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

FORM 10-Q

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

For the quarterly period ended September 30, 2020
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: 000-54495

REZOLUTE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**27-3440894**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
201 Redwood Shores Parkway, Suite 315, Redwood City, California	**94065**
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	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 8,351,911 shares of its $0.001 par value common stock outstanding as of November 9, 2020.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

Any or all of our forward-looking statements may turn out to be wrong. They can be affected by inaccurate assumptions or by known or unknown risks, uncertainties and other factors including, but not limited to, the risks described in "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended June 30, 2020 (the "2020 Form 10-K"), filed with the Securities and Exchange Commission ("SEC") on October 13, 2020.

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

Special Note About COVID-19

We have been actively monitoring the COVID-19 situation and its impact. Our primary objectives have remained the same throughout the pandemic: to support the safety of our team members and their families and continue to support our preclinical studies and clinical trials. While our financial results for the three months ended September 30, 2020 and the fiscal year ended June 30, 2020 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 continued good health of our employees, the ability of us to maintain operations, access to healthcare facilities and patient willingness to participate in our clinical trials, any further government and/or public actions taken in response to the pandemic and ultimately the length of the pandemic. The ultimate impact of the COVID-19 pandemic on our business operations, our ability to raise capital, as well as our preclinical studies and clinical trials remains uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. Any prolonged material disruption of our employees, suppliers, or manufacturing may negatively impact our consolidated financial position, results of operations and cash flows. We will continue to monitor the situation closely.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

Rezolute, Inc.

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

	September 30, 2020	June 30, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 6,404	$ 9,955
Prepaid expenses and other	491	563
Total current assets	6,895	10,518
Long-term assets:		
Right-of-use assets, net	325	383
Deferred offering costs	129	-
Property and equipment, net	30	33
Lease security deposits	31	31
Total assets	$ 7,410	$ 10,965
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 797	$ 893
Accrued liabilities:		
Compensation and benefits	79	120
Insurance premiums	94	188
Other	300	180
Current portion of license fees payable to Xoma	1,409	1,600
Current portion of operating lease liabilities	245	245
Total current liabilities	2,924	3,226
Long-term liabilities:		
Operating lease liabilities, net of current portion	104	165
License fees payable to Xoma, net of current portion	-	209
Total liabilities	3,028	3,600
Commitments and contingencies (Notes 4, 7 and 12)		
Stockholders' equity:		
Preferred Stock, $0.001 par value, 20,000 shares authorized; no shares issued and outstanding	-	-
Common Stock, $0.001 par value, 500,000 shares authorized; 5,867 shares issued and outstanding	6	6
Additional paid-in capital	155,232	154,595
Accumulated deficit	(150,856)	(147,236)
Total stockholders' equity	4,382	7,365
Total liabilities and stockholders' equity	$ 7,410	$ 10,965

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

Rezolute, Inc.

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

	Three Months Ended September 30,	
	2020	**2019**
Operating expenses:		
Research and development:		
Compensation and benefits, net of related party reimbursements	$ 1,212	$ 1,418
Clinical trial costs	758	991
Consultants and outside services	142	486
Material manufacturing costs	174	187
Facilities and other	58	152
Total research and development	2,344	3,234
General and administrative:		
Compensation and benefits	705	1,336
Professional fees	370	360
Facilities and other	204	249
Total general and administrative	1,279	1,945
Total operating expenses	3,623	5,179
Operating loss	(3,623)	(5,179)
Non-operating income - interest and other	3	99
Net loss	$ (3,620)	$ (5,080)
Net loss per common share - basic and diluted	$ (0.62)	$ (0.94)
Weighted average number of common shares outstanding - basic and diluted	5,867	5,409

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

Rezolute, Inc.

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

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Three Months Ended September 30, 2020:					
Balances as of June 30, 2020	5,867	$ 6	$ 154,595	$ (147,236)	$ 7,365
Stock-based compensation	-	-	634	-	634
Fair value of warrants issued to consultants for services	-	-	3	-	3
Net loss	-	-	-	(3,620)	(3,620)
Balances as of September 30, 2020	5,867	$ 6	$ 155,232	$ (150,856)	$ 4,382
Three Months Ended September 30, 2019:					
Balances as of June 30, 2019	4,208	4	$ 128,651	$ (126,903)	$ 1,752
Stock-based compensation	-	-	1,394	-	1,394
Fair value of warrants issued to consultants for services	-	-	2	-	2
Issuance of common stock for cash:					
Related parties at $14.50 per share	1,380	2	19,998	-	20,000
Other investors at $14.50 per share	279	-	4,050	-	4,050
Advisory fees and other offering costs	-	-	(1,500)	-	(1,500)
Net loss	-	-	-	(5,080)	(5,080)
Balances as of September 30, 2019	5,867	$ 6	$ 152,595	$ (131,983)	$ 20,618

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

Rezolute, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended September 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,620)	$ (5,080)
Stock-based compensation expense	634	1,394
Depreciation and amortization expense	3	5
Non-cash lease expense	59	53
Fair value of warrants issued for services	3	2
Changes in operating assets and liabilities:		
Decrease in prepaid expenses and other assets	72	117
Increase in receivables from related parties	-	(247)
Increase (decrease) in accounts payable	(107)	736
Decrease in other accrued liabilities	(195)	(1,018)
Decrease in license fees payable to Xoma	(400)	(4,891)
Net Cash Used In Operating Activities	(3,551)	(8,929)
CASH FLOWS FROM INVESTING ACTIVITIES	-	-
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of Common Stock:		
Related parties	-	20,000
Others	-	4,050
Payment of commissions and other deferred offering costs	-	(1,479)
Net Cash Provided by Financing Activities	-	22,571
Net increase (decrease) in cash, cash equivalents and restricted cash	(3,551)	13,642
Cash, cash equivalents and restricted cash at beginning of period	9,955	11,573
Cash, cash equivalents and restricted cash at end of period	$ 6,404	$ 25,215
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
Cash and cash equivalents, end of period	$ 6,404	$ 22,104
Restricted cash, end of period	-	3,111
Total cash, cash equivalents and restricted cash, end of period	$ 6,404	$ 25,215
SUPPLEMENTARY CASH FLOW INFORMATION:		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	-	-
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Right-of-use assets acquired in exchange for operating lease liabilities upon adoption of new accounting standard effective July 1, 2019	$ -	$ 605
Payables for deferred offering costs	129	21

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

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

Nature of Operations

Rezolute, Inc. (the "Company") is a clinical stage biopharmaceutical company incorporated in Delaware in 2010.

Reverse Stock Split

In August 2019, the Company's Board of Directors approved a reverse stock split that was subject to stockholder approval at a special meeting that was concluded on October 28, 2019. Stockholders approved the proposal whereby the Board of Directors had the ability at any time on or before October 23, 2020 to execute a reverse stock split and set an exchange ratio between 20 and 100 shares of the Company's outstanding Common Stock, $0.001 par value per share, into one issued and outstanding share of Common Stock, without any change in the par value per share or the number of shares of Common Stock authorized. On October 7, 2020, the Board of Directors approved a one share for 50 shares reverse stock split of the Company's $0.001 par value Common Stock (the "Reverse Stock Split"), resulting in the filing with the Delaware Secretary of State of a Certificate of Amendment (the "Amendment") to the Company's Articles of Incorporation. The Amendment was effective on October 9, 2020.

In connection with the Reverse Stock Split, proportionate adjustments were made to increase the per share exercise prices and decrease the number of shares of Common Stock issuable upon exercise of stock options and warrants whereby approximately the same aggregate price is required to be paid for such securities upon exercise as had been payable immediately preceding the Reverse Stock Split. In addition, any fractional shares that would otherwise be issued as a result of the Reverse Stock Split were rounded up to the nearest whole share. All references in the accompanying unaudited condensed consolidated financial statements to the number of shares of Common Stock and per share amounts have been retroactively adjusted to give effect to the Reverse Stock Split.

Basis of Presentation

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

The condensed consolidated balance sheet as of June 30, 2020, 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 2020 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 year ended June 30, 2020.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted, pursuant to the rules and regulations of the SEC for interim financial reporting. Accordingly, they do not include all the information and footnote disclosures necessary for a comprehensive presentation of financial position, results of operations, and cash flows. It is management's opinion, however, that all material adjustments (consisting of normal recurring adjustments) have been made which are necessary for a fair financial statement presentation. The interim results for the three months ended September 30, 2020 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, 2021.

Reclassifications

Certain amounts in the previously issued comparative interim financial statements for the three months ended September 30, 2019 have been reclassified to conform to the current interim financial statement presentation. These reclassifications had no effect on the previously reported net loss, working capital, cash flows and stockholders' equity.

Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts in the condensed consolidated financial statements and the accompanying notes. The Company bases its estimates and assumptions on current facts, historical experience, and various other factors that it believes are reasonable under the circumstances, to determine the carrying values of assets and liabilities that are not readily apparent from other sources. The Company's significant accounting estimates include, but are not necessarily limited to, fair value of share-based payments and warrants, management's assessment of going concern, clinical trial accrued liabilities, estimates of the probability and potential magnitude of contingent liabilities, and the valuation allowance for deferred tax assets due to continuing and expected future operating losses. Actual results could differ from those estimates.

Risks and Uncertainties

The Company's operations may be subject to significant risks and uncertainties including financial, operational, regulatory and other risks associated with a clinical stage company, including the potential risk of business failure as discussed further in Note 2, and the future impact of COVID-19 as discussed in Note 7.

Significant Accounting Policies

During the three months ended September 30, 2020, there have been no changes in our significant accounting policies as described in our Annual Report on Form 10-K for the fiscal year ended June 30, 2020.

Recent Accounting Pronouncements

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

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.* ASU 2016-13 amends the guidance on the impairment of financial instruments. This update adds an impairment model (known as the current expected credit losses model) that is based on expected losses rather than incurred losses. Under the new guidance, an entity recognizes, as an allowance, its estimate of expected credit losses. In November 2019, ASU 2016-13 was amended by ASU 2019-10, *Financial Instruments- Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)* whereby the effective date for ASU 2016-13 for smaller reporting companies is now required for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company does not expect the adoption of this accounting guidance 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. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Management has not completed its evaluation to determine the impact that adoption of this standard will have on the Company's consolidated financial statements.

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

NOTE 2 — LIQUIDITY

The Company is in the clinical stage and has not yet generated any revenues. For the fiscal year ended June 30, 2020, the Company incurred a net loss of $20.3 million and net cash used in operating activities amounted to $24.2 million. For the three months ended September 30, 2020, the Company incurred a net loss of $3.6 million and net cash used in operating activities amounted to $3.6 million. As of September 30, 2020, the Company had an accumulated deficit of $150.9 million, cash and cash equivalents of $6.4 million and total liabilities of $3.0 million.

As discussed in Note 12, on October 9, 2020 the Company received aggregate gross proceeds from investors in a private placement of $41.0 million from the issuance of units that consisted of approximately 2.5 million shares of Common Stock and warrants for the purchase of approximately 0.8 million shares of Common Stock. Management believes the Company's existing cash and cash equivalents balance plus the net proceeds from the private placement of approximately $37.5 million will be adequate to carry out currently planned activities until the second half of the fiscal year ending June 30, 2022.

As discussed in Note 7, COVID-19 has resulted in an economic environment that is unfavorable for many businesses to conduct operations and pursue new debt and equity financings. The U.S. economy has been largely shut down by mass quarantines and government mandated stay-in-place orders to halt the spread of the virus. While these orders are being lifted gradually, there is considerable uncertainty surrounding the recovery period for the U.S. economy. The long-term effects on the Company are expected to result in higher costs in order to comply with safeguards to protect patients and staff engaged in clinical activities, and extended periods of time may be required to complete clinical trials. The current economic environment and financial market volatility is expected to make it more challenging for the Company to obtain funding for its clinical programs in the future. Even if an economic recovery occurs faster and more robustly than currently expected, there are no assurances that the Company will be able to obtain equity and debt financings that will be necessary to fund ongoing operations after the fiscal year ending June 30, 2022. In addition, even if these financing sources are available, they may be on terms that are not acceptable to the Company's Board of Directors and stockholders.

NOTE 3 — OPERATING LEASES

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

	September 30, 2020	June 30, 2020
Right-of-Use Assets, net	$ 325	$ 383
Operating Lease Liabilities:		
Current	$ 245	$ 245
Long-term	104	165
Total	$ 349	$ 410

As of September 30, 2020, the weighted average remaining lease term under operating leases was 1.4 years, and the weighted average discount rate for operating lease liabilities was 10.0%. For the three months ended September 30, 2020 and 2019, cash paid for amounts included in the measurement of operating lease liabilities amounted to $69,000 and $68,000, respectively. These cash payments were included in the determination of net cash used in operating activities in the condensed consolidated statements of cash flows.

Future payments under operating lease agreements as of September 30, 2020 are as follows (in thousands):

Fiscal year ending June 30,	
Remainder of fiscal year 2021	$ 202
2022	170
Total lease payments	372
Less imputed interest	(23)
Present value of operating lease liabilities	$ 349

NOTE 4 — LICENSE AGREEMENTS

Xoma License Agreement

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

On March 31, 2020, the parties entered into Amendment No. 3 to the License Agreement to extend the payment schedule for the remaining balance of approximately $2.6 million. The revised payment schedule provided for seven quarterly payments to be paid from March 31, 2020 through September 30, 2021. For the three months ended September 30, 2020, presented below is a summary of activity related to the remaining payment obligations under the amended License Agreement (in thousands):

Scheduled Payment Date	**Balance June 30, 2020**	**Payments During Period**	**Balance September 30, 2020**
September 30, 2020	$ 400	$ (400)	$ -
December 31, 2020	400	-	400
March 31, 2021	400	-	400
June 30, 2021	400	-	400
September 30, 2021	209	-	209
Total	1,809	$ (400)	1,409
Less long-term portion of payable	(209)		-
Current portion of payable	$ 1,600		$ 1,409

As discussed in Note 12, the Company completed a private placement of equity securities for gross proceeds of $41.0 million in October 2020, which resulted in acceleration of the entire obligation. On October 23, 2020, the Company paid the outstanding balance of $1.4 million.

In addition to the License Agreement entered between the Company and Xoma in December 2017, both parties also entered into a stock purchase agreement ("Stock Purchase Agreement"). As of September 30, 2020, Xoma owns approximately 162,000 shares of the Company's Common Stock. The Stock Purchase Agreement provides Xoma with the right and option to require the Company to use its best efforts to facilitate orderly sales of the shares to a third party or purchase the shares (the "Put Option"). Xoma was permitted to exercise the Put Option for up to a total of 50,000 shares of Common Stock for the calendar year ending December 31, 2020, and up to an additional 50,000 shares thereafter. On November 3, 2020, the Company's shares of Common Stock were approved for listing on the Nasdaq Capital Market. Accordingly, the Put Option terminated pursuant to the terms of the Stock Purchase Agreement.

ActiveSite License Agreement

On August 4, 2017, the Company entered into a Development and License Agreement with ActiveSite Pharmaceuticals, Inc. ("ActiveSite") pursuant to which the Company acquired the rights to ActiveSite's Plasma Kallikrein Inhibitor program ("PKI Portfolio"). The Company is initially using the PKI Portfolio to develop an oral PKI therapeutic for diabetic macular edema (RZ402) and may use the PKI Portfolio to develop other therapeutics for different indications. The ActiveSite License Agreement requires various milestone payments up to $46.5 million. The first milestone payment for $1.0 million is due after acceptance of an Initial Drug Application, or IND, filed with the U.S. Food and Drug Administration ("FDA"). The Company is also required to pay royalties equal to 2.0% of any sales of products that use the PKI Portfolio. Through September 30, 2020, no events occurred that would result in the requirement to make milestone payments and no royalties have been incurred.

NOTE 5 — STOCKHOLDERS' EQUITY

Fiscal 2020 Private Placement

In connection with a Series AA Preferred Stock financing in January 2019, the Company granted call options to Handok, Inc. and Genexine, Inc. (collectively, "H&G") whereby upon the earlier of (i) December 31, 2020 and (ii) such date that the Company requested H&G to provide additional financing, each investor was entitled to purchase up to $10.0 million of Common Stock at a purchase price equal to the greater of (i) $14.50 per share or (ii) 75% of the volume weighted average closing price ("VWAP") of the Company's Common Stock during the thirty consecutive trading days prior to the date of the notice.

On June 19, 2019, the Company entered into a financial advisory agreement to undertake a private placement (the "Fiscal 2020 Private Placement") of (i) the shares of Common Stock issuable under the H&G call options for a total of $20.0 million, plus (ii) up to $10.0 million of equity or equity equivalent securities to be issued to other investors. On July 23, 2019, the Company entered into purchase agreements whereby H&G exercised their call options to purchase an aggregate of approximately 1.4 million shares of Common Stock for gross cash proceeds of $20.0 million at a purchase price of $14.50 per share. In addition, during July and August 2019 other investors purchased an aggregate of approximately 279,000 shares of Common Stock at a purchase price of $14.50 per share for gross cash proceeds of $4.1 million. Pursuant to the financial advisory agreement, the Company paid a fee of 6.0% of the gross proceeds received from the Fiscal 2020 Private Placement. The total advisory fees and other offering costs amounted to approximately $1.5 million, resulting in net proceeds of $22.6 million for the three months ended September 30, 2019.

Restricted Cash

One of the investors in the Fiscal 2020 Private Placement purchased approximately 262,000 shares of Common Stock for gross proceeds of $3.8 million. The Company agreed to spend the proceeds for certain research and development activities and for a planned uplisting of the Company's Common Stock to the Nasdaq Capital Market. For the three months ended September 30, 2019, the Company made qualified expenditures of $0.7 million leaving a restricted cash balance of $3.1 million. The Company expended the remainder of the restricted cash proceeds on qualified activities by March 31, 2020, whereby there were no restrictions on cash balances after that date.

NOTE 6 — STOCK-BASED COMPENSATION AND WARRANTS

Stock Option Plans

The Company currently has two active stock option plans consisting of the 2016 Non-Qualified Stock Option Plan, as amended (the "2016 Plan"), and the 2019 Non Qualified Stock Option Plan (the "2019 Plan"). On July 31, 2019, the 2019 Plan was adopted by the Board of Directors and provides authority to grant non-qualified stock options for up to 300,000 shares of the Company's Common Stock. The Company also has stock options outstanding to purchase up to approximately 44,000 shares of Common Stock under the 2014 Stock and Incentive Plan (the "2014 Plan") that terminated on March 21, 2019 and approximately 88,000 shares of Common Stock under the 2015 Stock and Incentive Plan (the "2015 Plan") that terminated on February 23, 2020. Stock options outstanding under the 2014 Plan and the 2015 Plan expire pursuant to their contractual provisions on various dates through 2029. Presented below is a summary as of September 30, 2020 of the number of shares authorized, outstanding, and available for future grants under each of the Company's stock option plans (in thousands):

	Termination	Number of Shares		
Description	Date	Authorized	Outstanding	Available
2014 Plan	March 2019	43	43	-
2015 Plan	February 2020	88	88	-
2016 Plan	October 2021	560	513	47
2019 Plan	July 2029	300	300	-
Total		991	944	47

Stock Options Outstanding

The following table sets forth a summary of the stock option activity for options with time-based vesting and hybrid vesting granted under all of the Company's stock option plans for the three months ended September 30, 2020 (shares in thousands):

	Shares	Price [1]	Term [2]
Outstanding, July 1, 2020	963	$ 33.06	8.1
Stock options forfeited:			
Awards with time-based vesting	(14)	14.50	
Awards with hybrid vesting conditions	(5)	14.50	
Outstanding, September 30, 2020	944	33.43	7.8
Vested, September 30, 2020	477	50.36	6.8

(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.

Stock-based compensation expense for the three months ended September 30, 2020 and 2019 is included in compensation and benefits under the following captions in the unaudited condensed consolidated statements of operations (in thousands):

	2020	2019
Research and development	$ 321	$ 574
General and administrative	313	820
Total	$ 634	$ 1,394

Unrecognized stock-based compensation expense related to stock options that provide solely for time-based vesting is approximately $2.6 million as of September 30, 2020. This amount is expected to be recognized over a remaining weighted average period of 1.7 years.

In July 2019, the Company granted employee stock options for approximately 0.2 million shares that commence vesting upon the achievement of market, performance and service conditions ('Hybrid Options"). The Hybrid Options will vest ratably over a period of 36 months beginning on the date that all of the following have occurred: (i) the option recipient has been employed by the Company for at least one year, (ii) the Company's shares of Common Stock have been listed for trading on a national stock exchange, and (iii) such date no later than July 31, 2023, when the Company's closing stock price exceeds $29.00 per share for 20 trading days in any consecutive 30 day period. The Company has not recognized any expense related to these stock options through September 30, 2020, since it was not probable that the performance condition to obtain a listing on a national stock exchange would be achieved. On November 3, 2020, the Company achieved this performance condition whereby its shares of Common Stock were approved for listing on the Nasdaq Capital Market. Accordingly, unrecognized compensation cost, net of estimated forfeitures, for the Hybrid Options of approximately $1.9 million will be recognized beginning in November 2020 when compensation cost of approximately $0.5 million will be recorded for the three months ending December 31, 2020, and the remainder of approximately $1.4 million will be recognized on a straight-line basis through July 2024 when the Hybrid options are expected to be fully vested.

Warrants

The Company has issued warrants in conjunction with various debt and equity financings and for services. As of September 30, 2020, the Company had warrants outstanding for approximately 0.6 million shares with a weighted average exercise price of $57.46. The weighted average remaining contractual term until the warrants expire is approximately 2.0 years. For the three months ended September 30, 2020, no warrants were granted, expired or exercised.

NOTE 7 — 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

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China, and by March 2020 the spread of the virus had resulted in a world-wide pandemic. The U.S. economy has been largely shut down by mass quarantines and government mandated stay-in-place orders to halt the spread of the virus. While these orders are being lifted gradually, a full recovery of the U.S. economy may not occur until 2021 or later. Federal and state governments in the U.S. have approved funding for many programs that may provide financial assistance to individuals and businesses. The Company intends to pursue all material types of government assistance that it may be entitled to. However, no assurance can be provided that the Company will qualify and realize any material benefits from such assistance.

COVID-19 has resulted in an economic environment that is unfavorable for many businesses to pursue new equity financings. Accordingly, the current economic environment is expected to present greater challenges for the Company to obtain additional funding for its clinical programs on terms that are acceptable to the Company's Board of Directors.

In February 2020, Rezolute announced the initiation of its Phase 2b trial in Congenital Hyperinsulinism ("CHI"). New site initiation and enrollment is on hold, similar to many other clinical studies conducted by other companies throughout the world. There are no mitigation strategies we can employ to help avoid potential timeline delays should there be an extended enrollment pause due to COVID-19. The long-term effects of COVID-19 are expected to require additional safeguards to protect patients and staff engaged in clinical activities, and extended periods of time required to complete clinical trials, both of which are expected to result in higher overall costs. While the current business disruption is expected to be temporary, the long-term financial impact and the duration cannot be reasonably estimated at this time.

Legal Matters

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of September 30, 2020, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the Company's results of operations. At each reporting period, the Company evaluates known claims to determine whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under ASC 450, *Contingencies*. Legal fees are expensed as incurred.

NOTE 8 — RELATED PARTY TRANSACTIONS

Related Party Licensing Agreement

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

Equity Issuances

As discussed in Note 5, on July 23, 2019 H&G agreed to purchase an aggregate of approximately 1.4 million shares of Common Stock at an issuance price of $14.50 per share for gross proceeds of $20.0 million. This purchase was made pursuant to the terms of call options that was issued in connection with an equity offering in January 2019 that resulted in gross proceeds of $25.0 million. As of September 30, 2020, H&G own an aggregate of approximately 65% of the Company's outstanding shares of Common Stock.

Master Services Agreement

Effective July 1, 2019, the Company entered into a Master Services Agreement ("MSA") with H&G whereby the Company agreed to assist H&G in an evaluation of their long acting growth hormone program referred to as GX-H9. For the three months ended September 30, 2019, the Company charged H&G for employee services of $103,000 and reimbursable expenses incurred with unrelated parties of $144,000, for a total of approximately $247,000. Amounts charged under the MSA for employee services are reflected as a reduction of research and development compensation costs in the accompanying unaudited condensed consolidated statement of operations for the three months ended September 30, 2019.

NOTE 9 — INCOME TAXES

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

For the three months ended September 30, 2020 and 2019, the Company did not record any income tax benefit due to a full valuation allowance on its deferred tax assets. The Company did not have any material changes to its conclusions regarding valuation allowances for deferred income tax assets or uncertain tax positions for the three months ended September 30, 2020 and 2019.

NOTE 10 — EARNINGS PER SHARE

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the periodFor the three months ended September 30, 2020 and 2019, basic and diluted net loss per share were the same since all common stock equivalents were anti-dilutive. As of September 30, 2020 and 2019, 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):

	2020	2019
Stock options	944	928
Warrants	618	911
Total	1,562	1,839

NOTE 11 — 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 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.

Due to the relatively short maturity of the respective instruments, the fair value of cash and cash equivalents, accounts payable and accrued liabilities approximated their carrying values as of September 30, 2020 and June 30, 2020. The Company did not have any assets and liabilities measured at fair value on a recurring basis as of September 30, 2020 and June 30, 2020. The Company's policy is to recognize asset or liability transfers among Level 1, Level 2 and Level 3 as of the actual date of the events or change in circumstances that caused the transfer. During the three months ended September 30, 2020 and 2019, the Company did not have any transfers of its assets or liabilities between levels of the fair value hierarchy.

Significant Concentrations

Financial instruments that subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains its cash and cash equivalents at high-quality financial institutions. For the three months ended September 30, 2020, cash deposits have exceeded the amount of federal insurance provided on such deposits. As of September 30, 2020 and June 30, 2020, the Company had cash and cash equivalents with a single financial institution with an aggregate balance of $6.4 million and $10.0 million, respectively. The Company has never experienced any losses related to its investments in cash and cash equivalents.

NOTE 12 — SUBSEQUENT EVENTS

Fiscal 2021 Financing

On September 15, 2020, the Company entered into financial advisory agreements to undertake a private placement of equity or equity equivalent securities (the "Fiscal 2021 Financing"). Pursuant to the financial advisory agreements, the Company agreed to pay transaction fees to the financial advisors for an aggregate of 6.0% of the gross proceeds plus out-of-pocket expenses. In addition, for any financing completed within 60 days of the closing of the Fiscal 2021 Financing, the financial advisors are entitled to additional transaction fees equal to 6.0% of the gross proceeds.

On October 9, 2020, the Company completed the Fiscal 2021 Financing through the sale of units (the "Units") consisting of (i) approximately 2.5 million shares of Common stock, and (ii) warrants entitling the holders to purchase approximately 0.8 million shares of Common Stock (the "Warrants"). The Warrants are exercisable at $19.50 per share for a period of seven years and may be exercised on a cash or cashless basis at the election of the holders.

The Units were issued for a purchase price of $16.50 per Unit, resulting in gross proceeds of $41.0 million. Pursuant to the financial advisory agreements, the Company paid transaction fees of $2.5 million, and costs for professional fees and other offering costs are estimated at approximately $1.0 million. After deducting the financial advisory fees and other offering costs, the estimated net proceeds amounted to approximately $37.5 million. Pursuant to the terms of the Fiscal 2021 Financing, the Company executed the Reverse Stock Split of one share for 50 shares as discussed in Note 1, and agreed to enable trading of its Common Stock on the Nasdaq Capital Market, whereby the Company's listing application was approved by Nasdaq on November 3, 2020. The Company also entered into a registration rights agreement ("RRA"), pursuant to which the Company agreed to use commercially reasonable efforts to register (i) the shares of Common Stock included in the Units, and (ii) the shares of Common Stock issuable upon exercise of the warrants. If the Company fails to register the shares pursuant to the terms of the RRA, liquidated damages up to a maximum of 6.0% of the gross proceeds of the Fiscal 2021 Financing may be assessed.

Early Payments to Xoma

Upon completion of a qualified financing of $20.0 million or more, the Company was obligated to repay the remaining outstanding balance due to Xoma within 15 days as discussed in Note 4. The completion of the Fiscal 2021 Financing resulted in acceleration of the remaining balance due to Xoma and the Company paid the outstanding balance of $1.4 million on October 23, 2020.

Reverse Stock Split

As discussed in Note 1, the Company effected a one share for 50 shares Reverse Stock Split on October 9, 2020. All references in the accompanying consolidated financial statements to the number of shares of Common Stock and per share amounts have been retroactively adjusted to give effect to the Reverse Stock Split.

Bonuses for Certain Officers and Employees

In October 2020, the Company's Board of Directors approved bonus payments for an aggregate of approximately $0.4 million to certain officers and employees upon completion of the Fiscal 2021 Financing discussed above. Accordingly, the Company paid these bonuses in October 2020 and will recognize the related bonus expense for the fiscal quarter ending December 31, 2020.

ActiveSite Milestone Payment

Pursuant to the license agreement with ActiveSite discussed in Note 4, the first milestone payment for $1.0 million is due upon effectiveness of an IND. On October 28, 2020, the Company submitted an IND to the FDA that is expected to trigger the first milestone payment upon completion of review and acceptance by the FDA.

Operating Lease

On October 28, 2020, the Company entered into an assignment, assumption and amendment of lease agreement for ancillary office space in Bend, Oregon. The lease space consists of approximately 5,000 square feet and provides for average monthly rent of approximately $8,700 through the expiration date in February 2024. The lease provides one option to renew the lease for an additional three years at market rates. The Company has not yet determined the amount of the ROU asset and the related operating lease liabilities that will be recognized at inception of this lease.

Unaudited Pro Forma Disclosure

Presented below is an unaudited pro forma balance sheet that gives effect to the Fiscal 2021 Financing and the Early Payments to Xoma, as if these events had occurred on September 30, 2020 (in thousands, except per share amount):

	Historical	Equity Financing: Gross Proceeds [1]	Equity Financing: Offering Costs [2]	Xoma: Early Payments [3]	Pro Forma
Assets					
Current assets:					
Cash and cash equivalents	$ 6,404	$ 41,000	$ (3,491)	$ (1,409)	$ 42,504
Prepaid expenses and other	491	-	-	-	491
Total current assets	6,895	41,000	(3,491)	(1,409)	42,995
Long-term assets:					
Right-of-use assets, net	325	-	-	-	325
Deferred offering costs	129	-	(129)	-	-
Other	61	-	-	-	61
Total assets	$ 7,410	$ 41,000	$ (3,620)	$ (1,409)	$ 43,381
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable	$ 797	$ -	$ -	$ -	$ 797
Accrued liabilities	473	-	(129)	-	344
Current portion of license fees payable to Xoma	1,409	-	-	(1,409)	-
Current portion of operating lease liabilities	245	-	-	-	245
Total current liabilities	2,924	-	(129)	(1,409)	1,386
Long-term liabilities:					
Operating lease liabilities, net of current portion	104	-	-	-	104
Total liabilities	3,028	-	(129)	(1,409)	1,490
Stockholders' equity:					
Common Stock, $0.001 par value, 500,000 shares authorized; see below for issued and outstanding	6	2	-	-	8
Additional paid-in capital	155,232	40,998	(3,491)	-	192,739
Accumulated deficit	(150,856)	-	-	-	(150,856)
Total stockholders' equity	4,382	41,000	(3,491)	-	41,891
Total liabilities and stockholders' equity	$ 7,410	$ 41,000	$ (3,620)	$ (1,409)	$ 43,381
Number of shares of Common Stock issued and outstanding	5,867	2,485	-	-	8,352

(1) Gives effect to the receipt of gross proceeds of $41.0 million on October 9, 2020, as a result of the private placement of units at an issuance price of $16.50 per unit. The units consisted of an aggregate of approximately 2.5 million shares of Common Stock and warrants for the purchase of an additional 0.8 million shares of Common Stock.

(2) Gives effect to the financial advisory fees of 6.0% of the gross proceeds and other estimated offering costs of approximately $1.0 million related to the Fiscal 2021 Financing, of which $0.1 million was incurred but unpaid as of September 30, 2020.

(3) Gives effect to the requirement discussed in Note 4 to repay the remaining obligations due to Xoma, since the Fiscal 2021 Financing met the definition of a qualified financing.

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

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

Recent Developments

On October 9, 2020, we completed a private placement of equity securities that resulted in net proceeds of approximately $37.5 million. The completion of this private placement triggered our obligations to Xoma with a remaining balance due of $1.4 million as of September 30, 2020. Effective October 9, 2020, we implemented a one share for 50 shares Reverse Stock Split of our $0.001 par value Common Stock. On November 3, 2020, we obtained approval from Nasdaq to have our shares of common stock listed on the Nasdaq Capital Market.

Please refer to our discussion under *Liquidity* below and in Notes 1, 4 and 12 to our unaudited condensed consolidated financial statements for further discussion of the private placement, Early Payments due to Xoma, and the Reverse Stock Split.

Special Note About COVID-19

We have been actively monitoring the COVID-19 situation and its impact. Our primary objectives have remained the same throughout the pandemic: to support the safety of our team members and their families and continue to support our preclinical studies and clinical trials. While our financial results for the three months ended September 30, 2020 and the fiscal year ended June 30, 2020 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 continued good health of our employees, the ability of us to maintain operations, access to healthcare facilities and patient willingness to participate in our clinical trials, any further government and/or public actions taken in response to the pandemic and ultimately the length of the pandemic. The ultimate impact of the COVID-19 pandemic on our business operations, our ability to raise capital, as well as our preclinical studies and clinical trials remains uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. Any prolonged material disruption of our employees, suppliers, or manufacturing may negatively impact our consolidated financial position, results of operations and cash flows. We will continue to monitor the situation closely.

Summary of Clinical Assets

Our lead clinical asset, RZ358, is an antibody therapy in Phase 2b development as a potential treatment for congenital hyperinsulinism ("CHI"), 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 abates in different regions, we are resuming clinical activities including trial site initiations. We believe that patient enrollment will recommence by the end of calendar year 2020. Further, if we can begin enrolling patients on this timeframe, we believe we will be able to complete the RIZE study in the second half of calendar year 2021.

In addition, in the first half of calendar year 2020, we had positive interactions with the U.S. Food and Drug Administration ("FDA"). In June 2020, we announced that FDA granted us Rare Pediatric Disease ("RPD") designation for RZ358, which qualifies us to receive a priority review voucher upon marketing approval of the drug in CHI. Such a voucher could be redeemed to receive a priority review of a subsequent marketing application for any drug candidate in any disease indication. Further, we submitted the RIZE protocol to FDA which allows us to expand the study to clinical sites in the United States. We believe that patient enrollment may commence in the United States in the first quarter of calendar year 2021.

Our next program, RZ402, is an oral therapy, targeting diabetic macular edema ("DME"). On October 28, 2020, we submitted an IND to the FDA that will require us to make the first milestone payment of $1.0 million within 15 days after acceptance of the IND by the FDA. Assuming the FDA accepts our IND filing by November 2020, we anticipate initiation of a Phase 1 clinical trial for RZ402 prior to the end of the first quarter of calendar year 2021.

RZ358

CHI is an ultra-rare pediatric genetic disorder characterized by excessive production of insulin by the pancreas. CHI is caused by mutations in about a dozen known genes associated with pancreatic beta cells and their secretion of insulin. If untreated, it can lead to dangerously low blood sugar levels. Rezolute's lead candidate, RZ358, is an antibody in Phase 2b development that is designed to prevent severe, persistent low blood sugar in patients with CHI.

RZ358 is an intravenously administered human monoclonal antibody that binds to a unique site on the insulin receptor found across effector cells throughout the body in the liver, fat, and muscle. This action allows RZ358 to counteract the effects of elevated insulin in the body. Its unique allosteric mechanism of action is reversible, depends on both insulin levels and blood sugar levels in a dose-dependent manner, and enables patients to achieve normal levels of insulin and glucose. Therefore, we believe that RZ358 is ideally suited as a potential therapy for conditions characterized by excessive insulin production and it is being developed to treat hyperinsulinemia and prevent low blood sugar for diseases such as CHI. As RZ358 acts downstream from the beta cells, across effector cells in the liver, fat, and muscle, it may be universally effective at treating CHI caused by any of the underlying genetic defects.

The RIZE study is a multi-center, open-label, repeat-dose Phase 2b study of RZ358 in four sequential dosing cohorts of patients with CHI who are at least two years old and have residual low blood sugar (<70 mg/dL) that is inadequately controlled on existing therapies. In addition to safety and pharmacokinetic evaluations, continuous glucose monitoring ("CGM") and self-monitored blood glucose will be utilized to evaluate several glycemic efficacy endpoints. The primary endpoint is the time within a glucose target range of 70-180 mg/dL by CGM during weeks 4 and 8 of treatment compared to baseline.

RZ402

DME is a severe complication of diabetes marked by progressive vision loss and blindness. Consistently high blood sugar levels can cause diabetic retinopathy, a complication characterized by damage to the blood vessels in the eye and fluid leakage into the light-sensitive tissue known as the retina. The accumulation of fluid may lead to DME, or swelling of the macula, the part of the retina responsible for sharp, straight-ahead vision. Currently available treatments for DME involve frequent burdensome injections into the eye or invasive laser surgery.

Rezolute is developing RZ402, a small molecule plasma kallikrein inhibitor ("PKI") for use in DME. As a once-daily oral investigational therapy, RZ402 is designed to improve compliance and treatment outcomes for patients with DME. Elevated plasma levels of the enzyme kallikrein have been associated with increased inflammation, vessel leakage and excess blood vessel growth in the eyes of patients with DME. Genetic and pharmacologic knockout of plasma kallikrein have been shown to protect against vascular endothelial growth factor ("VEGF") induced retinal blood vessel leakage in murine models without damaging long-term effects.

RZ402 is a bioavailable small molecule inhibitor of plasma kallikrein that has shown the potential to prevent the onset of and reverse vascular leakage in a dose-dependent manner in multiple rodent models of whole body and retinal vascular leakage. Target plasma concentrations were exceeded for 24 hours following oral dosing of RZ402 in monkeys and dogs, supporting the potential for once daily dosing in humans. We have completed toxicology studies and we filed an IND with the FDA on October 28, 2020.

Factors Impacting our Results Operations

We have not generated any revenues since our inception in March 2010. Since inception, we have engaged in organizational activities, conducted private placements to raise additional capital, built out a manufacturing suite and produced material for our lead product candidate under good laboratory practices ("GLP"), conducted studies using the GLP material, subsequently changed our strategy to a licensing model that resulted in disposal of our manufacturing assets, and conducted other research and development activities on our pipeline product candidates.

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

In December 2019, we received top-line results in our Phase 1 clinical study related to AB101 where we determined that additional formulation adjustments are required before further clinical studies can be undertaken. As a portfolio management decision, we have decided not to take the program further in development and expect that future expenditures related to the program will be insignificant.

Key Components of Consolidated Statements of Operations

Research and development expenses. Research and development expenses ("R&D") consist primarily of compensation and benefits for our personnel engaged in R&D activities, clinical trial costs, and consultants and outside services. Our research and development compensation and consulting costs include (i) an allocable portion of our cash and stock-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 expenses ("G&A") consist primarily of (i) an allocable portion of our cash and stock-based compensation, employee benefits and consulting costs 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, investor relations and other costs primarily related to our status as a public company.

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

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 2020 Form 10-K, we believe that the following accounting policies involve a greater degree of judgment and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of operations.

Research and Development

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

Stock-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 Black-Scholes-Merton ("BSM") option-pricing model and recognize the cost of the equity awards over the period that services are provided to earn the award. For awards granted which contain a graded vesting schedule, and the only condition for vesting is a service condition, compensation cost is recognized on a straight-line basis over the requisite service period as if the award was, in substance, a single award. We recognize the impact of forfeitures in the period that the forfeiture occurs, rather than estimating the number of awards that are not expected to vest in accounting for stock-based compensation.

We have granted stock options with vesting that is dependent on achieving certain market, performance and service conditions ("Hybrid Options"). For purposes of recognizing compensation cost, we determine the requisite service period as the longest of the derived, implicit and explicit vesting periods for each of the market, performance and service conditions, respectively. Compensation cost will be recognized beginning on such date that achievement of the performance condition is considered probable and continuing through the end of the requisite service period. Determination of the requisite service period of the Hybrid Options will be based on the date that the performance condition is considered probable. Unrecognized compensation cost for the Hybrid Options, calculated using the BSM pricing model, will be recognized beginning on the date that the performance condition is considered probable using the grant date fair value. If the Hybrid Options do not ultimately become exercisable as a result of failure to achieve the requisite service period, any previously recognized compensation cost will be reversed.

Results of Operations

Three months ended September 30, 2020 and 2019

Results of operations for the three months ended September 30, 2020 and 2019 reflect net losses of approximately $3.6 million and $5.1 million, respectively. Our unaudited condensed consolidated statements of operations for the three months ended September 30, 2020 and 2019, along with the changes between periods, are presented below (dollars in thousands):

			Changes	
	2020	2019	Amount	Percent
Operating expenses:				
Research and development:				
Compensation and benefits, net of related party reimbursements	$ 1,212	$ 1,418	$ (206)	-15%
Clinical trial costs	758	991	(233)	-24%
Consultants and outside services	142	486	(344)	-71%
Material manufacturing costs	174	187	(13)	-7%
Facilities and other	58	152	(94)	-62%
Total research and development	2,344	3,234	(890)	-28%
General and administrative:				
Compensation and benefits	705	1,336	(631)	-47%
Professional fees	370	360	10	3%
Facilities and other	204	249	(45)	-18%
Total general and administrative	1,279	1,945	(666)	-34%
Total operating expenses	3,623	5,179	(1,556)	-30%
Operating loss	(3,623)	(5,179)	1,556	-30%
Non-operating income - interest and other	3	99	(96)	-97%
Net loss	$ (3,620)	$ (5,080)	$ 1,460	-29%

Presented below is a discussion of the key factors that resulted in changes in our results of operations for these periods.

Revenue. As a clinical stage company, we did not generate any revenue for the three months ended September 30, 2020 and 2019. 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 decreased from approximately $3.2 million for the three months ended September 30, 2019 to $2.3 million for the three months ended September 30, 2020, a decrease of $0.9 million. As a result of the COVID-19 pandemic, we were forced to curtail many of our R&D activities for the three months ended September 30, 2020. Each category of our R&D expense decreased for the three months ended September 30, 2020, as discussed below.

For the three months ended September 30, 2020, we had a decrease of $0.2 million in compensation and benefits for our R&D workforce, which was attributable to a decrease of $0.3 million in stock-based compensation expense and $0.1 million related to the benefit from the CARES Act employee retention credit that was received in September 2020. These decreases amount to $0.4 million and were partially offset by higher costs for the three months ended September 30, 2020 since we did not receive any reimbursements from Handok and Genexine (collectively referred to as "H&G) under the Master Services Agreement entered into in July 2019. For the three months ended September 30, 2019, we charged H&G $0.2 million for employee services that were reflected as a reduction of R&D compensation expense. We anticipate that our stock-based compensation will increase for the second quarter of fiscal 2021 due to achievement of the performance condition related to the Hybrid Options.

For the three months ended September 30, 2020, we incurred $0.8 million for clinical trial costs primarily related to RZ358. For the three months ended September 30, 2019, we incurred $1.0 million for clinical trial costs that consisted of $0.6 million related to RZ358 and $0.4 million for AB101. In December 2019, we received top-line results in our Phase 1 clinical study related to AB101 where we determined that additional formulation adjustments are required before further clinical studies can be undertaken. As a portfolio management decision, we have decided not to take the program further in development and expect that future expenditures related to the program will be insignificant.

Consulting and outside services decreased from approximately $0.5 million for the three months ended September 30, 2019 to $0.1 million for the three months ended September 30, 2020. For the three months ended September 30, 2019, we incurred higher consulting spending of $0.1 million related to RZ358, $0.1 million for RZ402, and $0.2 million for patent maintenance costs. For the three months ended September 30, 2020, consulting and outside services of $0.1 million was primarily for a combination of RZ358, RZ402 and patent maintenance costs.

Costs allocable to R&D activities for facilities and other costs decreased from $0.2 million for the three months ended September 30, 2019 to $0.1 million for the three months ended September 30, 2020. The decrease was primarily attributable to reduced spending for travel and generally lower overall levels of R&D activity for the three months ended September 30, 2020.

As discussed below under the caption *Liquidity and Capital Resources*, we intend to use the proceeds from our recently completed financing to advance our clinical programs and fulfill our development obligations under the amended License Agreement with Xoma, and our milestone payments under the ActiveSite License Agreement entered into in August 2017.

General and administrative expenses. G&A expenses decreased from approximately $1.9 million for the three months ended September 30, 2019 to $1.3 million for the three months ended September 30, 2020, a decrease of $0.6 million. This decrease was primarily attributable to decreases in compensation and benefits for our administrative and executive workforce of $0.6 million.

The decrease of $0.6 million in compensation and benefits was primarily attributable to a decrease in stock-based compensation expense of $0.5 million and cash-based compensation of $0.1 million. Stock-based compensation decreased by $0.5 million primarily due to certain stock options that were immediately vested on the grant date in July 2019, whereby the expense was immediately recognized for the vested shares. Expense recognition after July 2019 is being recognized ratably over the remaining vesting period which resulted in lower expense for the three months ended September 30, 2020. Cash-based compensation decreased by $0.1 million for the three months ended September 30, 2020 due to a reduction in severance costs, and receipt of the CARES Act employee retention credit in September 2020. We anticipate that our stock-based compensation will increase for the second quarter of fiscal 2021 due to achievement of the performance condition related to the Hybrid Options.

Our facilities and other costs decreased by approximately $45,000 for the three months ended September 30, 2020, primarily due to reduced travel and office-related expenses due to COVID-19 restrictions.

Income Taxes. For the three months ended September 30, 2020 and 2019, we did not recognize any income tax benefit due to our net losses and our determination that a full valuation allowance was required for our deferred tax assets.

Liquidity and Capital Resources

As of September 30, 2020, we had cash and cash equivalents totaling approximately $6.4 million and working capital was approximately $4.0 million. We have incurred cumulative net losses of $150.9 million since our inception, and as a clinical stage company we have not generated any revenue to date.

As discussed below under Fiscal 2021 Financing, in October 2020 we received aggregate net proceeds from investors in a private placement of approximately $37.5 million from the issuance of units that consisted of approximately 2.5 million shares of Common Stock and warrants for the purchase of approximately 0.8 million shares of Common Stock. We believe our existing cash and cash equivalents balance plus the net proceeds from the private placement of $37.5 million will be adequate to carry out currently planned activities until the second half of the fiscal year ending June 30, 2022. We also have flexibility to delay future clinical programs to conserve our capital resources.

Beginning in March 2020, COVID-19 has resulted in an economic environment that is unfavorable for many businesses to conduct operations. The U.S. economy had been largely shut down by mass quarantines and government mandated stay-in-place orders to halt the spread of the virus. While these orders have been relaxed, a full recovery of the U.S. economy may not occur until after 2021. The long-term effects on us are expected to result in higher costs in order to comply with safeguards to protect patients and staff engaged in clinical activities, and extended periods of time may be required to complete clinical trials. The current economic environment and financial market volatility may make it more challenging for us to continue to obtain funding in the future for our clinical programs.

Presented below is further discussion of recent developments that impacted our liquidity and capital resources.

Fiscal 2021 Financing

On October 9, 2020, we completed a private placement of units (the "Units") consisting of (i) approximately 2.5 million shares of Common stock, and (ii) warrants entitling the holders to purchase approximately 0.8 million shares of Common Stock (the "Warrants"). The Warrants are exercisable at $19.50 per share for a period of 7 years and may be exercised on a cash or cashless basis at the election of the holders. The Units were issued for a purchase price of $16.50 per Unit, resulting in gross proceeds of $41.0 million. Pursuant to a financial advisory agreement, we agreed to pay the advisors a fee of 6.0% of the gross proceeds, and costs for professional fees and other offering costs are estimated at approximately 2.0% of the gross proceeds. After deducting the financial advisory fees and other offering costs, the estimated net proceeds amounted to approximately $37.5 million. Pursuant to the terms of the private placement, we executed the Reverse Stock Split, which was previously approved by the stockholders at our annual meeting on October 23, 2019 and that was effective on October 9, 2020. In addition, we are required to use commercially reasonable efforts to (i) list our shares of Common Stock for trading on the Nasdaq Capital Market which was approved by Nasdaq on November 3, 2020, (ii) register the shares of Common Stock included in the Units, and (iii) register the shares of Common Stock issuable upon exercise of the warrants. If we fail to register the shares pursuant to the terms of the RRA, liquidated damages up to a maximum of 6.0% of the gross proceeds of the Fiscal 2021 Financing may be assessed.

Xoma License Agreement

In December 2017, we entered into a license agreement ("License Agreement") with XOMA Corporation ("Xoma") pursuant to which Xoma granted us an exclusive global license to develop and commercialize RZ358 for all indications. In January 2019, the License Agreement was amended. with an updated payment schedule, as well as revising the amount we were required to expend on development of RZ358 and related licensed products, and revised provisions with respect to our diligence efforts in conducting clinical studies.

On March 31, 2020, we entered into Amendment No. 3 to the License Agreement to extend the previous payment schedule for the remaining balance of approximately $2.6 million. The revised payment schedule provided for seven quarterly payments to be paid beginning on March 31, 2020, whereby the outstanding balance was reduced to $1.4 million as of September 30, 2020. Pursuant to Amendment No. 3, we were obligated to repay the remaining outstanding balance within 15 days following the closing of a financing for $20.0 million or more. Accordingly, the completion of the Fiscal 2021 Financing resulted in acceleration of the $1.4 million outstanding obligation, which was paid in full on October 23, 2020.

Upon the achievement of certain clinical and regulatory events, we will be required to make up to $37.0 million in aggregate milestone payments to Xoma. The first such milestone payment of $2.0 million will be triggered upon enrollment of the last patient in our ongoing phase 2 clinical study. As a result of COVID-19, this study has been temporarily paused. Assuming we are able to resume the phase 2b study by the end of calendar year 2020, we believe we will be able to complete this study by the second half of calendar year 2021. Additionally, upon the future commercialization of RZ358, we will be required to pay royalties to Xoma based on the net sales of the related products, and milestone payments up to an additional $185.0 million if future annual sales related to RZ358 exceed targets ranging from $100.0 million to $1.0 billion..

ActiveSite License Agreement

In August 2017, we entered into a Development and License Agreement with ActiveSite Pharmaceuticals, Inc. ("ActiveSite") pursuant to which we acquired the rights to ActiveSite's Plasma Kallikrein Inhibitor program ("PKI Program"). We are planning to use the PKI Program to develop, file, manufacture, market and sell products for diabetic macular edema and other human therapeutic indications. The ActiveSite License Agreement requires various milestone payments ranging from $1.0 million to $10.0 million when milestone events occur, up to an aggregate of $46.5 million of aggregate milestone payments. The first milestone payment for $1.0 million is due after acceptance of an IND, which we filed with the FDA on October 28, 2020 and is currently under review. We will also be required to pay royalties equal to 2.0% of any sales of products that use the PKI Program.

Cash Flows Summary

Presented below is a summary of our operating, investing and financing cash flows for the three months ended September 30, 2020 and 2019 (in thousands):

	2020	2019	Change
Net cash provided by (used in):			
Operating activities	$ (3,551)	$ (8,929)	$ 5,378
Investing activities	-	-	-
Financing activities	-	22,571	(22,571)

Cash Flows Used in Operating Activities

For the three months ended September 30, 2020 and 2019, cash flows used in operating activities amounted to $3.6 million and $8.9 million, respectively. The key components in the calculation of our cash used in operating activities are as follows (in thousands):

	2020	2019	Change
Net loss	$ (3,620)	$ (5,080)	$ 1,460
Non-cash expenses	699	1,454	(755)
Changes in operating assets and liabilities, net	(630)	(5,303)	4,673
Total	$ (3,551)	$ (8,929)	$ 5,378

For the three months ended September 30, 2020, our net loss was $3.6 million compared to $5.1 million for the three months ended September 30, 2019. For further discussion about changes in our operating results for the three months ended September 30, 2020 and 2019, please refer to *Results of Operations* above.

For the three months ended September 30, 2020 and 2019, our non-cash expenses of $0.7 million and $1.5 million, respectively, were primarily attributable to stock-based compensation expense. For the three months ended September 30, 2020, net changes in operating assets and liabilities decreased operating cash flow by $0.6 million, primarily driven by a reduction in accrued liabilities of $0.6 million. This reduction was comprised of a $0.4 million decrease in payables to Xoma under the amended License Agreement, and a $0.2 million decrease in other accrued liabilities. For the three months ended September 30, 2019, net changes in operating assets and liabilities decreased operating cash flow by $5.3 million, which was primarily due to a decrease in payables to Xoma of $4.9 million under the amended license agreement.

Cash Flows Provided by Investing Activities

We did not have any cash flows from investing activities for the three months ended September 30, 2020 and 2019.

Cash Flows Provided by Financing Activities

We did not have any cash flows from financing activities for the three months ended September 30, 2020. Net cash provided by financing activities for the three months ended September 30, 2019 amounted to $22.6 million. This amount consisted of (i) $20.0 million received from the H&G in July 2019 for the purchase of approximately 1.4 million shares of Common Stock at a purchase price of $14.50 per share and (ii) $4.1 million received from other investors in July and August 2019 for the purchase of approximately 0.3 million shares of our Common Stock at a purchase price of $14.50 per share. The gross proceeds from these equity issuances totaled $24.1 million and was partially offset by fees of $1.5 million under a financial advisory agreement to result in net proceeds of $22.6 million.

Recent Accounting Pronouncements

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

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not required for smaller reporting companies.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive and financial officer), of the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended ("Exchange Act"). Based on that assessment under those criteria, our management has determined that, as of September 30, 2020, our internal control over financial reporting was not effective due to a material weakness in the system of internal control. A material weakness is a deficiency, or combination of deficiencies, that creates a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected in a timely manner.

The material weakness identified by management is 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, 2020, we hired a Director of Accounting 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.

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 (as defined in Rule 13(a)-15(f) or 15(d)-15(f)) that occurred during the period covered by this quarterly report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

None

ITEM 1A. RISK FACTORS.

Certain factors exist which may affect the Company's business and could cause actual results to differ materially from those expressed in any forward-looking statements. Factors that could cause our actual results to differ materially from those in this Report are any of the risks described in Item 1.A. *Risk Factors* of our 2020 Form 10-K, and the risk factor discussed below. Any of these factors could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations.

COVID-19 could continue to adversely impact our business, including our clinical trials.

Beginning in March 2020, COVID-19 has resulted in an economic environment that is unfavorable for many businesses to conduct operations and to pursue new debt and equity financings. The U.S. economy had been largely shut down by mass quarantines and government mandated stay-in-place orders to halt the spread of the virus. While these orders have been relaxed, a full recovery of the U.S. economy may not occur until 2021 or later. The extent to which COVID-19 may continue to impact our business and clinical trials 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 outbreak, 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, we will likely experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients or maintaining scheduled study visits in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our business or our clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people or as a result of the governmental imposition of "shelter in place" or similar working restrictions;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

COVID-19 is currently impacting countries, communities and markets. We require ongoing access to the capital markets to fund our future capital requirements. To the extent that our access to the capital markets is adversely affected by COVID-19, we may need to consider alternative sources of funding for our operations and for working capital, any of which could increase our cost of capital.

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation that may be initiated by our stockholders, including claims under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. Notwithstanding the foregoing, the exclusive provision shall not preclude or contract the scope of exclusive federal or concurrent jurisdiction for actions brought under the Securities Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended, or the respective rules and regulations promulgated thereunder."

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit Number	Description of Exhibits
31.1*	Certification of Chief Executive and Principal Financial Officer as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1*	Certification of Chief Executive and Principal Financial Officer as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS*	XBRL Instance Document
101.SC*	XBRL Taxonomy Extension Schema
101.CA*	XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LA*	XBRL Taxonomy Extension Label Linkbase
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase

* Filed herewith.

SIGNATURES

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

REZOLUTE, INC.

Date: November 12, 2020

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

EXHIBIT 31.1

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

I, Nevan Elam, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2020

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

EXHIBIT 32.1

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

In connection with the quarterly report of Rezolute, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nevan Elam, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2020

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. Inc. to be furnished to the Securities and Exchange Commission or its staff upon request.