

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 December 31, 2019

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

(State of other jurisdiction of incorporation or organization)

27-3440894

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

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

(Address of Principal Executive Offices)

94065

(Zip Code)

(650) 206-4507

(Registrant's Telephone Number, including Area Code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class  
None

Trading Symbol(s)  
None

Name of each exchange on which registered  
None

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 293,320,891 shares of its \$0.001 par value common stock outstanding as of February 7, 2020.

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## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

- projected operating or financial results, including anticipated cash flows used in operations;
- expectations regarding capital expenditures, research and development expense and other payments;
- 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, 2019 (the “2019 Form 10-K”), filed with the Securities and Exchange Commission (“SEC”) on September 10, 2019.

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

**PART I - FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS.**

**Rezolute, Inc.**

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

	<b>December 31, 2019</b>	<b>June 30, 2019</b>
<b><u>Assets</u></b>		
Current assets:		
Cash and cash equivalents	\$ 18,182	\$ 11,573
Restricted cash	1,530	-
Prepaid expenses and other	257	571
Total current assets	<u>19,969</u>	<u>12,144</u>
Right-of-use assets, net	497	-
Property and equipment, net	38	44
Intangible assets, net	26	29
Lease security deposits	35	35
Total assets	<u>\$ 20,565</u>	<u>\$ 12,252</u>
<b><u>Liabilities and Stockholders' Equity</u></b>		
Current liabilities:		
Accounts payable	\$ 1,253	\$ 563
Accrued liabilities:		
Compensation and benefits	800	790
Other	641	526
Current portion of license fees payable to Xoma	2,609	6,500
Current portion of operating lease liabilities	239	-
Total current liabilities	<u>5,542</u>	<u>8,379</u>
Operating lease liabilities, net of current portion	287	-
Other non-current liabilities	48	121
License fees payable to Xoma, net of current portion	-	2,000
Total liabilities	<u>5,877</u>	<u>10,500</u>
<b>Commitments and contingencies (Note 7)</b>		
Stockholders' equity:		
Preferred Stock, \$0.001 par value; 20,000 shares authorized, no shares issued	-	-
Common Stock, \$0.001 par value, 500,000 shares authorized; 293,321 and 210,390 shares issued and outstanding as of December 31, 2019 and June 30, 2019, respectively	293	210
Additional paid-in capital	153,044	128,445
Accumulated deficit	<u>(138,649)</u>	<u>(126,903)</u>
Total stockholders' equity	14,688	1,752
Total liabilities and stockholders' equity	<u>\$ 20,565</u>	<u>\$ 12,252</u>

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

Rezolute, Inc.

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2019	2018	2019	2018
Operating expenses:				
Research and development:				
Compensation and benefits, net of related party reimbursements	\$ 1,750	\$ 372	\$ 3,168	\$ 929
Clinical trial costs	1,922	1	2,913	4
Consulting and outside services	972	126	1,458	173
Material manufacturing costs	254	472	441	545
Facilities and other	140	338	292	588
Total research and development	<u>5,038</u>	<u>1,309</u>	<u>8,272</u>	<u>2,239</u>
General and administrative:				
Compensation and benefits	981	1,382	2,317	2,632
Professional fees	273	99	633	265
Facilities and other	428	292	677	531
Total general and administrative	<u>1,682</u>	<u>1,773</u>	<u>3,627</u>	<u>3,428</u>
Loss on sale of equipment	-	46	-	23
Impairment of long-lived assets	-	33	-	33
Total operating expenses	<u>6,720</u>	<u>3,161</u>	<u>11,899</u>	<u>5,723</u>
Operating loss	<u>(6,720)</u>	<u>(3,161)</u>	<u>(11,899)</u>	<u>(5,723)</u>
Non-operating income (expense):				
Interest and other income	54	287	153	395
Interest expense	-	(1,288)	-	(2,199)
Net loss	<u>\$ (6,666)</u>	<u>\$ (4,162)</u>	<u>\$ (11,746)</u>	<u>\$ (7,527)</u>
Net loss per common share - basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.07)</u>	<u>\$ (0.04)</u>	<u>\$ (0.12)</u>
Weighted average number of common shares outstanding - basic and diluted	<u>293,321</u>	<u>62,124</u>	<u>282,277</u>	<u>62,145</u>

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

Rezolute, Inc.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
<b>Six Months Ended December 31, 2019:</b>					
Balances, June 30, 2019	210,390	\$ 210	\$ 128,445	\$ (126,903)	\$ 1,752
Stock-based compensation	-	-	2,059	-	2,059
Fair value of warrants issued to consultants for services	-	-	73	-	73
Issuance of common stock for cash:					
Related parties at \$0.29 per share	68,966	69	19,931	-	20,000
Other investors at \$0.29 per share	13,965	14	4,036	-	4,050
Advisory fees and other offering costs	-	-	(1,500)	-	(1,500)
Net loss	-	-	-	(11,746)	(11,746)
Balances, December 31, 2019	<u>293,321</u>	<u>\$ 293</u>	<u>\$ 153,044</u>	<u>\$ (138,649)</u>	<u>\$ 14,688</u>
<b>Six Months Ended December 31, 2018:</b>					
Balances, June 30, 2018	62,166	\$ 62	\$ 90,161	\$ (94,184)	\$ (3,961)
Stock-based compensation	-	-	1,694	-	1,694
Fair value of warrants issued to consultants for services	-	-	6	-	6
Shareholder surrender of shares for no consideration	(300)	-	-	-	-
Net loss	-	-	-	(7,527)	(7,527)
Balances, December 31, 2018	<u>61,866</u>	<u>\$ 62</u>	<u>\$ 91,861</u>	<u>\$ (101,711)</u>	<u>\$ (9,788)</u>

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

Rezolute, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows  
(in thousands)

	Six Months Ended December 31,	
	2019	2018
<b>Cash Flows From Operating Activities:</b>		
Net loss	\$ (11,746)	\$ (7,527)
Stock-based compensation expense	2,059	1,694
Depreciation and amortization expense	9	42
Fair value of warrants issued for services	73	6
Accretion of debt discount and issuance costs	-	1,581
Impairment of long-lived assets	-	33
Loss on sale of equipment	-	23
Gain on lease termination	-	(168)
Gain from change in fair value of embedded derivatives	-	(74)
Changes in operating assets and liabilities:		
Decrease in prepaid expenses and other assets	423	249
Increase in accounts payable	690	337
Increase (decrease) in accrued liabilities	(28)	721
Decrease in license fees payable to Xoma	(5,891)	-
<b>Net cash used in operating activities</b>	<u>(14,411)</u>	<u>(3,083)</u>
<b>Cash Flows Provided by Investing Activities:</b>		
Proceeds from sale of equipment	-	195
<b>Cash Flows From Financing Activities:</b>		
Proceeds from issuance of Common Stock:		
Related parties	20,000	-
Other investors	4,050	-
Payments for advisory fees and other offering costs	(1,500)	-
Proceeds from Series AA financing exclusivity payment	-	1,500
<b>Net cash provided by financing activities</b>	<u>22,550</u>	<u>1,500</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	8,139	(1,388)
Cash, cash equivalents and restricted cash, beginning of period	11,573	1,646
Cash, cash equivalents and restricted cash, end of period	<u>\$ 19,712</u>	<u>\$ 258</u>
<b>Cash, Cash Equivalents and Restricted Cash:</b>		
Cash and cash equivalents, end of period	\$ 18,182	\$ 258
Restricted cash, end of period	<u>1,530</u>	<u>-</u>
Cash, cash equivalents and restricted cash, end of period	<u>\$ 19,712</u>	<u>\$ 258</u>
<b>Supplementary Cash Flow Information:</b>		
Cash paid for interest	\$ -	\$ -
Cash paid for income taxes	-	-

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

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

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

***Nature of Operations***

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

***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, 2019, 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 2019 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, 2019.

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 and six months ended December 31, 2019 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, 2020.

***Segment Information***

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

***Reclassifications***

Certain amounts in the previously issued comparative interim financial statements for the three and six months ended December 31, 2018 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 (deficit).

***Consolidation***

The Company has three wholly owned subsidiaries consisting of AntriaBio Delaware, Inc., Rezolute (Bio) Ireland Limited, and Rezolute Bio UK, Ltd. The accompanying 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 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.

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

***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.

***Research and Development Costs***

Research and development costs are expensed as incurred. Intangible assets for in-licensing costs incurred under license agreements with third parties are charged to expense, unless the licensing rights have separate economic value in alternative future research and development projects or otherwise.

***Clinical Trial Accruals***

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses 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. The Company determines 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 research and development activities, are deferred and recognized as expense in the period that the related goods are delivered, or services are performed.

***Stock Options with Market, Performance and Service Conditions***

The Company has granted stock options with vesting that is dependent on achieving certain market, performance and service conditions ("Hybrid Options"). For purposes of recognizing compensation cost, the Company determines 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 and valuation of the Hybrid Options using the Black-Scholes-Merton ("BSM") option-pricing model will be calculated on the date that the performance condition is considered probable. If the Hybrid Options do not ultimately vest as a result of failure to achieve a service condition, any previously recognized compensation cost will be reversed.

***Leases***

The Company determines if an arrangement includes a lease as of the date an agreement is entered into. Operating leases are included in right-of-use ("ROU") assets and operating lease liabilities in the Company's Condensed Consolidated Balance Sheets. ROU assets and operating lease liabilities are initially recognized based on the present value of the future minimum lease payments at the commencement date of the lease. The Company generally uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future payments. The Company's leases may include options to extend or terminate the lease; these options are included in the calculation of ROU assets and operating lease liabilities when it is reasonably certain that the Company will exercise the options. Lease expense is recognized on a straight-line basis over the lease term. The Company has elected not to apply the recognition requirements for short-term leases. For lease agreements with lease and non-lease components, the Company generally accounts for them separately.

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**Recent Accounting Pronouncements**

*Recently Adopted Standards.* The following accounting standards were adopted during the six months ended December 31, 2019:

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Updated (“ASU”) 2016-02, *Leases* (Topic 842). This ASU requires the Company to recognize right-of-use assets and operating lease liabilities on the balance sheet and also disclose key information about leasing arrangements. On July 1, 2019, the Company adopted this new standard using the modified retrospective approach in accordance with *Leases - Targeted Improvements* (ASU No. 2018-11). The Company elected the package of practical expedients permitted under the transition guidance within ASU No. 2018-11, which among other things, allowed the Company to carry forward the historical lease classification of those leases in place as of July 1, 2019. The impact of adoption resulted in the recognition of right-of-use assets and operating lease liabilities for the discounted present value of the future lease payments on leases that were in effect on July 1, 2019, as follows (in thousands):

Right-of-use assets recorded under new standard	\$	605
Operating lease liabilities recorded under new standard:		
Current	\$	227
Long-term		406
Total		633
Eliminate deferred rent liability under current accounting standard		(28)
Net increase in liabilities due to adoption of new standard	\$	605

Please refer to Note 3 for further information about the right-of-use assets and operating lease liabilities recognized under this standard. Due to the Company’s election to adopt this standard effective July 1, 2019, rent expense was recognized under the accounting standard that was previously in effect for all periods prior to July 1, 2019.

In June 2018, the FASB issued ASU 2018-07, "*Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*," which expands the scope of ASC 718 to include share-based payment transactions for acquiring goods and services from non-employees. The new standard does not apply to warrants issued to a lender or investor in a financing transaction. The Company adopted ASU 2018-07 effective July 1, 2019. Prior to the adoption of ASU 2018-07, the Company accounted for stock options and warrants granted to non-employees based on the fair value of the goods and services, or the equity instrument, whichever could be measured more reliably. If fair value of the equity instrument was more reliably determined, fair value of the equity instrument was required to be re-measured until the performance commitment date was achieved, which resulted in the recognition of subsequent changes in fair value. Under the new standard, the fair value of the goods and services acquired from non-employees is solely determined using the fair value of the equity instruments issued and measurement of fair value is fixed on the grant date. The Company also made an accounting policy election to recognize the impact of forfeitures of non-employee awards in the period that the forfeiture occurs. The impact of adopting this standard was immaterial to the Company’s unaudited condensed consolidated financial statements.

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

In June 2016, the FASB issued 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 2018, ASU 2016-13 was amended by ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments – Credit Losses*. ASU 2018-19 changes the effective date of the credit loss standards (ASU 2016-13) to fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Further, the ASU clarifies that operating lease receivables are not within the scope of ASC 326-20 and should instead be accounted for under the new leasing standard, ASC 842.

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 our financial statements upon adoption.

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**NOTE 2 — LIQUIDITY**

The Company is in the clinical stage and has not yet generated any revenues. For the fiscal year ended June 30, 2019, the Company incurred a net loss of \$30.4 million and net cash used in operating activities amounted to \$15.3 million. For the six months ended December 31, 2019, the Company incurred a net loss of \$11.7 million and net cash used in operating activities amounted to \$14.4 million. As of December 31, 2019, the Company had an accumulated deficit of \$138.6 million. As of December 31, 2019, the Company had cash, cash equivalents and restricted cash of \$19.7 million and total liabilities of \$5.9 million.

As discussed in Note 5, in July and August 2019 the Company received aggregate net proceeds of approximately \$22.6 million from the issuance of approximately 82.9 million shares of Common Stock to investors in a private placement. Management believes the Company's existing cash, cash equivalents and restricted cash balance of \$19.7 million will be adequate to carry out currently planned activities through February 2021. The Company has flexibility to delay clinical programs, if necessary, to ensure that adequate capital resources are available to fund activities for the next 12 months. Therefore, if additional financing is not obtained by the second quarter of calendar year 2020, management plans to delay clinical spending and reduce discretionary spending in order to ensure that the Company's most important clinical initiatives continue to be funded for the next 12 months. Management believes it has the ability to effectively manage these expenditures to enable the Company to have sufficient liquidity to operate through February 2021. The Company expects to continue pursuing equity and/or debt financings to provide funding for clinical programs and other planned activities for the foreseeable future. There are no assurances that the Company will be able to obtain additional financing equity offerings and bank financings in the future. Even if these financing sources are available, they may be on terms that are not acceptable to management and the Company's stockholders.

**NOTE 3 — RIGHT-OF-USE ASSETS**

As discussed in Note 1, the Company adopted ASU 2016-02, *Leases* (Topic 842) effective July 1, 2019. As of July 1, 2019, the Company had two leases in effect, consisting of (i) a lease for its headquarters location in Redwood City, California that was entered into on January 25, 2019, that provides for monthly rent of approximately \$21,000 through the expiration date in March 2022, and (ii) a lease for office space in Bend, Oregon entered into on February 7, 2019, that provides for monthly rent of approximately \$2,700 through the expiration date in February 2021. The impact of adoption of ASU 2016-02 resulted in the recognition of right-of-use ("ROU") assets for \$0.6 million and operating lease liabilities for the discounted present value of the future lease payments on these leases of approximately \$0.6 million. For the three and six months ended December 31, 2019, under ASC 842 the Company had operating lease expense of approximately \$71,000 and \$129,000, respectively. For the three and six months ended December 31, 2018, under the previous lease accounting standard the Company had operating lease expense of approximately \$151,000 and \$303,000, respectively.

The Company determined the operating lease liability of approximately \$633,000 as of July 1, 2019 based upon a discount rate of 10.0% and assuming that the Company will not exercise its option to extend the headquarters lease for an additional three years. The discount rate represents the Company's estimated incremental borrowing rate for debt with similar lender rights as the underlying operating lease terms.

**Balance Sheet Presentation**

As of December 31, 2019 and on the adoption date of July 1, 2019, the carrying value of ROU assets and operating lease liabilities are as follows (in thousands):

	December 31, 2019	July 1, 2019
<b>Right-of-Use Assets, net</b>	<u>\$ 497</u>	<u>\$ 605</u>
<b>Operating Lease Liabilities:</b>		
Current	\$ 239	\$ 227
Long-term	<u>287</u>	<u>406</u>
<b>Total</b>	<u>\$ 526</u>	<u>\$ 633</u>

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

As of December 31, 2019, the weighted average remaining lease term under operating leases was 2.1 years, and the weighted average discount rate for operating lease liabilities was 10.0%. For the six months ended December 31, 2019, cash paid for amounts included in the measurement of operating lease liabilities amounted to \$136,000, which is included in net cash used in operating activities in the unaudited condensed consolidated statement of cash flows.

**Future Lease Payments**

Future payments under operating lease agreements as of December 31, 2019 are as follows (in thousands):

<b>Fiscal year ending June 30,</b>	
Remainder of fiscal year 2020	\$ 139
2021	272
2022	170
Total lease payments	581
Less imputed interest	(55)
Present value of operating lease liabilities	<u>\$ 526</u>

**NOTE 4 — LICENSE AGREEMENTS**

**Xoma License Agreement**

On December 6, 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. On January 7, 2019, the License Agreement was amended whereby the Company was required to make five cash payments to Xoma totaling \$8.5 million on or before specified staggered future dates (the “Future Cash Payments”). As a result of this amendment to the License Agreement, the Company recognized a liability in January 2019 for the entire \$8.5 million of Future Cash Payments.

The amended License Agreement provides that if future qualified financings occur before the Future Cash Payments are fully paid, the Company is required to pay Xoma 15% of the net proceeds from such financings (“Early Payments”) to be credited against the remaining unpaid Future Cash Payments in the reverse order of their future payment date. Obligations to make the Future Cash Payments following a qualified financing and the obligations to make Early Payments shall end when the Future Cash Payments are fully paid for the total of \$8.5 million. As discussed in Note 5, the Company completed equity financings for net proceeds of approximately \$22.6 million in July and August 2019, which resulted in the obligation to make Early Payments of approximately \$3.4 million. Presented below is a summary of the amounts payable under the amended License Agreement along with cash payments made for the six months ended December 31, 2019 (in thousands):

<b>Scheduled Payment Date</b>	<b>Balance June 30, 2019</b>	<b>Cash Payments</b>		<b>Balance December 31, 2019</b>
		<b>Early Payments</b>	<b>Scheduled Payments</b>	
September 30, 2019	\$ 1,500	\$ -	\$ (1,500)	\$ -
December 31, 2019	1,000	-	(1,000)	-
March 31, 2020	2,000	-	-	2,000
June 30, 2020	2,000	(1,391)	-	609
September 30, 2020	2,000	(2,000)	-	-
Total	8,500	<u>\$ (3,391)</u>	<u>\$ (2,500)</u>	2,609
Less long-term portion of payable	(2,000)			-
Current portion of payable	<u>\$ 6,500</u>			<u>\$ 2,609</u>

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

The amendment to the License Agreement also revised the amount the Company is 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. Additionally, upon the future commercialization of RZ358, the Company would be required to pay royalties to Xoma based on the net sales of the related products.

As of December 31, 2019, Xoma owns approximately 8.1 million shares of the Company's Common Stock. The License 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 may exercise the Put Option for up to a total of 2.5 million shares of Common Stock for the calendar year ending December 31, 2020, and up to an additional 2.5 million shares thereafter. If Xoma exercises the Put Option, the Company is required to use its best efforts to assist Xoma in facilitating the sale of shares to third-party purchasers or purchase the shares for its own account. The price per share under the Put Option is equal to the average of the closing bid and asked prices of the Common Stock on the date the Put Option is exercised.

***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 ranging from \$1.0 million to \$10.0 million when milestone events occur, up to \$46.5 million of aggregate milestone payments. The first milestone payment for \$1.0 million is due after completion of the preclinical work and submission of an Initial Drug Application, or IND, to the U.S. Food and Drug Administration. The Company is also required to pay royalties equal to 2.0% of any sales of products that use the PKI Portfolio. Through December 31, 2019, no events occurred that would result in the requirement to make milestone payments and no royalties have been incurred.

**NOTE 5 — STOCKHOLDERS' EQUITY (DEFICIT)**

***Changes in Stockholders' Equity (Deficit)***

For changes in stockholders' equity (deficit) for the six months ended December 31, 2019 and 2018, please refer to the unaudited condensed consolidated statements of stockholders' equity (deficit) on page 3. The following table presents changes in stockholders' equity for the three months ended December 31, 2019 and 2018:

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
<b>Three Months Ended December 31, 2019:</b>					
Balances, September 30, 2019	293,321	\$ 293	\$ 152,308	\$ (131,983)	\$ 20,618
Stock-based compensation	-	-	665	-	665
Fair value of warrants issued to consultants for services	-	-	71	-	71
Net loss	-	-	-	(6,666)	(6,666)
Balances, December 31, 2019	<u>293,321</u>	<u>\$ 293</u>	<u>\$ 153,044</u>	<u>\$ (138,649)</u>	<u>\$ 14,688</u>
<b>Three Months Ended December 31, 2018:</b>					
Balances, September 30, 2018	62,166	\$ 62	\$ 91,044	\$ (97,549)	\$ (6,443)
Stock-based compensation	-	-	816	-	816
Fair value of warrants issued to consultants for services	-	-	1	-	1
Shareholder surrender of shares for no consideration	(300)	-	-	-	-
Net loss	-	-	-	(4,162)	(4,162)
Balances, December 31, 2018	<u>61,866</u>	<u>\$ 62</u>	<u>\$ 91,861</u>	<u>\$ (101,711)</u>	<u>\$ (9,788)</u>

**Equity Offerings**

In January 2019, the Company closed an equity offering with two new investors (the “New Investors”) that resulted in cash proceeds of \$25.0 million and the issuance of an aggregate of approximately 113.6 million shares of the Company’s Common Stock in April 2019. The Company granted each of the New Investors a call option whereby upon the earlier of (i) December 31, 2020 and (ii) such date that the Company requests the New Investors to provide additional financing, each New Investor was entitled to purchase up to \$10.0 million of Common Stock at a purchase price equal to the greater of (i) \$0.29 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 “Private Placement”) of (i) the shares of Common Stock issuable under the call option issued to the New Investors for a total of \$20.0 million, plus (ii) \$10 million of equity or equity equivalent securities to be issued to other investors. On July 23, 2019, the Company entered into a purchase agreement whereby the New Investors exercised their call option to purchase an aggregate of approximately 69.0 million shares of Common Stock for gross cash proceeds of \$20.0 million. Since VWAP for the previous thirty consecutive trading days was \$0.20 per share, the New Investors exercised the call option at a purchase price of \$0.29 per share. In addition, during July and August 2019 other investors purchased an aggregate of approximately 14.0 million shares of Common Stock at a purchase price of \$0.29 per share for gross cash proceeds of \$4.1 million. Pursuant to the financial advisory agreement, the Company agreed to pay a fee of 6.0% of the gross proceeds received from these private placements. The total advisory fees and other offering costs related to these issuances in July and August 2019 amounted to approximately \$1.5 million, resulting in net proceeds of \$22.6 million for the six months ended December 31, 2019. As discussed in Note 4, the completion of these financings resulted in the obligation to make Early Payments of approximately \$3.4 million under the License Agreement with Xoma. With the closing of the Private Placement, under the terms of the financial advisory agreement until August 2020, the financial advisors have a right of first refusal to serve as Joint Bookrunners or Joint Placement Agents in any offering the Company undertakes.

**Restricted Cash**

In connection with the private placement discussed above, one of the investors purchased approximately 13.1 million shares of Common Stock for gross proceeds of \$3.8 million. The Company agreed to spend the proceeds for research and development of RZ358 or for the Company’s planned uplisting of its Common Stock to a national stock exchange. For the three and six months ended December 31, 2019, the Company made qualified expenditures of \$1.6 million and \$2.3 million, respectively. As of December 31, 2019, the restricted cash balance amounted to \$1.5 million.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

*Reverse Stock Split*

In August 2019, the Company's Board of Directors approved a reverse stock split (the "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 has the ability at any time on or before October 23, 2020 to execute the Reverse Stock Split and set the 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. As of the date of this Report, the Board of Directors has not taken action to effect the Reverse Stock Split. If the Reverse Stock Split is subsequently implemented, the number of shares subject to outstanding stock options and warrants will also be adjusted with a corresponding increase in the related exercise prices.

**NOTE 6 — STOCK-BASED COMPENSATION AND WARRANTS**

*Stock Option Plans*

The Company currently has three active stock option plans consisting of the 2015 Non-Qualified Stock Option Plan (the "2015 Plan"), 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 15.0 million shares of the Company's Common Stock. The Company also has stock options outstanding to purchase up to approximately 2.2 million shares of Common Stock under the 2014 Stock and Incentive Plan (the "2014 Plan") that terminated on March 21, 2019. Stock options outstanding under the 2014 Plan expire pursuant to their contractual provisions on various dates in 2021. Presented below is a summary of the number of shares authorized, outstanding, and available for future grants under each of the Company's stock option plans (in thousands):

Description	Termination Date	Number of Shares		
		Authorized	Outstanding	Available
2014 Plan	March 2019	2,185	2,185	-
2015 Plan	February 2020	6,850	4,605	2,245
2016 Plan	October 2021	28,000	26,231	1,769
2019 Plan	July 2029	15,000	15,000	-
Total		52,035	48,021	4,014

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

July 2019 Grants

On July 31, 2019, the Board of Directors granted stock options for an aggregate of approximately 34.0 million shares of Common Stock to certain officers and employees at an exercise price of \$0.29 per share. The closing price of the Company's shares of Common Stock on the date of grant was approximately \$0.21 per share. The option grants were designated for approximately 19.0 million shares under the 2016 Plan and 15.0 million shares under the 2019 Plan. As of July 31, 2019, the number of shares subject to stock options, the related fair value and compensation that was immediately recognized for vested options are as follows (in thousands):

	Time-Based Vesting		Unvested Hybrid Options	Total
	Number of Shares			
	Vested	Unvested		
Executive officers	3,588 <sup>(1)</sup>	11,562 <sup>(1)(3)</sup>	7,550 <sup>(2)(3)</sup>	22,700
Other employees	921 <sup>(1)</sup>	6,629 <sup>(1)</sup>	3,700 <sup>(2)</sup>	11,250
Total	4,509	18,191	11,250 <sup>(6)</sup>	33,950
Total fair value	\$ 817 <sup>(4)</sup>	\$ 3,297 <sup>(5)</sup>		

- (1) Stock options are subject to time-based vesting in two tranches, whereby (i) 25% of such options are immediately exercisable for employees who have been employed by the Company for more than one year, and for employees that have been employed by the Company less than one year, 25% of such options will vest on the one year anniversary of the employee's start date, and (ii) the remaining 75% of the stock options will vest ratably over a period of 36 months beginning on the vesting date for the initial 25% tranche.
- (2) Stock options that commence vesting upon the achievement of market, performance and service conditions ("Hybrid Options"). These options will vest ratably over a period of 36 months beginning when 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 \$0.58 per share for 20 trading days in any consecutive 30 day period.
- (3) In August 2019, an executive officer terminated employment which resulted in forfeiture of stock options shown in the table above with time-based vesting for 0.8 million shares and Hybrid Options for 0.4 million shares.
- (4) Represents the aggregate grant date fair value for stock options that were immediately vested on the grant date, which is included in stock-based compensation expense for the six months ended December 31, 2019.
- (5) Represents the aggregate grant date fair value for stock options that were not immediately vested on the grant date and will be charged to expense from the grant date through the respective vesting dates through July 2023.
- (6) The Company has not recognized any expense related to these stock options for the three and six months ended December 31, 2019, since it is not yet probable that the performance condition will be achieved. The Company will begin recognizing compensation expense at such time that the performance condition is probable and continuing through the end of the requisite service period. Determination of the requisite service period and valuation of the Hybrid Options will be calculated on the date that the performance condition is considered probable.

In November 2019, the Company granted an additional 1,995,000 shares to certain employees, a director and members of the scientific advisory board at an exercise price of \$0.29. These options were granted under the 2015 Plan, vest ratably over periods ranging from 36 to 48 months and expire ten years after the grant date. The estimated fair value of these stock options was \$0.2 million as of the grant date.

Stock Options Outstanding

The following table sets forth a summary of the combined stock option activity under all of the Company's stock option plans for the six months ended December 31, 2019 (shares in thousands):

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

	Shares	Price <sup>(1)</sup>	Term <sup>(2)</sup>
Outstanding, beginning of period	13,865	\$ 1.60	6.4
Granted	35,945	0.29	
Forfeited	(1,789)	0.43	
Outstanding, end of period	<u>48,021</u>	0.66	8.6
Vested, end of period	<u>17,237</u>	1.20	7.0

(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 is included in compensation and benefits under the following captions in the unaudited condensed consolidated statements of operations (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2019	2018	2019	2018
Research and development	\$ 351	\$ 61	\$ 925	\$ 191
General and administrative	314	755	1,134	1,503
Total	<u>\$ 665</u>	<u>\$ 816</u>	<u>\$ 2,059</u>	<u>\$ 1,694</u>

Unrecognized stock-based compensation expense related to stock options that provide solely for time-based vesting as of December 31, 2019 is approximately \$4.8 million. This amount is expected to be recognized over a remaining weighted average period of 2.2 years. Unrecognized compensation cost has not yet been determined for an aggregate of 11,250,000 shares for the Hybrid Options since the valuation is required to be performed on the date that the performance condition becomes probable. However, based on preliminary estimates using the BSM option-pricing model, management believes the aggregate fair value will be approximately \$2.0 million before adjusting for forfeitures.

For the six months ended December 31, 2019, the aggregate fair value of stock options granted for approximately 24.7 million shares of Common Stock that provide solely for time-based vesting, amounted to \$4.3 million or approximately \$0.18 per share as of the grant date. Fair value was computed using the BSM option-pricing model and will result in the recognition of compensation cost ratably over the expected vesting period of the stock options. For the six months ended December 31, 2019, the fair value of each time-based option was estimated on the date of grant using the BSM option-pricing model, with the following weighted-average assumptions:

Valuation Inputs	
Fair value of common stock on grant date	\$ 0.21
Exercise price of stock options	0.29
Expected volatility	118%
Risk free interest rate	1.9%
Expected term (years)	6.5
Dividend yield	0%

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

**Warrants**

The Company has issued warrants in conjunction with various debt and equity financings and for services. For the three and six months ended December 31, 2019, no warrants were exercised. Presented below is a summary of warrant activity for the six months ended December 31, 2019 (shares in thousands):

	<u>Shares</u>	<u>Price <sup>(1)</sup></u>	<u>Term <sup>(2)</sup></u>
Outstanding, beginning of period	45,997	\$ 1.34	2.3
Warrants issued for consulting services	700 <sup>(3)</sup>	0.29	
Warrant expirations	(361)	1.90	
Outstanding, end of period	<u>46,336</u>	1.32	1.9

(1) Represents the weighted average exercise price.

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

(3) Represents warrants granted for consulting services in November 2019 with an expiration date in November 2024. The fair value the warrants of \$67,000 was determined using the BSM model. Since the warrants were immediately vested, this entire amount is included in consulting and outside services under research and development expenses for the three and six months ended December 31, 2019. Key assumptions for the valuation of these warrants included the closing price of the Company's shares of common stock of \$0.13 on the grant date, the exercise price of \$0.29 per share, historical volatility of 119%, and an expected term of 5 years.

**NOTE 7 — COMMITMENTS AND CONTINGENCIES**

**Commitments**

Please refer to Notes 4 and 5 for further discussion of commitments to make milestone payments and to pay royalties under license agreements, and to make certain qualified expenditures related to the Company's restricted cash balance.

**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 December 31, 2019, 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 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**

**Equity Issuances**

As discussed in Note 5, on July 23, 2019 the New Investors agreed to purchase an aggregate of approximately 69.0 million shares of Common Stock at an issuance price of \$0.29 per share for gross proceeds of \$20.0 million. This purchase was made pursuant to the terms of the call option that was issued in connection with an equity offering in January 2019 that resulted in gross proceeds of \$25.0 million. The New Investors currently own an aggregate of approximately 62% of the Company's outstanding shares of Common Stock.

**Rezolute, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**Master Services Agreement**

Effective July 1, 2019, the Company entered into a Master Services Agreement (“MSA”) with the New Investors whereby the Company agreed to assist the New Investors in an evaluation of their long acting growth hormone program referred to as GX-H9. For the six months ended December 31, 2019, the Company charged the New Investors for employee services of \$103,000 and reimbursable expenses incurred with unrelated parties of \$144,000, for a total of approximately \$247,000. As of December 31, 2019, the Company had collected all of these receivables. 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 six months ended December 31, 2019.

**NOTE 9 — SUPPLEMENTAL FINANCIAL INFORMATION**

**Bonuses and Termination of Employment Agreement**

On July 31, 2019, the Board of Directors approved cash bonus payments to three executive officers for past services totaling \$448,000. The liability is included in accrued compensation and benefits in the consolidated balance sheet as of June 30, 2019. In August 2019, the Company paid the cash bonus payments to the three executive officers. On July 31, 2019, the Company also entered into an employment agreement with an executive officer that provided for an annual base salary of \$265,000, which was subsequently terminated in August 2019.

**Interest and Other Income**

Interest and other income are as follows for the three and six months ended December 31, 2019 and 2018 (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2019	2018	2019	2018
Interest income	\$ 54	\$ -	\$ 153	\$ -
Gain on lease termination	-	168	-	168
Gain from change in fair value of embedded derivatives	-	55	-	74
Rental income	-	64	-	153
Total	<u>\$ 54</u>	<u>\$ 287</u>	<u>\$ 153</u>	<u>\$ 395</u>

**NOTE 10 — INCOME TAXES**

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

For the three and six months ended December 31, 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 and six months ended December 31, 2019 and 2018.

Rezolute, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 11 — EARNINGS PER SHARE

For the three and six months ended December 31, 2019 and 2018, basic and diluted net loss per share were the same since all common stock equivalents were anti-dilutive. As of December 31, 2019 and 2018, 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):

	<u>2019</u>	<u>2018</u>
Stock options	48,021	18,701
Warrants	46,194	45,666
Total	<u>94,215</u>	<u>64,367</u>

NOTE 12 — FINANCIAL INSTRUMENTS AND SIGNIFICANT CONCENTRATIONS

*Fair Value Measurements*

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

Due to the relatively short maturity of the respective instruments, the fair value of cash and cash equivalents, restricted cash, receivables from related parties, accounts payable and accrued liabilities approximated their carrying values as of December 31, 2019 and June 30, 2019. The Company did not have any assets and liabilities measured at fair value on a recurring basis as of December 31, 2019 and June 30, 2019. 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 and six months ended December 31, 2019 and 2018, 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 six months ended December 31, 2019, cash deposits have exceeded the amount of federal insurance provided on such deposits. As of December 31, 2019 and June 30, 2019, the Company had cash, cash equivalents, and restricted cash with a single financial institution with an aggregate balance of \$19.7 million and \$11.6 million, respectively. The Company has never experienced any losses related to its investments in cash and cash equivalents.

NOTE 13 — SUBSEQUENT EVENT

In January 2020, the Company's Board of Directors approved bonus payments to the Company's executive officers and employees for a total of approximately \$0.7 million. These bonuses related to services performed during 2019. Accordingly, the Company recognized this amount as compensation expense for the three and six months ended December 31, 2019.

## 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 consolidated financial statements or in the associated text. Certain other amounts that appear in this section may similarly not sum due to rounding.*

### General

At Rezolute we are developing therapies to address metabolic and rare diseases. We have two development programs in our pipeline including our lead program, RZ358, which is a human monoclonal antibody that has been developed to counteract the effects of congenital hyperinsulinism (CHI) which is a rare, genetic, pediatric endocrine disorder that leads to the inappropriate secretion of the hormone insulin by the pancreas. High levels of insulin in the blood result in episodes of low blood sugar (hypoglycemia) with associated suppression of ketone bodies, the only other potential source of fuel to the glucose-dependent brain. With high potency and selectivity to an allosteric site on the insulin receptor, RZ358 counteracts the effects of elevated insulin at its target tissues by diminishing the binding and downstream signaling of insulin at its receptor.

On February 10, 2020, we announced that we initiated the RIZE study (RZ358-606), a Phase 2b clinical trial of RZ358, in patients with CHI. We have screened the first patient and expect to make significant enrollment progress to enable attainment of mid-study results over the coming year. This multi-center, open-label, repeat-dose study will assess the safety, tolerability and efficacy of RZ358 in patients who are at least two years old with CHI and who have residual hypoglycemia that is inadequately controlled on existing therapies. In addition to safety and pharmacokinetic evaluations, continuous glucose monitoring and self-monitored blood glucose will be utilized to evaluate several glycemic efficacy endpoints. We intend to enroll four sequential dosing cohorts, each with six to eight patients, starting at a dose of 3 mg/kg and increasing to as high as 12 mg/kg in the final cohort, as needed and tolerated. RZ358 will be administered weekly for the first month and then bi-weekly for the second month, for a total treatment duration of 8 weeks. The study is being conducted at leading CHI centers by Rezolute and its global study partners.

Our second pipeline candidate is RZ402, an oral plasma kallikrein inhibitor (PKI), that is in development to address diabetic macular edema. We have completed GLP and GMP manufacturing of RZ402 and are in the process of completing monkey and rodent toxicology studies to support the filing of an IND and the advancement of the program into the clinic. We are currently planning on filing the IND for RZ402 mid-2020 and to initiate and complete a Phase 1 study in healthy volunteers prior to the end of the year.

In addition to advancing our two pipeline candidates in 2020, we are proceeding with our efforts to uplist our Common Stock to a national stock exchange and seek to expand our shareholder base.

### Recent Developments

Presented below is a summary of Recent Developments. For additional details, reference is made to the footnotes to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Report.

As discussed further in Note 5 to our interim financial statements, on October 28, 2019, our stockholders approved an amendment to our Certificate of Incorporation to provide authority for the Board of Directors to subsequently effect a Reverse Stock Split of our \$0.001 par value Common Stock at a ratio ranging between 1-to-20 and 1-to-100. To date, our Board of Directors has not exercised its authority to effect the Reverse Stock Split.

As discussed further in Note 5 to our interim financial statements, in July 2019 the New Investors exercised their call options, resulting in the issuance of an aggregate of approximately 69.0 million shares of Common Stock at a purchase price of \$0.29 per share for gross cash proceeds of \$20.0 million. In addition, during July and August 2019 other investors purchased an aggregate of approximately 14.0 million shares of Common Stock at a purchase price of \$0.29 per share for gross cash proceeds of approximately \$4.1 million. Pursuant to a financial advisory agreement entered into in June 2019, we agreed to pay a fee of 6.0% of the gross proceeds received from these private placements. The total advisory fees and other offering costs related to these issuances in July and August 2019 amounted to approximately \$1.5 million, resulting in net proceeds of \$22.6 million for the six months ended December 31, 2019.

As discussed further in Note 4 to our interim financial statements, the financings completed in July and August 2019 resulted in our obligation to make Early Payments of approximately \$3.4 million under the License Agreement with Xoma. The Early Payments were paid in August 2019 and eliminated the requirement to make Future Cash Payments that would have otherwise been due on September 30, 2020 for \$2.0 million and on June 30, 2020 for approximately \$1.4 million.

As discussed further in Note 6 to our interim financial statements, in July 2019 we adopted a new stock option plan that provides authority to grant 15.0 million shares of our Common Stock. For the six months ended December 31, 2019, we granted stock options for an aggregate of approximately 35.9 million shares of Common Stock to our executive officers and employees at an exercise price of \$0.29 per share.

In the fourth quarter of calendar year 2019 we completed a Phase 1 first-in-human clinical study of AB101, a potential ultra long-acting insulin. The study evaluated three different dose levels of AB101, administered as subcutaneous doses in sequential ascending dose cohorts of 4 to 8 patients per cohort, in patients with Type 1 diabetes mellitus on background continuous insulin by pump. In addition to evaluating safety, tolerability, and extended pharmacokinetics, the effects of AB101 on glucose utilization were evaluated using the hyperinsulinemic euglycemic clamp technique (glucose infusion rate), changes in background insulin requirements, and both fasting and continuous glucose monitoring, in order to characterize the extended time-action pharmacodynamic profile of AB101.

The study was initiated with the first cohort at a low starting dose with the intent of conservatively evaluating the safety of a single dose of ultra long-acting insulin. This cohort was completed in the second half of calendar year 2017 and demonstrated good safety without any evidence of sudden insulin release. Further, given the initial low dose, no pharmacologic effect was observed. Following the completion of corporate financing activities, we resumed the study in the second quarter of calendar 2019 by conducting two additional dosing cohorts. The additional cohorts spanned a significant and interpretable dose range and were high enough to draw definitive conclusions across the totality of the study. In cohorts 2 and 3, overall good safety and tolerability was observed without sudden insulin release, and notably a slow onset and sustained level of insulin in the body for a period of seven days or more. Further, there was clear insulin activity as evaluated by the pharmacodynamic endpoints described above. However, we also observed that the absorption and overall time profile was variable between patients. Additionally, in order to achieve the observed pharmacodynamic effects, we had to evaluate dose levels that were higher than originally anticipated which required splitting the single dose into 2 or 3 injections.

From a safety, regulatory, and commercial perspective, it is our belief that these combined findings (absorption-time profile and dose volume) indicate that additional formulation development is required. Given our business model, we do not intend to invest further in the program and instead hope to find a pharmaceutical development partner. No assurance can be given that a partner will be identified or that we will be successful in licensing AB101 to a third party on favorable terms.

### **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 activities are undertaken. Consistent with our stated strategy, we are now actively seeking participation by industry partners to out-license AB101 for further development. Accordingly, our future expenditures for AB101 are expected to be insignificant.

### **Key Components of Consolidated Statements of Operations**

**Research and development expenses.** Research and development expenses consist primarily of material manufacturing costs, clinical trial costs and in-licensing costs. Our research and development expenses also 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, and (ii) an allocable portion of our facilities and overhead costs related to such personnel.

**General and administrative expenses.** General and administrative expenses 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. General and administrative expenses also include travel, legal, auditing, investor relations and other costs primarily related to our status as a public company.

**Interest expense.** The components of interest expense include the amount of interest payable in cash at the stated interest rate, and accretion of debt discounts and issuance costs ("DDIC") using the effective interest method. DDIC arises from the issuance of debt instruments at a discount to the original principal balance, the fair value of warrants issued in connection with a debt instrument, and incremental and direct costs incurred to consummate the financing.

**Interest and other income.** Interest and other income consist primarily of interest income earned on temporary cash investment, rental income related to subleases that were in effect until December 2018, and gains on changes in the fair value of embedded derivatives that were terminated in January 2019.

## **Critical Accounting Policies and Significant Judgments and Estimates**

### ***Overview***

Our management's discussion and analysis of financial condition and results of operations 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 2019 Form 10-K and in Note 1 of this Report, 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 unaudited condensed consolidated financial condition and results of operations.

### ***Research and Development***

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

### ***Clinical Trial Accruals***

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses 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. The Company determines 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 research and development activities, are deferred and recognized as expense in the period that the related goods are delivered, or services are performed.

### ***Stock Options with Market, Performance and Service Conditions***

We have granted stock options with vesting conditions that are 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 and valuation of the Hybrid Options using the Black-Scholes-Merton ("BSM") option-pricing model will be calculated on the date that the performance condition is considered probable. If the Hybrid Options do not ultimately vest as a result of failure to achieve a service condition, any previously recognized compensation cost will be reversed.

### ***Valuation of Stock Options and Warrants***

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

### ***Debt***

DDIC incurred to obtain new debt financing or modify existing debt financing consists of incremental direct costs incurred for professional fees and due diligence services, and the fair value of warrants issued in connection with the financing. DDIC is accreted to interest expense using the effective interest method.

If we amend our debt arrangements, we evaluate the terms to determine if the amendment should be accounted for as a troubled debt restructuring ("TDR"), a modification or an extinguishment. If we determine that the lender has provided a concession and we are experiencing financial difficulties, we would generally recognize a TDR gain. If we conclude that accounting as a modification is required, then any costs incurred on behalf of the lenders is accounted for as additional DDIC. If we conclude that accounting as an extinguishment is required, we measure the extinguishment charge on the date of the amendment based on the amount by which the fair value of the new debt instrument exceeds the net carrying value of the original debt instrument, and all previously unaccreted issuance costs are charged to expense.

## Leases

We determine if an arrangement includes a lease as of the date we enter into an agreement. Operating leases are included in right-of-use (“ROU”) assets, and operating lease liabilities in our Condensed Consolidated Balance Sheets. ROU assets and operating lease liabilities are recognized based on the present value of the future lease payments as of the lease commencement date. We generally use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. Our leases may include options to extend or terminate the lease; the calculation of ROU assets and operating lease liabilities gives effect to these options when we believe it is reasonably certain that the options will be exercised. Lease expense is recognized on a straight-line basis over the lease term. We have elected not to apply the recognition requirements for short-term leases. For lease agreements with lease and non-lease components, we generally account for them separately.

## Results of Operations

**Overview.** Due to inadequate funding in 2018, we implemented a restructuring plan in April 2018 to discontinue manufacturing activities in Colorado. The restructuring plan included a reduction in the Company’s workforce by 30 employees, the decision to sell substantially all laboratory equipment and other manufacturing assets, the decision to begin efforts to terminate operating leases in Colorado, and the suspension of our clinical program activities until such time as adequate financing was obtained. Beginning in January 2019 and continuing through August 2019, we obtained approximately \$49 million of additional financing which allowed us to hire additional employees and resume activities on clinical programs. Accordingly, as discussed below our operating expenses have increased significantly for the three and six months ended December 31, 2019.

### Three Months Ended December 31, 2019 and 2018

Results of operations for the three months ended December 31, 2019 and 2018 reflect net losses of approximately \$6.7 million and \$4.2 million, respectively. Our unaudited condensed consolidated statements of operations for the three months ended December 31, 2019 and 2018, along with the changes between periods, are presented below (in thousands):

	2019	2018	Change
Operating expenses:			
Research and development:			
Compensation and benefits, net	\$ 1,750	\$ 372	\$ 1,378
Clinical trial costs	1,922	1	1,921
Consulting and outside services	972	126	846
Material manufacturing costs	254	472	(218)
Facilities and other	140	338	(198)
Total research and development	<u>5,038</u>	<u>1,309</u>	<u>3,729</u>
General and administrative:			
Compensation and benefits	981	1,382	(401)
Professional fees	273	99	174
Facilities and other	428	292	136
Total general and administrative	<u>1,682</u>	<u>1,773</u>	<u>(91)</u>
Loss on sale of equipment	-	46	(46)
Impairment of long-lived assets	-	33	(33)
Net operating expenses	<u>6,720</u>	<u>3,161</u>	<u>3,559</u>
Operating loss	<u>(6,720)</u>	<u>(3,161)</u>	<u>(3,559)</u>
Non-operating income (expense):			
Interest and other income	54	287	(233)
Interest expense	-	(1,288)	1,288
Net loss	<u>\$ (6,666)</u>	<u>\$ (4,162)</u>	<u>\$ (2,504)</u>

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 December 31, 2019 and 2018. 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.** Our research and development (“R&D”) expenses increased from approximately \$1.3 million for the three months ended December 31, 2018 to \$5.0 million for the three months ended December 31, 2019, an increase of \$3.7 million. This increase was primarily attributable to increases in compensation and benefits, clinical trials costs, and consulting and outside services as discussed below.

For the three months ended December 31, 2019, we had an increase of \$1.4 million in compensation and benefits for our R&D workforce, which was attributable to (i) calendar year 2019 bonus expense of \$0.4 million, (ii) increased salaries and benefits cost of \$0.4 million as we added an average of ten employees to our R&D workforce, (iii) an increase of \$0.3 million in stock-based compensation expense, and (iv) our R&D employees did not perform administrative and financing-related functions in 2019, whereas \$0.2 million was allocated to G&A expenses for the three months ended December 31, 2018, but is included in R&D expenses for the three months ended December 31, 2019.

For the three months ended December 31, 2019, we had a \$1.9 million increase in our clinical trial costs. This increase included \$1.6 million for the initiation of the Phase 2 clinical program for RZ358 where we expect to begin enrolling patients over the next several months. For the three months ended December 31, 2019, we also incurred \$0.3 million, primarily for contract research costs in our AB101 first-in-human Phase 1 study for which we received top-line results in December 2019. We believe that additional formulation development is required before advancing AB101 further in the clinic, and we are actively seeking participation by industry partners to continue development. For the three months ended December 31, 2018, we did not have any material spending related to our clinical trials.

Consulting and outside services increased from approximately \$0.1 million for the three months ended December 31, 2018 to \$1.0 million for the three months ended December 31, 2019, an increase of \$0.9 million. This increase consisted primarily of contract laboratory consulting services related to RZ402 for \$0.7 million and \$0.1 million for non-clinical services related to RZ358. The increased spending for consulting and outside services was associated with and supported our increased clinical spending. For the three months ended December 31, 2018, consulting and outside services of \$0.1 million was primarily for contract laboratory consulting costs.

Material manufacturing costs decreased from \$0.5 million for the three months ended December 31, 2018 to \$0.3 million for the three months ended December 31, 2019. For the three months ended December 31, 2019 and 2018, our material manufacturing costs were exclusively related to RZ358. We expect our material manufacturing costs will increase as our clinical programs proceed through development.

Costs allocable to R&D activities for facilities and other costs decreased from \$0.3 million for the three months ended December 31, 2018 to \$0.1 million for the three months ended December 31, 2019. The reduction in facilities costs was primarily attributable to our decision to sublease and ultimately terminate our facility leases in Colorado in December 2018.

As discussed below under the caption *Liquidity and Capital Resources*, we intend to use the proceeds from our recently completed financings 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. Accordingly, we expect to continue increasing our R&D spending over the next 12 months.

**General and Administrative Expenses.** General and administrative (“G&A”) expenses decreased from approximately \$1.8 million for the three months ended December 31, 2018 to \$1.7 million for the three months ended December 31, 2019, a decrease of \$0.1 million. This decrease was primarily attributable to a decrease in compensation and benefits for our administrative and executive workforce of \$0.4 million, partially offset by increases in professional fees of \$0.2 million and facilities and other of \$0.1 million.

The decrease of \$0.4 million in compensation and benefits was primarily attributable to a decrease of \$0.4 million in stock-based compensation expense. Stock-based compensation decreased since certain stock options were either forfeited or became fully vested by December 2018, resulting in no further compensation expense after that date. The favorable impact from these stock options amounted to \$0.5 million and was partially offset by incremental compensation cost of \$0.1 million associated with stock option grants in July and November 2019.

Cash-based compensation for our administrative and executive workforce increased from \$0.6 million for the three months ended December 31, 2018 to \$0.7 million for the three months ended December 31, 2019, an increase of \$0.1 million. This increase was due to calendar year 2019 bonuses of \$0.2 million and an increase in compensation of \$0.1 million primarily due to the addition of two accounting and finance employees. These increases in cash-based compensation and benefits totaled \$0.3 million and were partially offset by a reduction of \$0.2 million for compensation and benefits of four R&D employees that were performing administrative and financing-related functions in 2018, and these allocations were no longer needed for the three months ended December 31, 2019.

For the three months ended December 31, 2019, the increase in professional fees of \$0.2 million was attributable to higher consulting costs of \$0.1 million for information technology and quarterly financial reporting services and higher costs of \$0.1 million for investor relations and incremental consulting costs related to our application to uplist to a national stock exchange.

Our facilities and other costs increased from \$0.3 million for the three months ended December 31, 2018 to \$0.4 million for the three months ended December 31, 2019. This increase of \$0.1 million was primarily due to the final personal property tax assessment related to our prior operations in Colorado.

In order to support increases in our planned spending for R&D over the next 12 months, we expect to also increase our G&A spending in comparison to our historical results during 2019.

**Loss on Sale and Impairment of Property and Equipment.** For the three months ended December 31, 2018, we sold excess laboratory and other equipment from our former facility in Colorado for nominal proceeds, which resulted in the recognition of a loss of \$46,000. As we prepared to vacate the facility in December 2018, we also determined that the remaining cost of the equipment and leasehold improvements was impaired by \$33,000. For the three months ended December 31, 2019, we did not recognize any impairment of long-lived assets or losses from the sale of property and equipment.

**Interest Expense.** Interest expense was approximately \$1.3 million for the three months ended December 31, 2018. Interest expense attributable to the Fiscal 2018 Notes for the three months ended December 31, 2018 consisted of accretion of discount of \$0.9 million, and interest expense of \$0.4 million based on the contractual rate of 15.0%. Due to the repayment of the Fiscal 2018 Notes in January 2019, we did not incur any interest expense for the three months ended December 31, 2019.

**Interest and Other Income.** Interest and other income decreased from \$0.3 million for the three months ended December 31, 2018 to \$0.1 million for the three months ended December 31, 2019, a decrease of \$0.2 million. Interest and other income for the three months ended December 31, 2019 was solely attributable interest income earned on temporary cash investments. For the three months ended December 31, 2018, interest and other income included a gain of \$0.2 million from the termination of our lease and sublease agreements in Colorado, and a gain of \$0.1 million for embedded derivatives related to the Fiscal 2018 Notes. Effective with the conversion of the Fiscal 2018 Notes to equity in January 2019, we no longer have any embedded derivatives.

**Income Taxes.** For the three months ended December 31, 2019 and 2018, 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.

As of June 30, 2019, we had NOL carryforwards of approximately \$81.0 million for U.S. federal income tax purposes, of which approximately \$41.0 million does not expire and \$40.0 million will begin to expire in 2030. Under provisions of the Internal Revenue Code, substantial changes in ownership may result in limitations on the amount of NOL carryforwards that we can utilize in future years. Due to our recent financing activities, we experienced ownership changes that are expected to result in significant limitations to the future use of our NOL carryforwards. We are in the process of quantifying the extent of such limitations, which could result in our inability to utilize a significant portion of our net operating loss carryforwards that were generated prior to any change of control.

**Six Months Ended December 31, 2019 and 2018**

Results of operations for the six months ended December 31, 2019 and 2018 reflect net losses of approximately \$11.7 million and \$7.5 million, respectively. Our unaudited condensed consolidated statements of operations for the six months ended December 31, 2019 and 2018, along with the changes between periods, are presented below (in thousands):

	<u>2019</u>	<u>2018</u>	<u>Change</u>
Operating expenses:			
Research and development:			
Compensation and benefits, net	\$ 3,168	\$ 929	\$ 2,239
Clinical trial costs	2,913	4	2,909
Consulting and outside services	1,458	173	1,285
Material manufacturing costs	441	545	(104)
Facilities and other	292	588	(296)
Total research and development	<u>8,272</u>	<u>2,239</u>	<u>6,033</u>
General and administrative:			
Compensation and benefits	2,317	2,632	(315)
Professional fees	633	265	368
Facilities and other	677	531	146
Total general and administrative	<u>3,627</u>	<u>3,428</u>	<u>199</u>
Loss on sale of equipment	-	23	(23)
Impairment of long-lived assets	-	33	(33)
Net operating expenses	<u>11,899</u>	<u>5,723</u>	<u>6,176</u>
Operating loss	(11,899)	(5,723)	(6,176)
Non-operating income (expense):			
Interest and other income	153	395	(242)
Interest expense	-	(2,199)	2,199
Net loss	<u>\$ (11,746)</u>	<u>\$ (7,527)</u>	<u>\$ (4,219)</u>

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 six months ended December 31, 2019 and 2018. 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 costs increased from approximately \$2.2 million for the six months ended December 31, 2018 to \$8.3 million for the six months ended December 31, 2019, an increase of \$6.0 million. This increase was attributable to increases in compensation and benefits, clinical trials costs, and consulting and outside services as discussed below.

For the six months ended December 31, 2019, we had an increase of \$2.2 million in compensation and benefits for our R&D workforce, which was attributable to an increase of \$0.7 million in stock-based compensation expense and an increase in cash-based compensation and benefits of \$1.5 million. The increase of \$1.5 million in cash-based compensation and benefits for our R&D workforce was attributable to (i) increased salaries and benefits cost of \$0.8 million as we added an average of ten employees to our R&D workforce, (ii) calendar year 2019 bonus expense of \$0.4 million, and (iii) our R&D employees did not perform administrative and financing-related functions in 2019, whereas \$0.4 million was allocated to G&A expenses for the six months ended December 31, 2018, but is included in R&D expenses for the six months ended December 31, 2019. The total increases in cash-based compensation and benefits for our R&D workforce amounted to \$1.6 million and was partially offset by \$0.1 million billed to the New Investors under the Master Services Agreement discussed in Note 8 to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Report.

For the six months ended December 31, 2019, we had a \$2.9 million increase in our clinical trial costs. This increase included \$2.2 million for the initiation of Phase 2 clinical testing for RZ358 where we expect to begin enrolling patients over the next several months. For the six months ended December 31, 2019, we also incurred \$0.7 million, primarily for contract research costs in our AB101 first-in-human Phase 1 study for which we received top-line results in December 2019. For the six months ended December 31, 2018, we did not have any material spending related to our clinical trials.

Consulting and outside services increased from approximately \$0.2 million for the six months ended December 31, 2018 to \$1.5 million for the six months ended December 31, 2019, an increase of \$1.3 million. This increase consisted of contract laboratory consulting services related to RZ402 for \$0.8 million, general R&D consulting of \$0.2 million, and quality and non-clinical services related to RZ358 for \$0.2 million. The increased spending for consulting and outside services was associated with and supported our increased clinical spending. For the six months ended December 31, 2018, consulting and outside services of \$0.2 million was primarily for contract laboratory consulting costs.

Material manufacturing costs decreased from \$0.5 million for the six months ended December 31, 2018 to \$0.4 million for the six months ended December 31, 2019. For the six months ended December 31, 2019 and 2018, our material manufacturing costs were exclusively related to RZ358.

Costs allocable to R&D activities for facilities and other costs decreased from \$0.6 million for the six months ended December 31, 2018 to \$0.3 million for the six months ended December 31, 2019. The reduction in facilities costs accounted for \$0.2 million of this decrease, which was primarily attributable to our decision to sublease and ultimately terminate our facility leases in Colorado in December 2018.

**General and Administrative Expenses.** General and administrative (“G&A”) expenses increased from \$3.4 million for the six months ended December 31, 2018 to \$3.6 million for the six months ended December 31, 2019, an increase of \$0.2 million. For the six months ended December 31, 2019, compensation and benefits for our administrative and executive workforce decreased by \$0.3 million, whereas professional fees increased by \$0.4 million and facilities and other increased by \$0.1 million.

Compensation and benefits decreased from approximately \$2.6 million for the six months ended December 31, 2018 to \$2.3 million for the six months ended December 31, 2019. The decrease in compensation and benefits of \$0.3 million consisted of a decrease of \$0.4 million in stock-based compensation expense, and an increase of \$0.1 million in cash-based compensation expense. Stock-based compensation decreased since certain stock options were forfeited or became fully vested by December 2018, resulting in no further compensation expense after that date. The favorable impact from expiring and forfeited stock options amounted to \$1.2 million and was partially offset by incremental compensation cost of \$0.8 million associated with new stock option grants in July and November 2019 for our administrative and executive workforce.

The mix of cash-based compensation and benefits costs changed for 2019 where we had increases due to (i) calendar year 2019 bonuses of \$0.2 million, (ii) higher compensation and benefits costs of \$0.1 million, primarily due to the addition of two accounting and finance employees, and (iii) severance and recruiting costs of \$0.2 million. These increases in cash-based compensation and benefits totaled \$0.5 million and were partially offset by a reduction of \$0.4 million for compensation and benefits of four R&D employees that were performing administrative and financing-related functions in 2018, and these allocations were no longer needed for the six months ended December 31, 2019.

Professional fees increased by \$0.4 million for the six months ended December 31, 2019. This increase in professional fees was primarily attributable to legal and consulting fees incurred for (i) our proxy statement and Special Meeting of Stockholders to approve the Reverse Stock Split, (ii) investor relations and fees related to our application to uplist to a national stock exchange, (iii) several complex transactions reported in our annual and quarterly SEC filings, and (iv) a registration statement filed with the SEC.

Our facilities and other costs increased from \$0.5 million for the six months ended December 31, 2018 to \$0.7 million for the six months ended December 31, 2019. This increase of \$0.2 million was primarily due to the final personal property tax assessment related to our prior operations in Colorado.

**Loss on Sale and Impairment of Property and Equipment.** For the six months ended December 31, 2018, we sold excess laboratory and other equipment from our former facility in Colorado for \$0.2 million, which resulted in the recognition of a loss of \$23,000. As we prepared to vacate the facility in December 2018, we also determined that the remaining cost of the equipment and leasehold improvements was impaired by \$33,000. For the six months ended December 31, 2019, we did not recognize any impairment of long-lived assets or losses from the sale of property and equipment.

**Interest Expense.** Interest expense was approximately \$2.2 million for the six months ended December 31, 2018. Interest expense attributable to the Fiscal 2018 Notes for the six months ended December 31, 2018 consisted of accretion of discount of \$1.6 million, and interest expense of \$0.6 million based on the contractual rate of 15.0%. Due to the repayment of the Fiscal 2018 Notes in January 2019, we did not incur any interest expense for the six months ended December 31, 2019.

**Interest and Other Income.** Interest and other income decreased from \$0.4 million for the six months ended December 31, 2018 to \$0.2 million for the six months ended December 31, 2019, a decrease of \$0.2 million. Interest and other income for the six months ended December 31, 2019 was solely attributable interest income earned on temporary cash investments for \$0.2 million. For the six months ended December 31, 2018, interest and other income consisted of (i) a gain of \$0.2 million from the termination of our lease and sublease agreements in Colorado, (ii) a gain of \$0.1 million for embedded derivatives related to the Fiscal 2018 Notes, and (iii) an increase in rental income from subleases of \$0.1 million. Effective with the conversion of the Fiscal 2018 Notes to equity in January 2019, we no longer have any embedded derivatives.

**Income Taxes.** For the six months ended December 31, 2019 and 2018, 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.

As of June 30, 2019, we had NOL carryforwards of approximately \$81.0 million for U.S. federal income tax purposes, of which approximately \$41.0 million does not expire and \$40.0 million will begin to expire in 2030. Under provisions of the Internal Revenue Code, substantial changes in ownership may result in limitations on the amount of NOL carryforwards that we can utilize in future years. Due to our recent financing activities, we experienced ownership changes that are expected to result in significant limitations to the future use of our NOL carryforwards. We are in the process of quantifying the extent of such limitations, which could result in our inability to utilize a significant portion of our net operating loss carryforwards that were generated prior to any change of control.

### **Liquidity and Capital Resources**

As of December 31, 2019, we have cash, cash equivalent and restricted cash totaling approximately \$19.7 million and working capital was approximately \$14.4 million. We have incurred cumulative net losses of \$138.6 million since our inception and as a clinical stage company we have not generated any revenue to date. Presented below is a discussion of recent developments for the six months ended December 31, 2019 that have resulted in a significant improvement in our liquidity.

#### **July and August 2019 Financings**

In connection with the Series AA offering completed with the New Investors in January 2019, we granted a call option to provide additional financing whereby the New Investors were entitled to elect to purchase up to \$20.0 million of our Common Stock at a purchase price equal to the greater of (i) \$0.29 per share or (ii) 75% of the volume weighted average closing price ("VWAP") of the our Common Stock during the thirty consecutive trading days prior to the date of the notice. In June 2019, we entered into a financial advisory agreement to undertake a private placement of (i) the shares of Common Stock issuable under the call option issued to the New Investors for a total of \$20.0 million, plus (ii) between approximately \$20 million and \$30 million of equity or equity equivalent securities to be issued to other investors. On July 23, 2019, we entered into a purchase agreement whereby the New Investors exercised their call option to purchase an aggregate of approximately 69.0 million shares of Common Stock for gross cash proceeds of \$20.0 million. Since VWAP for the previous thirty consecutive trading days was \$0.20 per share, the New Investors exercised the call option at a purchase price of \$0.29 per share.

Pursuant to the financial advisory agreement entered into in June 2019, we issued approximately 14.0 million shares of Common Stock in July and August 2019 to other investors in a private placement. These shares were issued at a purchase price of \$0.29 per share and resulted in gross proceeds of approximately \$4.1 million. Total advisory fees and other offering costs related to the July and August 2019 financings amounted to approximately \$1.5 million, resulting in net proceeds of approximately \$22.6 million.

### *Xoma License Agreement*

In January 2019, we entered into an amendment of our License Agreement with Xoma. This amendment eliminated the previous requirement that equity securities would be issued to Xoma upon the closing of a qualified financing in consideration for the payment to Xoma of approximately \$5.9 million in cash in February 2019. Additionally, we agreed to make five cash payments to Xoma totaling \$8.5 million (the "Future Cash Payments") in quarterly installments between September 2019 and September 2020. We recognized a liability in January 2019 for the entire \$8.5 million of Future Cash Payments.

The amended License Agreement provides that if future qualified financings occur before the Future Cash Payments are fully paid, we are required to pay Xoma 15% of the net proceeds from such financings ("Early Payments") to be credited against the remaining unpaid Future Cash Payments in the reverse order of their future payment date. Obligations to make the Future Cash Payments following a qualified financing and the obligations to make Early Payments shall end when the Future Cash Payments are fully paid for the total of \$8.5 million. The completion of equity financings in July and August 2019 for net proceeds of approximately \$22.6 million triggered our obligation to make Early Payments of approximately \$3.4 million. Presented below is a summary of the amounts payable under the amended License Agreement along with cash payments made for the six months ended December 31, 2019 (in thousands):

<b>Future Payment Date</b>	<b>Balance</b>	<b>Cash Payments</b>		<b>Balance</b>
	<b>June 30, 2019</b>	<b>Early Payments</b>	<b>Scheduled Payments</b>	<b>December 31, 2019</b>
September 30, 2019	\$ 1,500	\$ -	\$ (1,500)	\$ -
December 31, 2019	1,000	-	(1,000)	-
March 31, 2020	2,000	-	-	2,000
June 30, 2020	2,000	(1,391)	-	609
September 30, 2020	2,000	(2,000)	-	-
<b>Total</b>	<b>\$ 8,500</b>	<b>\$ (3,391)</b>	<b>\$ (2,500)</b>	<b>\$ 2,609</b>

The amendment to the License Agreement also revised the amount we are required to expend on development of RZ358 and related licensed products, and revised provisions with respect to our diligence efforts in conducting clinical studies. 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.

### *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 would be due after completion of the preclinical work and submission of an Initial Drug Application, or IND, to the U.S. Food and Drug Administration for RZ402, which we are attempting to complete in calendar year 2020. We will also be required to pay royalties equal to 2.0% of any sales of products that use the PKI Program. Through December 31, 2019, no events occurred that would result in the requirement to make milestone payments and no royalties have been incurred.

### *Planned Spending*

As a result of equity financings completed in July and August 2019, we believe our existing cash balance of \$19.7 million as of December 31, 2019, will be adequate to carry out currently planned activities at least through October 2020. We have the flexibility to delay our clinical programs, if necessary, to ensure that adequate capital resources are available to fund activities for the next 12 months. Therefore, if additional financing is not obtained by the second quarter of calendar year 2020, we plan to delay clinical spending and reduce substantially all discretionary spending in order to ensure that our most important clinical initiatives continue to be funded for the next 12 months. We believe we have the ability to effectively manage these expenditures to enable us to have sufficient liquidity to operate through February 2021. We expect to continue pursuing equity and/or debt financings to provide funding for clinical programs and other planned activities for the foreseeable future. There are no assurances that we will be able to obtain any additional financing. Even if additional financing sources are available, they may not be pursued if the terms are not acceptable to us. Our planned spending on clinical programs includes \$1.5 million of restricted cash that we are required to spend on development of RZ358 and our planned uplisting of our Common Stock to a national stock exchange.

### Cash Flows Summary

Presented below is a summary of our operating, investing and financing cash flows for the six months ended December 31, 2019 and 2018 (in thousands):

	<u>2019</u>	<u>2018</u>	<u>Change</u>
Net cash provided by (used in):			
Operating activities	\$ (14,411)	\$ (3,083)	\$ (11,328)
Investing activities	-	195	(195)
Financing activities	22,550	1,500	21,050

### Cash Flows Used in Operating Activities

For the six months ended December 31, 2019 and 2018, cash flows used in operating activities amounted to \$14.4 million and \$3.1 million, respectively. The key components in the calculation of our cash used in operating activities are as follows (in thousands):

	<u>2019</u>	<u>2018</u>	<u>Change</u>
Net loss	\$ (11,746)	\$ (7,527)	\$ (4,219)
Non-cash expenses	2,141	3,379	(1,238)
Non-cash gains	-	(242)	242
Changes in operating assets and liabilities, net	(4,806)	1,307	(6,113)
Total	<u>\$ (14,411)</u>	<u>\$ (3,083)</u>	<u>\$ (11,328)</u>

For the six months ended December 31, 2019, our net loss was \$11.7 million compared to \$7.5 million for the six months ended December 31, 2018. For further discussion about changes in our operating results for the six months ended December 31, 2019 and 2018, please refer to *Results of Operations* above.

For the six months ended December 31, 2019, substantially all of our non-cash expenses of \$2.1 million were attributable to stock-based compensation expense. For the six months ended December 31, 2018, non-cash expenses totaled \$3.4 million, which included stock-based compensation expense of approximately \$1.7 million and accretion of debt discounts and issuance costs related to the Fiscal 2018 Notes of \$1.6 million.

We did not have any non-cash gains for the six months ended December 31, 2019. For the six months ended December 31, 2018, non-cash gains consisted of a gain of \$0.2 million from the termination of our leases and subleases at our former Colorado facility and a gain of \$0.1 million on the change in fair value of embedded derivatives related to the Fiscal 2018 Notes.

For the six months ended December 31, 2019, net changes in operating assets and liabilities reduced operating cash flow by \$4.8 million which was primarily due to a \$5.9 million decrease in payables to Xoma under the amended License Agreement. This use of operating cash flow was partially offset by an increase in accounts payable of \$0.7 million, and a decrease in prepaid expenses and other assets of \$0.4 million.

For the six months ended December 31, 2018, net changes in operating assets and liabilities increased operating cash flow by \$1.3 million, which was due to an increase in accounts payable of \$0.3 million, an increase in accrued expenses of \$0.7 million, and a decrease in prepaid expenses and other assets of \$0.3 million.

#### *Cash Flows Provided by Investing Activities*

We did not have any cash flows from investing activities for the six months ended December 31, 2019. Net cash provided by investing activities for the six months ended December 31, 2018 amounted to \$0.2 million, which was attributable to proceeds from the sale of equipment that was no longer needed as a result of the termination of the leases for our former facilities in Colorado.

#### *Cash Flows Provided by Financing Activities*

Net cash provided by financing activities for the six months ended December 31, 2019 amounted to \$22.6 million. This amount consisted of (i) \$20.0 million received from the New Investors in July 2019 for the purchase of approximately 69.0 million shares of Common Stock at a purchase price of \$0.29 per share and (ii) \$4.1 million received from other investors in July and August 2019 for the purchase of approximately 14.0 million shares of our Common Stock at a purchase price of \$0.29 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.

Net cash provided by financing activities for the six months ended December 31, 2018 amounted to \$1.5 million. In December 2018, the New Investors expressed interest in investing in the Company and affirmed their intent to enter into exclusive diligence and negotiations regarding a potential equity financing. In December 2018, the New Investors provided an exclusivity payment for \$1.5 million in exchange for our agreement to cease any and all discussions and negotiations with all other third parties. In January 2019, the New Investors decided to proceed and closing of the Series AA Financing occurred on January 30, 2019.

#### **Recent Accounting Pronouncements**

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

#### **Off-Balance Sheet Arrangements**

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

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Not required for smaller reporting companies.

### **ITEM 4. CONTROLS AND PROCEDURES.**

#### **Evaluation of Disclosure Controls and Procedures**

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial and accounting 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, at December 31, 2019, our internal control over financial reporting was not effective due to material weaknesses in the system of internal control. A material weakness is a deficiency, or combination of deficiencies, that creates a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected in a timely manner.

The material weaknesses identified by management were that (1) due to our limited number of employees, we have not adequately segregated certain duties, (2) we have not implemented measures that would prevent employees from overriding the internal control system, (3) one employee was responsible for complex accounting issues without additional internal reviews, and (4) we did not have effective review controls over financial reporting and related disclosures in accordance with U.S. GAAP and SEC rules and regulations. Beginning in the three months ended March 31, 2019, we began mitigating these weaknesses through hiring additional employees and engaging a consulting firm to supplement our technical accounting and financial reporting resources.

#### **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 2019 Form 10-K, in Part II, Item 1A of our quarterly report for the fiscal quarter ended September 30, 2019, 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.

*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.**

<b>Exhibit Number</b>	<b>Description of Exhibits</b>
<a href="#"><u>31.1*</u></a>	<a href="#"><u>Certification of Chief Executive Officer as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*</u></a>
<a href="#"><u>31.2*</u></a>	<a href="#"><u>Certification of Chief Financial Officer as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*</u></a>
<a href="#"><u>32.1*</u></a>	<a href="#"><u>Certification of Chief Executive Officer as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*</u></a>
<a href="#"><u>32.2*</u></a>	<a href="#"><u>Certification of Chief Financial Officer as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*</u></a>
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

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\* 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: February 12, 2020

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

Date: February 12, 2020

By: /s/ Keith Vendola  
**Keith Vendola**  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

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

I, Nevan Elam, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Rezolute, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report.
4. As the Registrant's certifying officer, I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. As the Registrant's certifying officer, I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors:
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: February 12, 2020

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

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

I, Keith Vendola, 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: February 12, 2020

By: /s/ Keith Vendola  
Keith Vendola  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

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

In connection with the quarterly report of Rezolute, Inc. (the "Company") on Form 10-Q for the period ended December 31, 2019, 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: February 12, 2020

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

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

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

In connection with the quarterly report of Rezolute, Inc. (the "Company") on Form 10-Q for the period ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Keith Vendola, Chief Financial 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: February 12, 2020

By: /s/ Keith Vendola  
Keith Vendola  
Chief Financial Officer  
(Principal Financial and Accounting 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.

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