ 265
Long-term	<u>107</u>	<u>187</u>
Total	<u>\$ 214</u>	<u>\$ 452</u>

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

For the three and nine months ended March 31, 2022 and 2021, operating lease expense was as follows (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2022	2021	2022	2021
Research and development	\$ 66	\$ 75	\$ 216	\$ 185
General and administrative	32	28	75	83
Total	<u>\$ 98</u>	<u>\$ 103</u>	<u>\$ 291</u>	<u>\$ 268</u>

As of March 31, 2022, the weighted average remaining lease term under operating leases was 1.9 years, and the weighted average discount rate for operating lease liabilities was 6.0%. Future payments under all operating lease agreements as of March 31, 2022 are as follows (in thousands):

<b>Fiscal year ending June 30.</b>	
Remainder of fiscal year 2022	\$ 29
2023	117
2024	79
Total lease payments	225
Less imputed interest	(11)
Present value of operating lease liabilities	<u>\$ 214</u>

As discussed in Note 13, the Company entered into a new lease agreement in April 2022 that provides for total cash payments of approximately \$2.9 million over the 60-month lease term. These payments are excluded from the table set forth above.

**NOTE 4 — LICENSE AGREEMENTS**

***Xoma License Agreement***

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

In January 2022, the Company was required to make a milestone payment under the Xoma License Agreement of \$2.0 million that became due upon the dosing of the last patient in the Company’s ongoing Phase 2b Clinical Trial for RZ358. Upon the achievement of certain clinical and regulatory events under the License Agreement, the Company will be required to make up to \$32.0 million in aggregate milestone payments to Xoma. The next milestone payment of \$5.0 million will be due upon dosing of the first patient in a Phase 3 clinical trial for RZ358.

***ActiveSite License Agreement***

On August 4, 2017, the Company entered into a Development and License Agreement (the “ActiveSite License Agreement”) with ActiveSite Pharmaceuticals, Inc. (“ActiveSite”) pursuant to which the Company acquired the rights to ActiveSite’s Plasma Kallikrein Inhibitor program (“PKI Portfolio”). The Company is initially using the PKI Portfolio to develop an oral PKI therapeutic for diabetic macular edema (RZ402) and may use the PKI Portfolio to develop other therapeutics for different indications. The ActiveSite 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 next milestone payment of \$3.0 million will be due upon dosing of the first patient in a Phase 2 clinical trial for RZ402.

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**NOTE 5 — LOAN AND SECURITY 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) term B and C loans for an aggregate of \$15.0 million, which were subject to the Company’s ability to obtain prescribed amounts of financing and the achievement of certain clinical milestones. The Company did not achieve the initial clinical milestones by January 2022 and, accordingly, the term B and term C loans are no longer a source of liquidity. The term A loan has a maturity date of April 1, 2026 (the “Maturity Date”).

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 was required beginning on December 31, 2021. Accordingly, the Company has classified \$5.0 million as a long-term restricted cash asset in the accompanying unaudited condensed consolidated balance sheet as of March 31, 2022. 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 under the Loan Agreement 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 February 28, 2022, the IEBA rate for a term of one month was approximately 0.12% per annum. For the period from February 28, 2022 through March 31, 2022, the IEBA rate for a term of one month was approximately 0.23% per annum. Therefore, the contractual rate was 8.98% and 8.87% as of March 31, 2022 and June 30, 2021, respectively. The Company is permitted to make interest-only payments on the term A loan through May 1, 2023. At the Company’s request, the interest-only period can be extended until May 1, 2024, provided that 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 the term A loan that was funded (the “Facility Fee”), and (ii) a final fee equal to 4.75% of the aggregate amount of the term A loan that was funded (the “Final Fee”). As of March 31, 2022, the Company incurred debt discounts for an aggregate of \$1.7 million that consisted of \$0.4 million for financial advisory and legal fees, an aggregate of \$0.9 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 whereby the effective interest rate amounted to 12.7% and 12.6% as of March 31, 2022 and June 30, 2021, respectively.

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

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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 of their rights and remedies as set forth in the Loan Agreement.

As of March 31, 2022, 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 \$1.4 million, the net carrying value was \$14.3 million as of March 31, 2022. Future minimum principal payments and the net carrying value of the term A loan are as follows as of March 31, 2022 (in thousands):

<b>Fiscal year ending June 30.</b>	
Remainder of fiscal year 2022	\$ —
2023	833
2024	5,000
2025	5,000
2026	4,880
Total contractual payments	15,713
Less unaccreted debt discount	(1,427)
Net carrying value	\$ 14,286

**NOTE 6 — SHAREHOLDERS' EQUITY**

***Changes in Shareholders' Equity for the Three Months Ended March 31, 2022 and 2021***

The following table presents changes in shareholders' equity for the three months ended March 31, 2022 and 2021 (in thousands):

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>			
<b>Three Months Ended March 31, 2022:</b>					
Balances, December 31, 2021	15,556	\$ 16	\$ 250,816	\$ (188,567)	\$ 62,265
Share-based compensation	—	—	850	—	850
Net loss	—	—	—	(11,208)	(11,208)
Balances, March 31, 2022	<u>15,556</u>	<u>\$ 16</u>	<u>\$ 251,666</u>	<u>\$ (199,775)</u>	<u>\$ 51,907</u>
<b>Three Months Ended March 31, 2021:</b>					
Balances, December 31, 2020	8,352	\$ 8	\$ 193,831	\$ (157,953)	\$ 35,886
Share-based compensation	—	—	530	—	530
Reclassification of derivative liability for authorized share deficiency	—	—	(3,591)	—	(3,591)
Fair value of warrants issued to consultants for services	—	—	2	—	2
Net loss	—	—	—	(3,695)	(3,695)
Balances, March 31, 2021	<u>8,352</u>	<u>\$ 8</u>	<u>\$ 190,772</u>	<u>\$ (161,648)</u>	<u>\$ 29,132</u>

For changes in shareholders' equity for the nine months ended March 31, 2022 and 2021, please refer to the unaudited condensed consolidated statements of shareholders' equity.

***Underwritten Public Offering***

On October 12, 2021, the Company entered into an underwriting agreement with Oppenheimer & Co., Inc., as representative of the underwriters listed therein (the "2021 Underwriters") for the planned issuance and sale of equity securities in an underwritten public offering (the "2021 Underwritten Offering"). On October 15, 2021, closing occurred for the 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

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warrants to purchase 1,661,461 shares of common stock at an issuance price of \$6.49 per warrant (the “2021 PFWs”) for gross proceeds of \$10.8 million. The aggregate gross proceeds from the Underwritten Offering amounted to \$50.0 million, excluding the Underwriters’ Option discussed below, and 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 2021 Underwriters a 30-day option to purchase up to an additional 1,153,845 shares of its common stock in the 2021 Underwritten Offering at a public offering price of \$6.50 per share, less underwriting discounts and commissions (the “Underwriters’ Option”). In November 2021, the Underwriters’ Option was partially exercised for 116,266 shares resulting in gross proceeds of approximately \$0.8 million.

***2021 Pre-Funded Warrants***

The 2021 PFWs 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 2021 PFW is exercisable at any time and from time to time after issuance with no stated expiration date. In the event of certain corporate transactions, the holders of the 2021 PFWs will be entitled to receive, upon exercise of the 2021 PFWs, the kind and amount of securities, cash or other property that the holders would have received had they exercised the 2021 PFWs immediately prior to such transaction. The 2021 PFWs do not entitle the holders thereof to any voting rights or any of the other rights or privileges to which holders of Common Stock are entitled.

The gross proceeds of \$10.8 million received from issuance of the 2021 PFWs was recorded as a component of shareholders’ equity within additional paid-in capital. In accordance with the terms of the warrant agreement, holders of the outstanding warrants are not entitled to exercise any portion of the Pre-Funded Warrant if, upon exercise of such portion of the warrant, the holder’s aggregate ownership of the Company’s common stock or the combined voting power beneficially owned by such holder would exceed a designated percentage elected by the holder ranging from 4.99% to 19.99%, after giving effect to the exercise (the “Maximum Ownership Percentage”). Upon at least 61 days’ prior notice to the Company, any warrant holder may elect to increase or decrease the Maximum Ownership Percentage to any other percentage not to exceed 19.99%. As of March 31, 2022, no shares underlying the 2021 PFWs have been exercised.

***2021 Registered Direct Offering***

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

***Equity Distribution Agreement***

In December 2020, the Company and Oppenheimer & Co. Inc. (the “Agent”) entered into an Equity Distribution Agreement (the “EDA”) that provides for an “at the market offering” for the sale of up to \$50.0 million in shares of the Company’s common stock (the “Placement Shares”) through the Agent. The Agent was acting as sales agent and was required to use commercially reasonable efforts to sell all of the Placement Shares requested to be sold by the Company, consistent with the Agent’s normal trading and sales practices, on mutually agreed terms between the Agent and the Company. The EDA was scheduled to terminate when all of the Placement Shares had been sold, or earlier upon the election of either the Company or the Agent. As discussed in Note 13, the Company provide the Agent with notice of termination of the EDA in May 2022 and no further shares will be issued under this agreement.

Under the terms of the EDA, the Company agreed to pay the Agent a commission equal to 3.0% of the gross sales price of the Placement Shares plus certain expenses incurred by the Agent in connection with the offering. For the nine months ended March 31, 2022, the Company sold 138,388 shares of its common stock pursuant to the EDA for net proceeds of approximately \$1.5 million.

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***LPC Purchase Agreement***

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

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

On September 17, 2021, the Company submitted a Regular Purchase Notice, resulting in the sale of 20,000 Purchase Shares to LPC for net proceeds of approximately \$0.2 million. As discussed in Note 13, the Company provided LPC with notice of termination of the Purchase Agreement in May 2022 and no further shares are issuable under this agreement.

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.

***Derivative Liability for Authorized Share Deficiency***

On February 17, 2021, the Company filed a certificate of correction (the “Charter Revision”) with the Secretary of State of Delaware. The Charter Revision changed the number of authorized shares of Common Stock from 500,000,000 shares to 10,000,000 on February 17, 2021. Upon filing the Charter Revision, the Company had approximately 8,352,000 shares of common stock issued and outstanding, plus approximately 2,428,000 shares were required to be reserved for issuance pursuant to the Company’s stock option plans and outstanding warrant agreements. Since the Charter Revision reduced authorized shares to 10,000,000 shares, a deficiency of approximately 780,000 shares existed as of February 17, 2021. As a result of this deficiency, it was not possible to issue up to an aggregate of 780,000 shares of common stock under outstanding stock options and warrants as of February 17, 2021. Therefore, the Company could have been required to settle in cash for the fair value of the 780,000 shares subject to this deficiency, which required liability classification for these instruments beginning on February 17, 2021.

The Company made an accounting policy election to select the stock options and warrant agreements with the earliest issuance dates to compute the estimated fair value of the financial instruments associated with the authorized share deficiency. These stock options and warrants were generally those with the highest exercise prices that were least likely to be exercised. The fair value of such stock options and warrants was accounted for as a derivative liability that amounted to \$3.6 million as of February 17, 2021. As a result of the expiration of stock options for approximately 40,000 shares in March 2021, the authorized share deficiency was reduced to approximately 740,000 as of March 31, 2021. Primarily due to the reduction in the market price of the Company’s common stock, the fair value of stock options and warrants for an aggregate of 740,000 shares amounted to \$1.8 million as of March 31, 2021. Presented

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**Notes to Unaudited Condensed Consolidated Financial Statements**

below is a summary of the derivative liability associated with stock options and warrants as of February 17, 2021 and March 31, 2021 (in thousands, except per share amounts):

	February 17, 2021			March 31, 2021		
	Stock Options	Warrants	Total	Stock Options	Warrants	Total
Number of shares	253	527	780	213	527	740
Weighted average fair value per share	\$ 6.46	\$ 3.71	\$ 4.60	\$ 4.03	\$ 1.80	\$ 2.44
Fair value of derivative liability	\$ 1,638	\$ 1,953	\$ 3,591	\$ 858	\$ 949	\$ 1,807

Due to the reduction in fair value of the derivative liability from February 17, 2021 to March 31, 2021, the Company recognized a non-cash gain of approximately \$1.8 million in the accompanying unaudited condensed consolidated statements of operations for the three and nine months ended March 31, 2021. In order to determine the fair value of the stock options and warrants set forth above, the Company used the BSM option-pricing model with the following weighted-average assumptions for the valuations performed as of February 17, 2021 and March 31, 2021:

	February 17, 2021			March 31, 2021		
	Stock Options	Warrants	Total	Stock Options	Warrants	Total
Market price of Common Stock	\$ 11.99	\$ 11.99	\$ 11.99	\$ 7.06	\$ 7.06	\$ 7.06
Exercise price	\$ 84.19	\$ 63.88	\$ 70.48	\$ 70.48	\$ 63.84	\$ 65.75
Risk-free interest rate	0.6 %	0.1 %	0.3 %	1.0 %	0.2 %	0.4 %
Dividend rate	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %
Remaining contractual term (years)	4.6	1.5	2.5	5.3	1.4	2.5
Historical volatility	112.6 %	123.5 %	119.9 %	118.4 %	112.0 %	113.9 %

On May 26, 2021, the Company's shareholders approved an increase in authorized shares of common stock from 10.0 million shares to 40.0 million shares. As a result, the authorized share deficiency was eliminated, and the related stock options and warrants were no longer accounted for a derivative liability after May 26, 2021 and were reclassified to equity.

**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 March 31, 2022 (in thousands):

Description	Plan Termination Date	Number of Shares		
		Authorized	Outstanding	Available
2015 Plan	February 2020	45	45	—
2016 Plan	October 2021	260	260	—
2019 Plan	July 2029	200	200	—
2021 Plan	March 2030	1,200	1,082	118
Total		1,705	1,587	118



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**Notes to Unaudited Condensed Consolidated Financial Statements**

***Stock Options Outstanding***

The following table sets forth a summary of the activity under all of the Company's stock option plans for the nine months ended March 31, 2022 (shares in thousands):

	Shares	Price <sup>(1)</sup>	Term <sup>(2)</sup>
Outstanding, June 30, 2021	1,285	\$ 16.35	8.7
Granted	421	5.37	
Expired	(61)	20.19	
Forfeited	(58)	10.28	
Outstanding, March 31, 2022	<u>1,587</u>	13.41	8.6
Vested, March 31, 2022	<u>620</u>	19.23	7.5

(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 nine months ended March 31, 2022, the aggregate fair value of stock options granted for approximately 0.4 million shares of common stock that provide solely for time-based vesting, amounted to \$1.7 million or approximately \$4.09 per share as of the grant dates. Fair value was computed using the BSM option-pricing model and will result in the recognition of compensation cost ratably over the expected vesting period of the stock options. For the nine months ended March 31, 2022, the fair value of stock options was estimated on the date of grant, with the following weighted-average assumptions:

Market price of common stock on grant date	\$ 4.09
Expected volatility	94 %
Risk free interest rate	1.8 %
Expected term (years)	6.1
Dividend yield	0 %

Share-based compensation expense for the three and nine months ended March 31, 2022 and 2021 is included under the following captions in the unaudited condensed consolidated statements of operations (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2022	2021	2022	2021
Research and development	\$ 327	\$ 284	\$ 1,014	\$ 1,098
General and administrative	523	246	1,687	1,207
Total	<u>\$ 850</u>	<u>\$ 530</u>	<u>\$ 2,701</u>	<u>\$ 2,305</u>

Unrecognized share-based compensation expense is approximately \$6.8 million as of March 31, 2022. This amount is expected to be recognized over a weighted average period of 3.0 years.

***Warrants***

In connection with the 2021 Underwritten Offering discussed in Note 6, the Company issued 1,661,461 2021 PFWs to purchase 1,661,461 shares of common stock at an issuance price of \$6.49 per warrant for gross proceeds of \$10.8 million. The 2021 PFWs may be exercised at any time by paying the exercise price of \$0.01 per share, subject to the terms discussed in Note 6.

**Rezolute, Inc.****Notes to Unaudited Condensed Consolidated Financial Statements**

In addition, 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 (excluding the 2021 PFWs) for the nine months ended March 31, 2022 (shares in thousands):

	Shares	Price <sup>(1)</sup>	Term <sup>(2)</sup>
Outstanding, beginning of period	1,252	\$ 28.91	4.8
Warrant expirations	(94)	95.79	
Outstanding, end of period	<u>1,158</u>	23.45	4.4

(1) Represents the weighted average exercise price.

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

**NOTE 8 — COMMITMENTS AND CONTINGENCIES*****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 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, the Company could experience disruptions, including delays or difficulties in enrolling patients in 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. The economic and business disruptions caused by COVID-19 may also impact the Company's ability to raise additional capital on a timely basis or at all, which could negatively impact long-term liquidity.

***Registration Rights Agreement***

In connection with the LPC Purchase Agreement discussed in Note 6, the Company entered into a Registration Rights Agreement that requires all the shares issuable under the Purchase Agreement to be registered. 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 March 31, 2022, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the Company's results of operations. At each reporting period, the Company evaluates known claims to determine whether a potential loss amount or a potential range of loss is probable and reasonably estimable under ASC 450, *Contingencies*. Legal fees are expensed as incurred.

**Rezolute, Inc.****Notes to Unaudited Condensed Consolidated Financial Statements****NOTE 9 — RELATED PARTY TRANSACTIONS**

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

In addition, Handok and certain of its affiliates were the sole investors in the 2021 RDO discussed in Note 6 and the private placement discussed in Note 13.

**NOTE 10 — INCOME TAXES**

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

For the three and nine months ended March 31, 2022 and 2021, the Company did not record any income tax benefit due to a full valuation allowance on its deferred tax assets. The Company did not have any material changes to its conclusions regarding valuation allowances for deferred income tax assets or uncertain tax positions for the three and nine months ended March 31, 2022 and 2021.

**NOTE 11 — NET LOSS PER SHARE**

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares and 2021 PFWs outstanding during the period, without consideration for potentially dilutive securities. The 2021 PFWs are included in the computation of basic and diluted net loss per share since the exercise price is negligible and the 2021 PFWs are fully vested and exercisable. Accordingly, the weighted average number of shares outstanding is computed as follows for the three and nine months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2022	2021	2022	2021
Common Stock	15,557	8,352	12,735	7,445
2021 PFWs	1,661	—	1,013	—
Total	<u>17,218</u>	<u>8,352</u>	<u>13,748</u>	<u>7,445</u>

For the three and nine months ended March 31, 2022 and 2021, basic and diluted net loss per share were the same since all other common stock equivalents were anti-dilutive. As of March 31, 2022 and 2021, the following outstanding potential common stock equivalents were excluded from the computation of diluted net loss per share since the impact of inclusion was anti-dilutive (in thousands):

	2022	2021
Stock options	1,590	874
Warrants	1,158	1,437
Total	<u>2,748</u>	<u>2,311</u>

**Rezolute, Inc.****Notes to Unaudited Condensed Consolidated Financial Statements****NOTE 12 — FINANCIAL INSTRUMENTS AND SIGNIFICANT CONCENTRATIONS*****Fair Value Measurements***

Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. When determining fair value, the Company considers the principal or most advantageous market in which it transacts and considers assumptions that market participants would use when pricing the asset or liability. The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement:

Level 1—Quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.

Level 2—Other than quoted prices included in Level 1 that are observable for the asset and liability, either directly or indirectly through market corroboration, for substantially the full term of the asset or liability.

Level 3—Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any market activity for the asset or liability at the measurement date.

The Company's embedded derivative liabilities are classified under Level 3 of the hierarchy and are required to be measured and recorded at fair value on a recurring basis. Fair value is determined based on management's assessment of the probability and timing of occurrence for the Exit Events discussed in Note 5 using a discount rate equal to the effective interest rate for the term A loan. The following table sets forth changes in the fair value of the embedded derivative liabilities for the nine months ended March 31, 2022 (in thousands):

Fair value as of June 30, 2021	\$	387
Gain from change in fair value		8
Fair value as of March 31, 2022	\$	<u>395</u>

Except for the embedded derivative liabilities, the Company did not have any other assets or liabilities measured at fair value on a recurring basis as of March 31, 2022 and June 30, 2021.

Due to the relatively short maturity of the respective instruments, the fair value of cash and cash equivalents, restricted cash, accounts payable, and accrued liabilities approximated their carrying values as of March 31, 2022 and June 30, 2021. Due to the unique terms of the Loan Agreement discussed in Note 5, it was measured on a non-recurring basis at fair value using Level 3 inputs when it was entered into in April 2021. Due to the lack of observable inputs, the Company was unable to determine fair value of the Loan Agreement as of March 31, 2022.

The Company's policy is to recognize asset or liability transfers among Level 1, Level 2 and Level 3 as of the actual date of the events or change in circumstances that caused the transfer. During the nine months ended March 31, 2022 and 2021, the Company did not have any transfers of its assets or liabilities between levels of the fair value hierarchy.

***Significant Concentrations***

Financial instruments that subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and restricted cash. The Company maintains its cash, cash equivalents and restricted cash at high-quality financial institutions. For the nine months ended March 31, 2022, cash deposits have exceeded the amount of federal insurance provided on such deposits. As of March 31, 2022 and June 30, 2021, the Company had cash, cash equivalents and restricted cash with a single financial institution with an aggregate balance of \$68.4 million and \$41.0 million, respectively. The Company has never experienced any losses related to its investments in cash, cash equivalents and restricted cash.

**Rezolute, Inc.****Notes to Unaudited Condensed Consolidated Financial Statements****NOTE 13 — SUBSEQUENT EVENTS*****Headquarters Lease***

In April 2022, the Company entered into a lease agreement for a new corporate headquarters in Redwood City, California. The space consists of approximately 9,300 square feet and provides for total base rent payments of approximately \$2.9 million through the expected expiration of the lease in July 2027. The landlord is required to make improvements to the facility before it is suitable for occupancy by the Company. The lease provides for a six-month rent abatement period beginning upon commencement of the lease term which is expected to occur in August 2022. In addition, the lease provides an allowance of approximately \$0.1 million that may be utilized by the Company for the purchase of furniture and equipment. The average base rent payable in cash over the 60-month lease term is approximately \$48,000 per month. During the fourth quarter of the fiscal year ending June 30, 2022, the Company expects to recognize a right-of-use asset and a related operating lease liability for approximately \$2.3 million.

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

<b>Fiscal year ending June 30.</b>	
Remainder of fiscal year 2022	\$ 50
2023	199
2024	614
2025	632
Thereafter	1,377
Total lease payments	<u>\$ 2,872</u>

***Financing Activities***

On May 1, 2022, the Company entered into (i) an underwriting agreement with Jefferies LLC, as representative of the underwriters listed therein, relating to the issuance and sale of equity securities in an underwritten registered direct offering (the “2022 RDO”), and (ii) a placement agency agreement with Jefferies LLC, that provides for a private placement of equity securities (the “Private Placement”). The 2022 RDO resulted in the issuance of (i) approximately 18.0 million shares of the Company’s common stock, at a public offering price of \$3.80 per share, (ii) Class A pre-funded warrants (the “Class A PFWs”) to purchase up to approximately 2.0 million shares of Common Stock at a public offering price of \$3.799 per Class A PFW and (iii) Class B pre-funded warrants (the “Class B PFWs”) to purchase up to 10.9 million shares of Common Stock at a public offering price of \$3.799 per Class B PFW. The 2022 RDO closed on May 4, 2022 and resulted in net proceeds of approximately \$110.5 million. The gross proceeds of the 2022 RDO amounted to \$117.6 million, before deducting an aggregate of \$7.1 million incurred for underwriting discounts and commissions and other offering expenses payable by the Company. In connection with the 2022 RDO, certain of the Company’s officers and directors agreed not to sell or otherwise dispose of any common stock held by them through July 30, 2022.

Pursuant to the Private Placement, the Company entered into a securities purchase agreement (“SPA”) on May 4, 2022 with Handok and certain of its affiliates (the “Purchasers”) whereby the Company agreed to sell to the Purchasers 3.3 million Class C Warrants (the “Class C PFWs”) to purchase shares of common stock, at a purchase price of \$3.799 per Class C PFW. The closing of the Private Placement will take place upon satisfaction of the closing conditions set forth in the placement agency agreement and the SPA. The net proceeds of the Private Placement, after deducting the placement agent fees and estimated offering expenses payable by the Company, are expected to be approximately \$11.4 million. Closing of the Private Placement is expected to occur in May 2022.

***Terms of Pre-Funded Warrants***

The offering price of \$3.799 per share for the Class A PFWs, the Class B PFWs and the Class C PFWs (collectively, the “2022 PFWs”) represents the public offering price for the shares of common stock issued in the 2022 RDO less the \$0.001 per share price that is required to be paid upon exercise of the 2022 PFWs. The exercise price of the 2022 PFWs 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 and

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

also upon any distributions for no consideration of assets to the Company's shareholders. In the event of certain corporate transactions, the holders of the 2022 PFWs will be entitled to receive, upon exercise of the 2022 PFWs, the kind and amount of securities, cash or other property that the holders would have received had they exercised the 2022 PFWs immediately prior to such transaction. The 2022 PFWs do not entitle the holders thereof to any voting rights or any of the other rights or privileges to which holders of common stock are entitled.

Each Class A PFW is exercisable upon issuance. The Class B PFWs and the Class C PFWs will only be exercisable for shares of common stock upon receipt of shareholder approval for an increase in the number of authorized shares of common stock as discussed below under the caption *Required Shareholder Approval*.

***Required Shareholder Approval***

The closing of the 2022 RDO resulted in the issuance of the approximately 18.0 million shares of common stock and Class A PFWs for approximately 2.0 million shares. After these issuances, the Company had utilized the entire 40.0 million of authorized shares of common stock available under its corporate charter, consisting of issued shares and shares of common stock reserved for issuance under stock option plans and outstanding warrants discussed in Note 7. Accordingly, the Company did not have a sufficient number of shares of common stock available to permit exercise of any of the Class B PFWs and the Class C PFWs. Therefore, the Class B PFWs and the Class C PFWs will only be exercisable for shares of common stock to the extent that shareholders subsequently approve an increase in the number of authorized shares (the "Shareholder Approval"), which the Company is required to use its best efforts to obtain at an annual meeting of shareholders to be held by June 30, 2022. If the Company does not obtain Shareholder Approval by June 30, 2022, it will be required to (i) pay liquidated damages of 2.0% of the aggregate purchase price paid by each holder of Class B PFWs and Class C PFWs, and (ii) hold additional shareholder meetings every three months thereafter until approval is obtained. For each subsequent failure to obtain Shareholder Approval, the Company will be required to pay an additional 2.0% of the purchase price as liquidated damages. The aggregate purchase price of the Class B PFWs and the Class C PFWs amounts to \$54.2 million whereby the initial liquidated damages payment would be approximately \$1.1 million if the Company fails to obtain Shareholder Approval by June 30, 2022.

The Company expects to account for the gross proceeds of \$41.6 million received from the issuance of the Class B PFWs and \$12.6 million expected to be received from the issuance of the Class C PFWs as derivative liabilities whereby future changes in the fair value of the derivative liabilities will result in gains or losses until such time that Shareholder Approval is obtained.

***Registration Rights Agreement***

In connection with the offer of the Class B PFWs and the Class C PFWs, the Company entered into registration rights agreements with the purchasers. Pursuant to the registration rights agreements, the Company will be required to file a registration statement with the SEC to register for resale the shares issuable upon exercise of the Class B PFWs and the Class C PFWs, within two days of receipt of Shareholder Approval, and to have such registration statement declared effective by June 30, 2022 in the event the registration statement is not reviewed by the SEC, or by July 30, 2022 in the event the registration statement is reviewed by the SEC. The Company will be obligated to pay certain liquidated damages to the purchasers if the Company (i) fails to file the registration statement when required, (ii) fails to cause the registration statement to be declared effective by the SEC when required, or (iii) fails to maintain the effectiveness of the registration statement. If the Company fails to comply with the registration rights agreement, it will be obligated to pay 2.0% of the purchase price of the Class B PFWs and the Class C PFWs for an aggregate of approximately \$1.1 million as liquidated damages. If liquidated damage payments are required in the future, they will be charged to expense in the period incurred.

***EDA and Purchase Agreement Termination***

In May 2022, the Company provided notice of termination to the Agent in accordance with the EDA entered in December 2020. Additionally, the Company provided notice of termination to LPC for the Purchas Agreement entered in August 2021. As a result of these termination notices, no further equity securities are issuable under either agreement.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

*Certain figures, such as interest rates and other percentages included in this section have been rounded for ease of presentation. Percentage figures included in this section have not in all cases been calculated on the basis of such rounded figures but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this section may vary slightly from those obtained by performing the same calculations using the figures in our unaudited condensed consolidated financial statements or in the associated text. Certain other amounts that appear in this section may similarly not sum due to rounding. As used in the discussion below, "we," "our," "us," and the "Company" refers to Rezolute, Inc.*

### Special Note About COVID-19

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

While our financial results for the three and nine months ended March 31, 2022 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 and Omicron variants, resurgences in the number and rates of infection, the continued good health of our employees, the ability of us to maintain operations, access to healthcare facilities and patient willingness to participate in our clinical trials, any further government and/or public actions taken in response to the pandemic, and ultimately the length of the pandemic. The ultimate impact of the COVID-19 pandemic on our business operations, our ability to raise capital, our preclinical studies and clinical trial timeliness remain uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. Any prolonged material disruption of our employees, suppliers, or manufacturing may negatively impact our financial position, results of operations, and cash flows. We will continue to monitor the situation closely.

### Recent Developments

#### *Headquarters Lease*

In April 2022, we entered into a lease agreement for a new corporate headquarters facility in Redwood City, California. The space consists of approximately 9,300 square feet and provides for total base rent payments of approximately \$2.9 million through the expected expiration of the lease in July 2027. The lease provides for a six-month rent abatement period beginning upon commencement of the lease term which is expected to occur in August 2022.

#### *Financing Activities*

On May 1, 2022, we entered into (i) an underwriting agreement with Jefferies LLC, as representative of the underwriters listed therein, relating to the issuance and sale of equity securities in an underwritten registered direct offering (the "**2022 RDO**"), and (ii) a placement agency agreement with Jefferies LLC, that provides for a private placement of equity securities (the "**Private Placement**"). The 2022 RDO resulted in the issuance of approximately (i) 18.0 million shares of our common stock at a public offering price of \$3.80 per share, (ii) Class A pre-funded warrants (the "**Class A PFWs**") to purchase up to 2.0 million shares of Common Stock at a public offering price of \$3.799 per Class A PFW, and (iii) Class B pre-funded warrants (the "**Class B PFWs**") to purchase up to 10.9 million shares of Common Stock at a public offering price of \$3.799 per Class B PFW. The 2022 RDO closed on May 4, 2022 and resulted in net proceeds of approximately \$110.5 million. The gross proceeds of the 2022 RDO amounted to \$117.6 million, before deducting an aggregate of \$7.1 million incurred for underwriting discounts and commissions and other offering expenses payable by us. In connection with the 2022 RDO, certain of our officers and directors agreed not to sell or otherwise dispose of any common stock held by them through July 30, 2022.

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Pursuant to the Private Placement, we entered into a securities purchase agreement (“SPA”) on May 4, 2022 with Handok, Inc. and certain of its affiliates (the “Purchasers”) whereby we agreed to sell to the Purchasers 3.3 million Class C Warrants (the “Class C PFWs”) to purchase shares of common stock, at a purchase price of \$3.799 per Class C PFW. The closing of the Private Placement will take place upon satisfaction of the closing conditions set forth in the placement agency agreement and the SPA. The net proceeds of the Private Placement, after deducting the placement agent fees and estimated offering expenses payable by us, are expected to be approximately \$11.4 million. We expect the closing of the Private Placement will occur in May 2022.

### ***Terms of Pre-Funded Warrants***

The offering price of \$3.799 per share for the Class A PFWs, the Class B PFWs and the Class C PFWs (collectively, the “2022 PFWs”) represents the public offering price for the shares of common stock issued in the 2022 RDO less the \$0.001 per share price that is required to be paid upon exercise of the 2022 PFWs. The exercise price of the 2022 PFWs 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 and also upon any distributions for no consideration of assets to our shareholders. In the event of certain corporate transactions, the holders of the 2022 PFWs will be entitled to receive, upon exercise of the 2022 PFWs, the kind and amount of securities, cash or other property that the holders would have received had they exercised the 2022 PFWs immediately prior to such transaction. The 2022 PFWs do not entitle the holders thereof to any voting rights or any of the other rights or privileges to which holders of common stock are entitled.

Each Class A PFW is exercisable upon issuance. The Class B PFWs and the Class C PFWs will only be exercisable for shares of common stock upon receipt of shareholder approval for an increase in the number of authorized shares of common stock as discussed below under the caption *Required Shareholder Approval*.

### ***Required Shareholder Approval***

The closing of the 2022 RDO resulted in the issuance of the approximately 18.0 million shares of common stock and Class A PFWs for approximately 2.0 million shares. After these issuances, we had utilized our entire 40.0 million of authorized shares of common stock available under our corporate charter, consisting of issued shares and shares of our common stock reserved for issuance under our stock option plans and outstanding warrants. Accordingly, we did not have a sufficient number of shares of common stock available to permit exercise of any of the Class B PFWs and the Class C PFWs. Therefore, the Class B PFWs and the Class C PFWs will only be exercisable for shares of common stock to the extent that our shareholders subsequently approve an increase in the number of authorized shares (the “Shareholder Approval”), which we are required to use our best efforts to obtain at an annual meeting of shareholders to be held by June 30, 2022. If we do not obtain Shareholder Approval by June 30, 2022, we will be required to (i) pay liquidated damages of 2.0% of the aggregate purchase price paid by each holder of Class B PFWs and Class C PFWs, and (ii) hold additional shareholder meetings every three months thereafter until approval is obtained. For each subsequent failure to obtain Shareholder Approval, we will be required to pay an additional 2.0% of the purchase price as liquidated damages. The aggregate purchase price of the Class B PFWs and the Class C PFWs amounts to \$54.2 million whereby the initial liquidated damages payment would be approximately \$1.1 million if we fail to obtain Shareholder Approval by June 30, 2022.

### ***Registration Rights Agreement***

In connection with the offer of the Class B PFWs and the Class C PFWs, we entered into registration rights agreements with the purchasers. Pursuant to the registration rights agreements, we will be required to file a registration statement with the SEC to register for resale the shares issuable upon exercise of the Class B PFWs and the Class C PFWs, within two days of receipt of Shareholder Approval, and to have such registration statement declared effective by June 30, 2022 in the event the registration statement is not reviewed by the SEC, or by July 30, 2022 in the event the registration statement is reviewed by the SEC. We will be obligated to pay certain liquidated damages to the purchasers if we (i) fail to file the registration statement when required, (ii) fail to cause the registration statement to be declared effective by the SEC when required, or (iii) fail to maintain the effectiveness of the registration statement. Based on our planned timing for the first shareholder meeting, it is unlikely that we will be able to avoid incurring a liquidated damages fee of approximately \$1.1 million due to the failure to meet the requirements for an effective registration statement.

### ***EDA and Purchase Agreement Termination***

As discussed below under the caption *Liquidity and Capital Resources*, we entered the EDA with Oppenheimer & Co. Inc. in December 2020 and a Purchase Agreement with LPC in August 2021. In May 2022, we provided notices to Oppenheimer and Co. Inc. and LPC



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whereby the EDA and Purchase Agreement were terminated. As a result of these termination notices, no further equity securities are issuable under either agreement.

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

### **RZ358**

On March 23, 2022, we reported positive topline results from the Phase 2b (“RIZE”) study. These results were presented at the Pediatric Endocrine Society Meeting on May 1, 2022. Refer to *Summary of Clinical Assets* below for further discussion of the RZ358 program.

### **RZ402**

On February 22, 2022, we reported positive topline results from the Phase 1b multiple-ascending dose (“MAD”) study. Refer to *Summary of Clinical Assets* below for further discussion of the RZ402 program.

### **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. We reported positive topline results from the RIZE study in March 2022. These results were presented at the Pediatric Endocrine Society Meeting on May 1, 2022.

The RIZE study enrolled 23 patients across diverse ages, gender, and genetic types. RZ358 (pooled doses) resulted in a > 50% improvement in hypoglycemic events and approximately 75% improvement at the mid (6 mg/kg) and top (9 mg/kg) doses. Time-in-range (“TIR”) by continuous glucose monitoring (“CGM”) improved by 7% across all doses and 16% at the top dose. There were no adverse drug reactions, dose-limiting toxicities, or drug-related serious adverse events. We believe that these positive results from the RIZE study will be Phase-3 enabling and we plan to interact with the regulatory authorities in the second half of calendar year 2022. If we obtain clearance, we plan to initiate our Phase 3 study in the first half of calendar year 2023.

In addition, during the first half of calendar year 2020, we had positive interactions with the United States Food and Drug Administration (“FDA”) whereby we were granted Rare Pediatric Disease (“RPD”) designation for RZ358, which qualified 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.

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 recently completed the Phase 1 development program. 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 reported positive results in February 2022. The results further validated and supported the potential for once daily oral dosing and showed dose-dependent increases in systemic exposures, with repeat-dosing to steady-state resulting in the highest concentrations of RZ402 explored to date, exceeding 200 ng/mL and 50 ng/mL at peak and 24-hour trough, respectively. Given that the in-vivo EC<sub>90</sub> for RZ402 in animal models of DME is ~6 ng/mL, the results at both peak and 24-hour trough substantially exceeded target concentrations based on a combination of in-vitro and in-vivo profiling. The MAD study results showed that RZ402 was generally safe and well-tolerated, including at higher doses than previously tested in the Phase 1 single-ascending dose (“SAD”) study. There were no serious adverse events, adverse drug reactions or identified risks. We are now advancing developmental activities toward a Phase 2a proof-of-concept study, which we plan to initiate 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 RPD designation in the United States as well as Orphan Drug Designation in both the United States and the European Union. RZ358 recently completed its Phase 2b study ("RIZE study"), RZ358-606. The RIZE study was 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 were utilized to evaluate several glycemic efficacy endpoints. The primary endpoint was 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 United States and elsewhere. Chronic exposure to high blood sugar levels can lead to inflammation, cell damage, and the breakdown of blood vessel walls. Specifically, in DME, blood vessels behind the back of the eye become porous and permeable leading to the unwanted infiltration of fluid into the macula. This fluid leakage creates distorted vision, and if left untreated could result in 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, obtained debt financing, and conducted private placements and public offerings to raise additional capital. During 2019 we changed our strategy to a licensing model to focus on research and development activities for our pipeline of product candidates.

Due to the time required to conduct clinical trials and obtain regulatory approval for all of our product candidates, we anticipate it will be several years 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 provide assurance that we will continue to be successful in securing adequate financing or that it will be adequate for the long-term execution of our business strategy. Even if we obtain additional financing, it may be costly and may require us to agree to covenants or other provisions that will favor new investors over our existing shareholders.

## Key Components of Consolidated Statements of Operations

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

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

**Interest 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.

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

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

## 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.

### Accounting for Complex Financings

In order to account for complex financing transactions, we are required to make judgments, assumptions, and estimates to determine the appropriate amounts reported in our consolidated financial statements. These financing transactions typically involve entering into several distinct legal agreements, whereby we are required to identify and account for each freestanding financial instrument separately. The freestanding financial instruments may be classified as debt, temporary equity or permanent equity instruments depending on the results of our evaluation. In addition, we evaluate if any of the financial instruments contain embedded features that are required to be accounted for as derivatives at fair value. Each freestanding financial instrument is required to be recognized at fair value on the closing

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date of the financing. The fair value of warrants is generally determined using the Black-Scholes-Merton (“BSM”) valuation model and the fair value of Common Stock is based on the trading price of our shares on the closing date.

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

**Share-Based Compensation Expense**

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

**Research and Development**

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

**Clinical Trial Accruals**

Clinical trial costs are a component of R&D expenses. We accrue and recognize expenses for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with clinical research organizations and clinical trial sites. We determine the estimates through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. Nonrefundable advance payments for goods and services that will be used or rendered in future R&D activities, are deferred and recognized as expense in the period that the related goods are delivered, or services are performed.

**Results of Operations**

**Three months ended March 31, 2022 and 2021**

**Revenue.** As a clinical stage company, we did not generate any revenue for the three months ended March 31, 2022 and 2021. 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 the three months ended March 31, 2022 and 2021 were as follows (in thousands, except percentages):

	2022	2021	Increase	
			Amount	Percent
Total R&D expenses	\$ 8,686	\$ 3,758	\$ 4,928	131 %

The increase in R&D expenses of \$4.9 million for the three months ended March 31, 2022 was primarily attributable to an increase in licensing costs of \$2.0 million. We did not incur any licensing costs for the three months ended March 31, 2021, whereas for the three months ended March 31, 2022, we incurred \$2.0 million under our licensing agreement with Xoma, Inc. (“XOMA”). This payment to XOMA was triggered by the last patient dosing in the Phase 2b clinical study pursuant to the License Agreement entered into by us and

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XOMA on December 6, 2017. As discussed below under the caption *Liquidity and Capital Resources*, additional expenses will be incurred under our license agreements as we achieve certain clinical milestone events in future periods. In addition to the license cost increase, an increase of \$2.1 million was due to higher spending for drug substance and drug product manufacturing and related activities to support ongoing clinical trials, consisting of increases of \$1.5 million for RZ358 and increase of \$0.6 million for RZ402.

Compensation and benefits for our R&D workforce increased by approximately \$0.7 million that was primarily attributable to an increase in the average number of R&D employees from 18 for the three months ended March 31, 2021 to 26 for the three months ended March 31, 2022. Various consulting and outside service costs also increased by approximately \$0.1 million for the three months ended March 31, 2022 for ongoing developmental support of RZ358 and RZ402.

**General and administrative expenses.** G&A expenses for the three months ended March 31, 2022 and 2021 were as follows (in thousands, except percentages):

	2022	2021	Increase	
			Amount	Percent
Total G&A expenses	\$ 2,068	\$ 1,725	\$ 343	20 %

The increase in G&A expenses of \$0.3 million for the three months ended March 31, 2022 was primarily attributable to an increase in share-based compensation expense of \$0.3 million due to options granted to employees in the quarter.

**Interest Expense.** Interest expense was approximately \$0.4 million for the three months ended March 31, 2022, whereas we did not incur any interest expense for the same period in 2021. Interest expense for the three months ended March 31, 2022 was solely attributable to the Loan Agreement (as defined below) entered into in April 2021 and consisted of (i) interest expense of \$0.3 million based on the weighted average contractual rate of 9.0%, and (ii) accretion of discount of \$0.1 million.

**Gain (loss) on changes in fair value of derivative liabilities.** On February 17, 2021, we recognized a derivative liability of \$3.6 million related to a deficiency in our authorized shares of common stock, since there was a possibility that we could have been required to settle a portion of our outstanding stock options and warrants in cash. This derivative liability was adjusted to fair value at the end of each reporting period and amounted to \$1.8 million as of March 31, 2021. The change in fair value of \$1.8 million is reflected as a non-cash gain for the three months ended March 31, 2021. For the period from February 17, 2021 through March 31, 2021, a decrease in the market price of our Common Stock was the primary driver that resulted in the reduction in fair value and the resulting non-cash gain. On May 26, 2021, our shareholders approved an increase in authorized shares of common stock that eliminated the authorized share deficiency. Accordingly, the related stock options and warrants were no longer accounted for a derivative liability after May 26, 2021.

For the three months ended March 31, 2022, we recognized a loss of \$12,000 due to changes in fair value of embedded derivative liabilities related to the Loan Agreement entered into in April 2021, as discussed below under the caption *Liquidity and Capital Resources*. For the three months ended March 31, 2021, we did not have any gains or losses on changes in fair value of embedded derivative liabilities.

**Income Taxes.** For the three months ended March 31, 2022 and 2021, we did not recognize any income tax benefit due to our net losses, and our determination that a valuation allowance was required for all of our deferred tax assets.

**Nine months ended March 31, 2022 and 2021**

**Revenue.** As a clinical stage company, we did not generate any revenue for the nine months ended March 31, 2022 and 2021. 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.

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**Research and development expenses.** R&D expenses for the nine months ended March 31, 2022 and 2021 were as follows (in thousands, except percentages):

	2022	2021	Increase	
			Amount	Percent
Total R&D expenses	\$ 23,912	\$ 10,598	\$ 13,314	126 %

The increase in R&D expenses of \$13.3 million for the nine months ended March 31, 2022 was primarily attributable to an increase of \$6.0 million due to higher spending for drug substance and drug product manufacturing related activities for RZ358 of \$4.5 million and for RZ402 of \$1.5 million. Additional increases in clinical trial costs were incurred of approximately \$1.7 million for RZ358 due to our RZ358 Phase 2b study and \$1.4 million for RZ402 Phase 1 studies. An additional \$0.9 million was due to an increase in patent maintenance activities and development related consulting not included above to support the RZ402 and RZ358 programs. In addition to the increases in clinical trial costs, an increase of approximately \$1.0 million was incurred related to licensing costs. Licensing costs of \$2.0 million were incurred in the nine months ended March 31, 2022 due to the last patient dosed in our RZ358 Phase 2b study, under our licensing agreement with XOMA. In comparison, license costs of \$1.0 million were incurred for the nine months ended March 31, 2021 under our license agreement with ActiveSite, upon acceptance of our IND by the FDA in December 2020.

Compensation and benefits for our R&D workforce increased by approximately \$2.3 million which was primarily attributable to an increase in the average number of R&D employees from 16 for the nine months ended March 31, 2021 to 24 for the nine months ended March 31, 2022.

**General and administrative expenses.** G&A expenses for the nine months ended March 31, 2022 and 2021 were as follows (in thousands, except percentages):

	2022	2021	Increase	
			Amount	Percent
Total G&A expenses	\$ 6,632	\$ 5,660	\$ 972	17 %

The increase in G&A expenses of \$1.0 million for the nine months ended March 31, 2022 was primarily attributable to an increase in professional fees associated with pipeline candidate market research assessments, consulting services, and strategic financial advisory services related to ongoing financing efforts, totaling approximately \$0.7 million. In addition to the professional fee increases, there was an increase of approximately \$0.2 million in employee compensation, mainly related to increase in stock-based compensation due to options granted in the nine months ended March 31, 2022.

**Interest Expense.** Interest expense was approximately \$1.3 million for the nine months ended March 31, 2022, whereas we did not incur any interest expense for the same period in 2021. Interest expense for the nine months ended March 31, 2022 was solely attributable to the Loan Agreement (as defined below) entered into in April 2021 and consisted of (i) interest expense of \$1.0 million based on the weighted average contractual rate of 9.0%, and (ii) accretion of discount of \$0.3 million.

**Gain (loss) on changes in fair value of derivative liabilities.** On February 17, 2021, we recognized a derivative liability of \$3.6 million related to a deficiency in our authorized shares of common stock, since there was a possibility that we could have been required to settle a portion of our outstanding stock options and warrants in cash. This derivative liability was adjusted to fair value at the end of each reporting period and amounted to \$1.8 million as of March 31, 2021. The change in fair value of \$1.8 million is reflected as a non-cash gain for the nine months ended March 31, 2021. For the period from February 17, 2021 through March 31, 2021, a decrease in the market price of our Common Stock was the primary driver that resulted in the reduction in fair value and the resulting non-cash gain. On May 26, 2021, our shareholders approved an increase in authorized shares of common stock that eliminated the authorized share deficiency. Accordingly, the related stock options and warrants were no longer accounted for a derivative liability after May 26, 2021.

For the nine months ended March 31, 2022, we recognized a loss of \$8,000 due to changes in fair value of embedded derivative liabilities related to the Loan Agreement entered into in April 2021, as discussed below under the caption *Liquidity and Capital Resources*. For the nine months ended March 31, 2021, we did not have any gains or losses on changes in fair value of embedded derivative liabilities.

**Employee Retention Credit.** Employee retention credit income was \$0.2 million for the nine months ended March 31, 2022. This amount is a result of the benefits we qualified for under the Coronavirus Aid, Relief, and Economic Security Act during the nine months ended March 31, 2022. We did not recognize any income for employee retention credits for the nine months ended March 31, 2021.

**Income Taxes.** For the nine months ended March 31, 2022 and 2021 we did not recognize any income tax benefit due to our net losses, and our determination that a valuation allowance was required for all of our deferred tax assets.

### **Liquidity and Capital Resources**

We have incurred cumulative net losses of \$199.8 million since our inception, and as a clinical stage company we have not generated any revenue to date. For the nine months ended March 31, 2022, we incurred a net loss of \$31.6 million and we used \$27.5 million of cash in our operating activities. As of March 31, 2022, our unrestricted cash and cash equivalents balance was \$63.4 million and working capital was approximately \$61.5 million. Presented below is a summary of the key events affecting our liquidity and capital resources for the nine months ended March 31, 2022, and the expected impact of financing activities completed in April and May 2022.

In October and November 2021, we completed an underwritten offering that resulted in net proceeds of \$47.3 million (the “**2021 Underwritten Offering**”) and a registered direct offering that resulted in net proceeds of \$5.0 million (the “**2021 RDO**”), for total net proceeds of approximately \$52.3 million.

In December 2020, we entered into an Equity Distribution Agreement (the “**EDA**”) with Oppenheimer & Co. Inc. as sales agent that provided for an “at the market offering” for the sale of up to \$50.0 million in shares of our common stock (the “**Placement Shares**”). For the nine months ended March 31, 2022, we sold 138,388 Placement Shares for which aggregate net proceeds of approximately \$1.5 million were received. We provided notice of termination of the EDA to Oppenheimer & Co. Inc. in May 2022 and no further equity securities are issuable under the agreement. Accordingly, the EDA is no longer a potential source of liquidity. For additional information about the EDA, please refer to Note 6 to the financial statements included in Part I, Item 1 of this Report.

In August 2021, we entered into a purchase agreement (the “**Purchase Agreement**”) with Lincoln Park Capital Fund, LLC (“**LPC**”), which provides that we may sell to LPC up to an aggregate of \$20.0 million of shares of our common stock (the “**Purchase Shares**”). The aggregate number of shares that we can sell to LPC under the Purchase Agreement was 1,669,620 shares of common stock. For the nine months ended March 31, 2022, LPC purchased 115,708 Purchase Shares and we received net proceeds of \$1.2 million. We provided notice of termination of the Purchase Agreement to LPC in May 2022 and no further equity securities are issuable under the agreement. Accordingly, the Purchase Agreement is no longer a potential source of liquidity. For additional information about the Purchase Agreement, please refer to Note 6 to the financial statements included in Part I, Item 1 of this Report.

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) term B and term C loans for an aggregate of \$15.0 million that were subject to our ability to obtain prescribed amounts of financing and the achievement of certain clinical. We did not achieve the initial clinical milestones by January 2022 and accordingly, term B and term C loans are no longer a potential source of liquidity.

The term A loan has a maturity date of April 1, 2026. Outstanding borrowings under the term A loan 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 December 31, 2021, the IEBA rate for a term of one month was approximately 0.12% per annum. As of March 31, 2022, the IEBA rate for a term of one month was approximately 0.23% per annum. Therefore, the contractual rate was 8.98% as of March 31, 2022 and 8.87% as of June 30, 2021. We are permitted to make interest-only payments on the term A loan at least through May 1, 2023.

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 was required beginning on December 31, 2021. 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 cured 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.

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As discussed in Note 4 to the financial statements included in Part I, Item 1 of this Report, we are subject to license agreements that require future contractual payments upon achievement of various milestone events. Pursuant to the ActiveSite Agreement, the next milestone will consist of a \$3.0 million payment upon dosing of the first patient in a Phase 2 clinical trial for RZ402. Additionally, pursuant to the Xoma Agreement, the next milestone payment is a \$5.0 million payment that will be due upon dosing of the first patient in a Phase 3 clinical trial for RZ358.

As discussed above under the caption *Recent Developments*, in April 2022 we entered into a lease agreement for a new corporate headquarters facility in Redwood City, California. This lease provides for total base rent payments of approximately \$2.9 million through the expected expiration of the lease in July 2027.

As discussed above under the caption *Recent Developments*, we received net proceeds of approximately \$110.5 million upon closing of the 2022 RDO on May 4, 2022. This amount consists of \$41.6 million related to the issuance of 10.9 million Class B PFWs that are subject to Shareholder Approval, and the remainder relates to unrestricted issuances of equity securities. In addition, we entered into the SPA on May 4, 2022, whereby we agreed to sell 3.3 million Class C PFWs that are also subject to Shareholder Approval and are expected to result in net proceeds of \$11.4 million upon closing of the Private Placement in May 2022. No assurance can be provided that Shareholder Approval will ultimately be obtained and that we will be able to avoid incurring substantial liquidated damages payments.

We believe our unrestricted cash and cash equivalents balance of \$63.4 million as of March 31, 2022, combined with the unrestricted net proceeds received from the 2022 RDO, will be adequate to meet our contractual obligations, and carry out clinical trials and other planned activities at least through May 2023.

### Cash Flows Summary

Presented below is a summary of our operating, investing, and financing cash flows for the nine months ended March 31, 2022 and 2021 (in thousands):

	2022	2021	Change
Net cash provided by (used in):			
Operating activities	\$ (27,506)	\$ (15,211)	\$ (12,295)
Investing activities	—	—	—
Financing activities	54,875	37,245	17,630

### Cash Used in Operating Activities

For the nine months ended March 31, 2022 and 2021, cash used in operating activities amounted to \$27.5 million and \$15.2 million, respectively. The key components in the calculation of our cash used in operating activities are as follows (in thousands):

	2022	2021	Change
Net loss	\$ (31,637)	\$ (14,412)	\$ (17,225)
Non-cash expenses	3,259	2,544	715
Non-cash gains, net	—	(1,784)	1,784
Changes in operating assets and liabilities, net	872	(1,559)	2,431
Total	\$ (27,506)	\$ (15,211)	\$ (12,295)

For the nine months ended March 31, 2022, our net loss was \$31.6 million compared to \$14.4 million for the nine months ended March 31, 2021. For further discussion about changes in our operating results for the nine months ended March 31, 2022 and 2021, please refer to *Results of Operations* above.

For the nine months ended March 31, 2022 and 2021, our non-cash expenses of \$3.3 million and \$2.5 million, respectively, were primarily attributable to share-based compensation expense, accretion of debt discount and issuance costs, and non-cash lease expense. For the nine months ended March 31, 2022, net changes in operating assets and liabilities increased operating cash flow by \$0.9 million, primarily driven by an increase in accounts payable of \$0.5 million and an increase in other accrued liabilities of \$0.3 million. For the nine months ended March 31, 2021, net changes in operating assets and liabilities decreased operating cash flow by \$1.6 million,



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primarily driven by a \$1.8 million decrease in payables to Xoma under the amended License Agreement, partially offset by a decrease of \$0.4 million in prepaid expenses and other assets.

*Cash Provided by Investing Activities*

We did not have any cash flows from investing activities for the nine months ended March 31, 2022 and 2021.

*Cash Provided by Financing Activities*

Net cash provided by financing activities for the nine months ended March 31, 2022 amounted to \$54.9 million. This amount consisted of proceeds of (i) \$50.7 million from the Underwritten Offering, (ii) \$5.0 million from the 2021 RDO, (iii) \$1.5 million from the EDA, and (iv) \$1.2 million from the Purchase Agreement. The total proceeds from equity financing activities of \$58.4 million were partially offset by payments of \$3.4 million for underwriting discounts and other costs related to equity offerings, and \$0.1 million of payments for debt issuance costs.

Net cash provided by financing activities for the nine months ended March 31, 2021 was \$37.2 million. This amount consisted of \$41.0 million received from a private placement of Units in October 2020 for the purchase of approximately 2.5 million shares of common stock at a purchase price of \$16.50 per share and (ii) warrants entitling the holders to purchase approximately 0.8 million shares of common stock. The gross proceeds of \$41.0 million were partially offset by financial advisory fees and offering costs of approximately \$3.7 million related to the issuance of Units, and prepaid debt discount and issuance costs related to the Loan Agreement entered into in April 2021.

**Recent Accounting Pronouncements**

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

**Off-Balance Sheet Arrangements**

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

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

Not applicable.

**Item 4. Controls and Procedures.**

**Evaluation of Disclosure Controls and Procedures**

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive and financial officer), of the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (“**Exchange Act**”). Based on that assessment under those criteria, our management has determined that our internal control over financial reporting was not effective due to 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 Vice President 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.

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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 certificate of correction with the Secretary of State of Delaware (“**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**

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

## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings.

None

### Item 1A. Risk Factors.

The risk factor set forth below should be read in conjunction with the risk factors set forth under “Item 1A. Risk Factors” in our 2021 Form 10-K (referred to as our “Legacy Risk Factor Disclosures”). The developments described in the additional risk factor below have heightened, or in some cases manifested, certain of the Legacy Risk Factor Disclosures. Except as described herein, there have been no material changes with respect to Legacy Risk Factor Disclosures.

You should carefully consider the Legacy Risk Factor Disclosures in addition to the other information set forth in this Report and in our 2021 Form 10-K, including the *Management’s Discussion and Analysis of Financial Condition and Results of Operations* sections and the consolidated financial statements and related notes. These risks, some of which have occurred and any of which may occur in the future, can have a material adverse effect on our business, financial condition, results of operations or the prices of our publicly traded securities. The risk factor described below and the Legacy Risk Factor Disclosures are not the only risks we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, may occur or become material in the future and adversely affect our business, reputation, financial condition, results of operations or the prices of our publicly traded securities. Therefore, historical operating results, financial and business performance, events and trends are often not a reliable indicator of future operating results, financial and business performance, events or trends.

*If we are unable to obtain shareholder approval for the Class B PFWs and, if then issued, the Class C PFWs, will be required to pay liquidated damages.*

As soon as practicable following the closing of our May 4, 2022 equity offering, we are required to hold an annual meeting of shareholders for the purpose of obtaining stockholder approval of an increase in authorized shares. We are required to use our best efforts to hold the shareholder meeting no later than June 30, 2022, obtain shareholder approval and cause the Board of Directors to recommend to the shareholders that they approve such matter. If shareholder approval is not obtained on or prior to June 30, 2022, we are required to hold an additional shareholder meeting every three months thereafter until such shareholder approval is obtained.

If we do not obtain shareholder approval by June 30, 2022, we are required to pay liquidated damages of 2.0% of the aggregate purchase price paid by each holder of Class B PFWs, and if then issued, the Class C PFWs. For any subsequent failure to obtain shareholder approval, we are required to pay an additional 2.0% as liquidated damages.

### 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.

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**Item 6. Exhibits.**

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

<b>Exhibit Number</b>	<b>Description of Exhibits</b>
31.1*	<a href="#">Certification of Chief Executive and Principal Financial Officer as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*</a>
32.1*	<a href="#">Certification of Chief Executive and Principal Financial Officer as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*</a>
101.INS*	Inline XBRL Instance Document
101.SC*	Inline XBRL Taxonomy Extension Schema
101.CA*	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase
101.LA*	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File, formatted in Inline XBRL (included as Exhibit 101)

\* Filed herewith.

**SIGNATURES**

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

**REZOLUTE, INC.**

Date: May 12, 2022

By: /s/ Nevan Elam

\_\_\_\_\_  
Nevan Elam

Chief Executive Officer

(Principal Executive and Financial Officer)

**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: May 12, 2022

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

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

In connection with the quarterly report of Rezolute, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nevan Elam, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2022

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.

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