

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

FORM 10-K

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

For fiscal year ended June 30, 2018

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.)

1450 Infinite Drive, Louisville CO

(Address of Principal Executive Offices)

80027

(Zip Code)

(303)222-2128

(Registrant's Telephone Number, including Area Code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT: **None**

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: **Common Stock, par value \$0.001**

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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 checkmark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to the Form 10-K.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company (as defined in Rule 12b-2 of the Exchange Act), or an emerging growth company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and ask price of such common equity as of the last business day of the registrants most recently completed second fiscal quarter (December 31, 2017) was \$47,194,889

Number of shares of issuer's common stock outstanding as of October 15, 2018: 62,166,309

Portions of the registrant's Proxy Statement for the registrant's Annual Meeting of Shareholders to be held on December 4, 2018 are incorporated by reference into Part III, Items 10-14 of this Annual Report on Form 10-K.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Annual 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 Annual 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 expenses 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, among others:

- the loss of key management personnel or sponsored research partners on whom we depend;*
- the progress and results of clinical trials for our product candidates;*
- our ability to navigate the regulatory approval process in the United States and other countries, and our success in obtaining required regulatory approvals for our product candidates;*
- commercial developments for products that compete with our product candidates;*
- the actual and perceived effectiveness of our product candidates, and how those product candidates compare to competitive products;*
- the ability to obtain intellectual property protection, the strength of our intellectual property protection, and our success in avoiding infringing the intellectual property rights of others;*
- adverse developments in our research and development activities;*
- potential liability if our product candidates cause illness, injury or death, or adverse publicity from any such events;*
- our ability to operate our business efficiently, manage capital expenditures and costs (including general and administrative expenses) and obtain financing when required.*

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 Annual 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 Annual 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 Annual Report, except as otherwise required by applicable law.

PART I

ITEM 1. BUSINESS

Rezolute, Inc. (“**Rezolute**”, the “**Company**”, “**we**” or “**us**”) is a clinical stage biopharmaceutical company specializing in the development of innovative drug therapies to improve the lives of patients with metabolic and orphan diseases.

We leverage metabolic and corporate development expertise to bring forward a compelling portfolio. This past year, we advanced a strategy we feel will be increasingly attractive to investors. This included executing our in- / out-licensing model, with two successful program acquisitions, closing down in-house manufacturing, and plans to seek a strategic partner for AB101 upon completion of its Phase 1 study during calendar year 2019.

Our Pipeline

RZ358

RZ358 is the leading asset within our portfolio. We intend to fully develop and market this compound.

On December 6, 2017, we licensed from XOMA LLC (“**XOMA**”) the exclusive rights to develop and commercialize XOMA 358 (now RZ358) for an orphan indication, Congenital Hyperinsulinism (“**CHI**”).

CHI is a rare genetic disorder that affects 1 in 30,000 newborns. It is also the most common cause of persistent hypoglycemia in children. About 60 percent of infants with CHI experience a hypoglycemic episode within the first month of life. Other affected children develop hypoglycemia by early childhood.

Ordinarily, beta cells in the pancreas secrete just enough insulin to keep blood sugar in the normal range. With CHI, the secretion of insulin is not properly regulated as the beta cells secrete too much insulin resulting in excessive low blood sugar, severe hypoglycemia.

In infants and young children, these episodes are characterized by lethargy, irritability, and difficulty feeding. Repeated episodes of hypoglycemia increase the risk of serious complications such as breathing difficulties, seizures, developmental delays, intellectual disability, vision loss, brain damage, coma, and possibly death.

To avoid hypoglycemia, many children require frequent glucose monitoring and feeding, including intravenous or intestinal administration of sugar solutions, particularly overnight. This burdensome treatment regimen has a substantially negative effect on the quality of life for these children and their families.

A significant number of children cannot be adequately treated with, or do not tolerate, existing medical therapies. Surgical removal of all or part of the pancreas is a cornerstone of management for many children, but is invasive and diabetes inducing.

RZ358 is a first-in-class fully human monoclonal antibody that counteracts the effects of elevated insulin (hyperinsulinemia) by, in effect, turning down the insulin receptor when too much insulin is present. As such, it is well-suited as a treatment for severe, persistent hypoglycemia. XOMA demonstrated clinical proof-of-concept for RZ358 in Phase 1 and Phase 2a studies.

RZ358 has designated orphan status in the US and EU.

We plan to launch Phase 2b studies in calendar year 2018 or 2019 with the potential to accelerate late-stage pivotal trials for an abbreviated path-to-market strategy.

RZ402 and RZ602

On August 4, 2017, we licensed from ActiveSite Pharmaceuticals, Inc. (“**ActiveSite**”) their oral plasma kallikrein inhibitor portfolio (“**Portfolio**”) targeting the treatment of diabetic macular edema (“**DME**”) and other plasma kallikrein-mediated diseases such as hereditary angioedema (“**HAE**”).

RZ402

It is estimated that approximately 50 million individuals worldwide suffer from vision-threatening complications of diabetes, including DME, which is one of the main causes of vision loss in working-age adults globally. With the growth of diabetes, DME is expected to increase in prevalence beyond its current estimate of 750,000 individuals in the US and 21 million worldwide.

DME is a metabolic disease that results from an increase in retinal vascular permeability (RVP) in the setting of diabetic retinopathy (abnormal retinal blood vessel growth caused by poorly controlled blood sugar levels). Vascular leakage from retinal blood vessels leads to swelling of the retina, including the macula, an area of the retina that is very important for vision. The kinin system and the production of bradykinin have been implicated in the vascular leakage associated with DME.

Current treatment approaches are onerous, involving injections into the eye by retinal specialists on a monthly or bimonthly basis. In addition to a segment of the DME population that does not respond to these treatments, the extent of therapeutic benefit directly correlates with adherence to this route of administration and regimen. Intravitreal injection represents a route of administration with significant burden for both patients and their healthcare providers, leading to high rates of non-adherence and ultimately, suboptimal therapeutic outcomes.

RZ402 is a potential new therapy for DME from the PKI portfolio. RZ402 has been shown to normalize RVP in clinically-relevant animal models of macular edema as effectively as the current injectable treatments, thereby supporting its potential as a stand-alone therapy for macular edema resulting from diabetes and other causes.

We plan to file an IND for RZ402 in calendar year 2019 and afterwards, embark upon Phase 1 studies.

RZ602

Approximately one in 50,000 patients worldwide have HAE.

HAE is an orphan disease characterized by recurring attacks of sudden and extreme swelling that can affect the face and mucous membranes, abdomen, and genitalia. Attacks can be painful, debilitating, varied in frequency and even life-threatening, due to swelling around the airway.

The disease is caused by a problem with a gene that controls the management of a specific protein, the C1 inhibitor. When there is an imbalance in the C1 inhibitor, there may be excessive bradykinin production causing tiny blood vessels to “leak” or push fluid into parts of the patient’s body, resulting in an HAE attack. The trigger for an attack is variable from person to person and even time to time.

Currently available therapies target the prevention or termination of attacks, but are highly invasive and inconvenient due to the subcutaneous / intravenous routes of administration or have an undesirable side effect profile.

RZ602 is a potential new therapy for HAE from the PKI portfolio. Similar to our efforts with RZ402 for DME, the objective of RZ602 is to stop the inflammatory cascade by inhibiting the production of kallikrein and thereby halting the downstream release of bradykinin and eventual swelling.

We plan to file an IND for RZ602 in calendar year 2020 and afterwards, embark upon Phase 1 studies.

AB101

Our next product candidate (“**AB101**”), a microsphere formulation of PEGylated human recombinant insulin, is being developed as an extended acting basal insulin intended for once-weekly subcutaneous injection, for use alone and in combination with bolus prandial insulin or oral glucose lowering therapies, to improve glycemic control in patients with Type 1 and Type 2 Diabetes Mellitus.

We believe AB101 has the potential to provide a near peak-less, slow and uniform release of basal insulin. The current standard of care in the \$11 billion basal insulin market is daily or twice-a-day injections.

In July of 2017, we dosed our first patient in our Phase 1 first-in-human clinical trial of AB101. The Phase 1 clinical trial is a first-in-human single ascending dose study to assess the safety and tolerability, pharmacokinetics and pharmacodynamics of AB101 in patients with Type 1 Diabetes Mellitus.

The first study part will be sequential cohort dose ranging of AB101, while an optional second study part will compare one or more tested doses of AB101 from part 1 to active comparator Lantus[®] (insulin glargine). In addition to safety and pharmacokinetic assessments, the time-action pharmacology of AB101 (onset, peak, and end of action) will be evaluated using several measures of glycemic response, including the hyperinsulinemic euglycemic clamp technique, continuous glucose monitoring, and background insulin use.

Following the completion of the first part of the study, we expect to review data and high-level results within calendar year 2018 or 2019. Afterwards, we will evaluate out-licensing potential.

Competition

We face competition from pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and private research organizations in recruiting and retaining highly qualified scientific personnel and consultants and in the development and acquisition of technologies.

There are a handful of companies developing therapies for CHI that could pose as potential competitors to RZ358. Zealand Pharma, Xeris Pharma, and Hanmi are three such companies.

There are a handful of companies developing therapies for diabetic macular edema that could pose as potential competitors to the plasma kallikrein inhibitor therapy we recently acquired from ActiveSite Pharmaceuticals. KalVista Pharmaceuticals, Verseon, and Thrombogenics are three such companies.

If successfully commercialized, AB101 would compete directly against Sanofi’s Lantus and Toujeo, Novo Nordisk’s Levemir and Tresiba, Eli Lilly’s Basaglar as well as any other branded or biosimilar basal insulin therapies that obtain regulatory approval in advance of AB101.

Government Regulation

Regulation by governmental authorities in the US and other countries is a significant factor in the development, manufacture and marketing of pharmaceutical products. All of our potential products will require regulatory approval by governmental agencies prior to commercialization. In particular, pharmaceutical therapies are subject to rigorous preclinical testing and clinical trials and other pre-market approval requirements by the FDA and regulatory authorities in foreign countries. Various federal, state and foreign statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of such products.

We are also subject to various federal, state, and local laws, regulations and recommendations relating to safe working conditions; laboratory and manufacturing practices; the experimental use of animals; and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research, development and manufacturing.

Research and Development

We incurred approximately \$17,280,000 and \$12,095,000 in research and development expenses for the years ended June 30, 2018 and 2017, respectively.

Employees

As of June 30, 2018, we had twenty full-time employees as well as one contract employee, all of whom have experience with pharmaceutical, biotechnology or medical product companies. None of our employees or contractors are covered by collective bargaining agreements.

Corporate Information

We were incorporated in Delaware in 2010. We maintain executive offices located at 1450 Infinite Drive, Louisville, Colorado 80027 and our phone number is 303-222-2128. Our website is located at www.rezolutebio.com. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into this document.

ITEM 1A. RISK FACTORS.

Investors should consider carefully the following information about these risks before deciding to purchase any of our securities. If any of the events or developments described below actually occur, our business, results of operations and financial condition would likely suffer and Investors may lose all or part of their investment. In addition, it is also possible that other risks and uncertainties that affect our business may arise or become material in the future.

Risks Related to Our Business

We will need substantial additional capital to fund our operations. If we fail to obtain additional capital, we may be unable to sustain operations.

Our operations consume substantial amounts of cash and we expect that our cash used by operations will continue to increase for the next several years. As of June 30, 2018, we had approximately \$1.6 million in cash on hand. We will need to raise additional capital in order to sustain our operations. If we are unable to raise additional capital, we may have to significantly delay, scale back or discontinue one or more of our drug development or research and development programs. We may be required to cease operations or seek partners for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available. In the absence of additional capital we may also be required to relinquish, license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available.

Our corporate objectives are dependent upon one another and to the extent that there is a delay or complication in any one objective, our ability to timely complete our other goals could be adversely impacted.

Our corporate objectives are dependent upon one another and to the extent that there is a delay, complication or failure in any one objective, our ability to complete our other goals in a timely fashion could be adversely impacted. For example, we are currently conducting a Phase 1 first-in-human clinical study of AB101, a once-weekly injectable basal insulin for patients with Type 1 and Type 2 diabetes mellitus (“Study”) while concurrently expanding our pipeline and advancing additional potential drug candidates towards clinical studies. We anticipate generating results from the Study in calendar year 2018 or 2019 when we also anticipate needing to raise additional capital. It is likely that potential investors and / or partners will want to review the results from the Study prior to making an investment decision. In the event that the results from the Study do not meet or exceed expectations, we may not be able to raise capital and advance additional pipeline candidates or sustain operations.

Results of preclinical testing or earlier clinical studies are not necessarily predictive of future results, therefore none of the product candidates we advance into clinical studies may have favorable results in later clinical studies or receive regulatory approval.

Success in preclinical testing does not ensure that clinical studies will generate adequate data to demonstrate the efficacy and safety of an investigational drug or biologic. Even if the Study or other clinical studies for additional programs produces promising results, there is no assurance that such results will be replicated or exceeded in later clinical studies. A number of companies in the biopharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in clinical studies, even after seeing promising results in earlier preclinical and clinical studies. We do not know whether the Study or any other clinical studies that we may conduct will demonstrate adequate efficacy and safety to justify the continuing advancement of a program. If later stage clinical studies do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that our product candidates have performed satisfactorily in preclinical testing and clinical studies, we may still fail to obtain FDA approval for our product candidates.

We may experience delays in our clinical trials that could adversely affect our financial position.

Many factors could affect the timing of the Study and other clinical trials that we may conduct, including lack of Current Good Manufacturing Practice (“cGMP”) drug product, slow patient recruitment, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new drugs approved for the conditions we are investigating. Other companies may be conducting clinical trials or may announce plans for future trials that will be seeking patients with the same indications as those we are studying. As a result of all of these factors, our trials may take longer to enroll patients than we anticipate. Delays in patient enrollment in the trials may increase our costs and slow down our product development and approval process. Our product development costs will also increase if we need to perform more or larger clinical trials than planned. Any delays in completing our clinical trials could adversely impact our cash position and ability to support ongoing operations.

Due to our reliance on contract research organizations or other third parties to conduct clinical trials, we may not have complete control over the timing, conduct and expense of our clinical trials.

We rely primarily on third parties to conduct our clinical trials. As a result, we will have less control over the conduct of the clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trial than would be the case if our own staff conducted all clinical trials. Communicating with outside parties can also be challenging, potentially leading to mistakes and difficulties in coordinating activities. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. We may experience unexpected increased costs that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be impossible to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

Adverse events in our clinical trials may force us to stop development of our product candidates or prevent regulatory approval of our product candidates.

Our product candidates may produce serious adverse events in patients during clinical trials. These adverse events could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA, or other regulatory authorities requesting additional preclinical data or denying approval of our product candidates for any or all targeted indications. An institutional review board, independent data safety monitoring board, the FDA, other regulatory authorities or the Company itself may suspend or terminate clinical trials at any time. We cannot assure you that any of our product candidates will prove safe for human use.

We may not be successful in our efforts to partner AB101 or any of our programs with larger pharmaceutical companies.

We intend to seek a partner for AB101 upon completion of the Phase 1 trial. Our failure to partner AB101 could have a material and adverse impact on our ability to further develop the program or continue our overall operations.

We may not be successful in our efforts to identify, discover or formulate product pipeline candidates.

Research and development programs require substantial technical, financial and human resources to identify new product pipeline candidates. Our research and development programs may initially demonstrate success in identifying potential product pipeline candidates but subsequently fail to yield them. Through our research and development programs, if we are unable to formulate innovative long-acting therapies based on our microsphere platform technology or otherwise, our long-term business, financial position, income, expansion and outlook may be materially adversely affected.

Our competitors may develop and market drugs that are less expensive, more effective or safer than our product candidates.

The pharmaceutical market is highly competitive. It is possible that our competitors will develop and market products that are less expensive, more effective or safer than our future products or that will render our products obsolete. Other pharmaceutical and biotechnology companies may develop improved formulations of the same drugs that compete with drug products we are developing. We expect that competition from pharmaceutical and biotechnology companies, universities and public and private research institutions will increase. Many of these competitors have substantially greater financial, technical, research and other resources than we do. We may not have the financial resources, technical and research expertise or marketing, distribution or support capabilities to successfully compete with these competitors.

After the completion of our clinical studies, we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates and we cannot, therefore, predict the timing of any future revenue from these product candidates.

Even if we achieve positive clinical results and file for regulatory approval, we cannot commercialize any of our product candidates until the appropriate regulatory agencies have reviewed and approved the applications for such product candidates. We cannot assure that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidate we develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical studies and FDA regulatory review.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory hurdles.

Even if US regulatory approval is obtained for a particular drug candidate, the FDA may still impose significant restrictions on marketing, indicated uses and/or require potentially costly post-approval studies or post-market surveillance. For example, the label ultimately approved, if any, may include restrictions on use. Further, the FDA may require that long-term safety data may need to be obtained as a post-market requirement. Even if the FDA or a foreign regulatory agency approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product and may impose requirements for post-approval studies, including additional research and development and clinical trials. The FDA and other agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including substantial monetary penalties and withdrawal of product approval.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices and regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

If any of our product candidates for which we receive regulatory approval does not achieve broad market acceptance, the revenue that we generate from its sales, if any, will be limited

The commercial success of our product candidates for which we obtain marketing approval from the FDA or other regulatory agencies will depend upon the acceptance of these products by the medical community, including physicians, patients and payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- prevalence and severity of any adverse effects;
- limitations or warnings contained in a product's FDA-approved labeling;
- availability of alternative treatments;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

Our manufacturing experience is limited.

The manufacture of drugs for clinical trials and for commercial sale is subject to regulation by the FDA under cGMP regulations and by other regulators under other laws and regulations. We cannot assure you that we can successfully manufacture our products under cGMP regulations or other laws and regulations in sufficient quantities for clinical trials or for commercial sale, or in a timely or economical manner.

If our product candidates do not meet safety or efficacy requirements, they will not receive regulatory approval and we will be unable to market them.

The process of drug development, regulatory review and approval typically is expensive, takes many years and the timing of any approval cannot be accurately predicted. If we fail to obtain regulatory approval for our current or future product candidates, we will be unable to market and sell such products and therefore may never be profitable.

As part of the regulatory approval process, we must conduct preclinical studies and clinical trials for each product candidate to demonstrate safety and efficacy. The number of preclinical studies and clinical trials that will be required varies depending on the product candidate, the indication being evaluated, the trial results and regulations applicable to any particular product candidate.

The results of preclinical studies and initial clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials. We cannot assure you that the data collected from the preclinical studies and clinical trials of our product candidates will be sufficient to support approval by FDA or a foreign regulatory authority. In addition, the continuation of a particular study after review by an independent data safety monitoring board does not necessarily indicate that our product candidate will achieve the clinical endpoint.

The FDA and other regulatory agencies can delay, limit or deny approval for many reasons, including:

- a product candidate may not be safe or effective;
- our manufacturing processes or facility may not meet the applicable requirements; and
- changes in regulatory agency approval policies or adoption of new regulations may require additional clinical trials or work on our end.

Any delay in, or failure to receive or maintain, approval for any of our products could prevent us from ever generating meaningful revenues or achieving profitability.

Our product candidates are prone to the risks of failure inherent in drug development. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate safety in preclinical studies and effectiveness with substantial evidence gathered in well-controlled clinical studies. With respect to approval in the US, to the satisfaction of the FDA and, with respect to approval in other countries, to the satisfaction of regulatory authorities in those countries, we must demonstrate that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate.

Despite our efforts, our product candidates may not:

- offer therapeutic benefit or other improvements over existing, comparable therapeutics;
- be proven safe and effective in clinical studies;
- meet applicable regulatory standards;
- be capable of being produced in sufficient quantities at acceptable costs;
- be successfully commercialized; or
- obtain favorable reimbursement.

We are not permitted to market any of our other product candidates in the US until we receive approval of a new drug application, or approval of a biologics license application, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We have not submitted a new drug application or biologics license application or received marketing approval for any of our product candidates.

Preclinical testing and clinical studies are long, expensive and uncertain processes. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage. Negative or inconclusive results or adverse medical events during a clinical study could also cause us or the FDA to terminate a clinical study or require that we repeat it or conduct additional clinical studies. Additionally, data obtained from a clinical study is susceptible to varying interpretations and the FDA or other regulatory authorities may interpret the results of our clinical studies less favorably than we do. The FDA and equivalent foreign regulatory agencies have substantial discretion in the approval process and may decide that our data is insufficient to support a marketing application and require additional preclinical, clinical or other studies.

Any failure or delay by our third-party suppliers on which we rely or intend to rely to provide materials necessary to develop and manufacture our drug products may delay or impair our ability to commercialize our product candidates.

We rely upon a small number of third-party suppliers for the manufacture of certain raw materials that are necessary to formulate our drug products for preclinical and clinical testing purposes. We intend to continue to rely on them in the future. We also expect to rely upon third parties to produce materials required for the commercial production of our product candidates if we succeed in obtaining necessary regulatory approvals. If we are unable to arrange for third-party sources, or do so on commercially unreasonable terms, we may not be able to complete development of or market our product candidates.

There are a small number of suppliers for raw materials that we use to manufacture our drugs. Such suppliers may not sell these raw materials at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete the clinical study, any significant delay in the supply of raw material components needed to produce a product candidate for a clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If we or our manufacturers are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply of such product candidates, which would impair our ability to generate revenues from the sale of our product candidates.

If we successfully commercialize any of our product candidates, we may be required to establish commercial manufacturing capabilities of larger scale. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical study and commercial manufacturing capacity. We have no experience manufacturing pharmaceutical products on a commercial scale and we may need to rely on third-party manufacturers with capacity for increased production scale to meet our projected needs for commercial manufacturing, the satisfaction of which on a timely basis may not be met.

Recently enacted and future legislation or regulatory reform of the health care system in the US and foreign jurisdictions may affect our ability to sell our products profitably.

Our ability to commercialize our future products successfully, alone or with collaborators, will depend in part on the extent to which reimbursement for the products will be available from government and health administration authorities, private health insurers and other third-party payors. The continuing efforts of the US and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set fair prices for our products, generate revenues and achieve and maintain profitability.

Specifically, in both the US and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could impact our ability to sell our products profitably. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and also may increase our regulatory burdens and operating costs. We expect further federal and state proposals and health care reforms to continue to be proposed by legislators, which could limit the prices that can be charged for the products we develop and may limit our commercial opportunity.

Also in the US, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The continuing efforts of government and other third-party payors to contain or reduce the costs of health care through various means may limit our commercial opportunity. It will be time-consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and government and third-party private health insurance coverage and reimbursement may not be available to patients for any of our future products or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by the MMA, the Health Care Reform Law, and additional prescription drug coverage legislation, by the possible effect of this legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the US will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our profitability.

In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take up to 12 months or longer after the receipt of regulatory marketing approval for a drug product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical study that compares the cost effectiveness of our product candidates to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our products is unavailable, limited in scope or amount or if pricing is set at unsatisfactory levels.

We face potential product liability exposure, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We currently have clinical trial insurance active clinical programs. This product liability insurance coverage for our clinical studies may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for any of our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain this product liability insurance on commercially reasonable terms. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including toxic chemical and biological materials. We could be held liable for any contamination, injury or other damages resulting from these hazardous substances. In addition, our operations produce hazardous waste products. While third parties are responsible for disposal of our hazardous waste, we could be liable under environmental laws for any required cleanup of sites at which our waste is disposed. Federal, state, foreign and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials. If we fail to comply with these laws and regulations at any time, or if they change, we may be subject to criminal sanctions and substantial civil liabilities, which may harm our business. Even if we continue to comply with all applicable laws and regulations regarding hazardous materials, we cannot eliminate the risk of accidental contamination or discharge and our resultant liability for any injuries or other damages caused by these accidents.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We currently do not have dedicated staff for the sale, marketing and distribution of drug products. The cost of establishing and maintaining such a staff may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Guidelines and recommendations published by various organizations may adversely affect the use of any products for which we may receive regulatory approval.

Government agencies issue regulations and guidelines directly applicable to us and to our product candidates. In addition, professional societies, practice management groups, private health or science foundations and organizations involved in various diseases from time to time publish guidelines or recommendations to the medical and patient communities. These various sorts of recommendations may relate to such matters as product usage and use of related or competing therapies. For example, organizations like the American Diabetes Association have made recommendations about therapies in the diabetes therapeutics market. Changes to these recommendations or other guidelines advocating alternative therapies could result in decreased use of any products for which we may receive regulatory approval, which may adversely affect our results of operations.

Our independent registered public accounting firm's report, contained herein, includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.

Our financial statements have been prepared on the basis that we will continue as a going concern. For the period from March 24, 2010 to June 30, 2018, we have an accumulated deficit of \$94,183,738. As of June 30, 2018, our total stockholder's deficit was \$3,960,755 and we had working deficit of \$4,240,227. We expect to continue to incur losses for the foreseeable future as we develop and commercialize our pipeline, and we must raise additional capital from external sources in order to sustain our operations. Primarily as a result of our history of losses and limited cash balances, our independent registered public accounting firm has included in their audit report an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is contingent upon, among other factors, our ability to obtain financing to continue to fund our operations. We cannot provide any assurance that we will be able to raise additional capital. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in the development of our product candidates.

We are at an early stage of development as a company and we do not have, and may never have, any products that generate significant revenues.

We are at an early stage of development as a proprietary product specialty pharmaceutical company and we do not 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. Our efforts may not lead to commercially successful products, for a number of reasons, including:

- our product candidates may not prove to be safe and effective in clinical trials;
- we may not be able to obtain regulatory approvals for our product candidates or approved uses may be narrower than we seek;
- we may not have adequate financial or other resources to complete the development and commercialization of our product candidates; or
- any products that are approved may not be accepted or reimbursed in the marketplace.

We do not expect to be able to market any of our product candidates for a number of years. If we are unable to develop, receive approval for, or successfully commercialize any of our product candidates, we will be unable to generate significant revenues. If our development programs are delayed, we may have to raise additional capital or reduce or cease our operations.

Initially, we expect to derive all of our revenues, if any, from current product candidates. As we cannot currently enter the market nor guarantee out-licensing partnerships, it is uncertain whether these candidates will achieve and sustain high levels of demand and market acceptance. Our success will depend to a substantial extent on our ability to successfully commercialize, market and / or partner our products. Failure of consumers or potential partners to accept would significantly adversely affect our revenues and profitability.

We have never generated any revenues and may never become profitable.

Since inception, we have not generated any revenues. We expect to continue to incur substantial operating losses for the next several years as we move our product candidates into clinical trials and continue our research and development efforts. To become profitable, we must successfully develop, manufacture and market our product candidates, either alone or in conjunction with possible collaborators. We may never have any revenues or become profitable.

Our limited operating history makes it difficult to evaluate our business and prospects.

Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights, conducting preclinical studies and producing product under cGMP conditions. We have not demonstrated an ability to conduct clinical trials, obtain regulatory approval for or commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully testing, developing and commercializing pharmaceutical products.

If we are unable to successfully remediate the material weaknesses in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

In connection with the audit of the fiscal 2018 consolidated financial statements of Rezolute, Inc., we noted material weaknesses in our controls, principally as a result of not having segregated duties as one employee can initiate and complete transactions, not having measures that would prevent the employees from overriding the internal control system, one employee is responsible for complex accounting issues without additional reviews within the Company and the Company did not have effective review controls over financial reporting over the financial statements and related disclosures in accordance with U.S. GAAP and SEC rules and regulations. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting that results in more than reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. We have also begun evaluating and implementing additional procedures to improve the segregation of duties. We cannot assure that these or other measures will fully remediate the deficiencies or material weaknesses described above. We also cannot assure you that we have identified all of our existing significant deficiencies and material weaknesses, or that we will not in the future have additional significant deficiencies or material weaknesses.

Operations outside the United States may be affected by different local politics, business and cultural factors, different regulatory requirements and prohibitions between jurisdictions.

Operations outside the United States may be affected by different local business and cultural factors, different regulatory requirements and prohibitions between jurisdictions, including the Foreign Corrupt Practices Act and local laws prohibiting corrupt payments; and changes in regulatory requirements for financing activities.

The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results.

Many of the world's largest economies and financial institutions continue to be impacted by a weak ongoing global economic and financial environment, with some continuing to face financial difficulty, liquidity problems and limited availability of credit. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. Such uncertain times may have a material adverse effect on our results of operations, financial condition and, if circumstances worsen, our ability to raise capital at reasonable rates.

In addition, the varying effects of difficult economic times on the economies, currencies and financial markets of different countries could unpredictably impact, the conversion of our operating results into our reporting currency, the US dollar. Alternately, inflation could accelerate, which could lead to higher interest rates, which would increase our costs of raising capital.

In addition, increasing political and social instability around the world may lead to significant business disruptions or other adverse business conditions. Similarly, increased scrutiny of corporate taxes and executive pay may lead to significant business disruptions or other adverse business conditions, and may interfere with our ability to attract and retain qualified personnel.

Risks Related to Our Intellectual Property

Our current patent positions and license portfolio may not include all patent rights needed for the full development and commercialization of our product candidates. We cannot be sure that patent rights we may need in the future will be available to license on commercially reasonable terms, or at all.

We typically develop our product candidates using compounds that we have acquired or in-licensed, including the original composition of matter patents and patents that claim the activities and methods for such compounds' production and use. For example, in 2017 we in-licensed a kallikrein inhibitor portfolio from ActiveSite Pharmaceuticals and in consideration for such license, we will owe milestone payments and royalties to ActiveSite if and when we progress product candidates through development.

As we learn more about the mechanisms of action and new methods of manufacture and use of these product candidates, we may file additional patent applications for these new inventions or we may need to ask our licensors to file them. We may also need to license additional patent rights or other rights on compounds, treatment methods or manufacturing processes because we learn that we need such rights during the continuing development of our product candidates.

Although our patents may prevent others from making, using or selling similar products, they do not ensure that we will not infringe the patent rights of third parties. We may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our product candidates or proposed product candidates. For example, because we sometimes identify the mechanism of action or molecular target of a given product candidate after identifying its composition of matter and therapeutic use, we may not be aware until the mechanism or target is further elucidated that a third party has an issued or pending patent claiming biological activities or targets that may cover our product candidate. US patent applications filed after November 29, 2000 are confidential in the US Patent and Trademark Office for the first 18 months after such applications' earliest priority date, and patent offices in other countries often publish patent applications for the first time six months or more after filing. Furthermore, we may not be aware of published or granted conflicting patent rights. Any conflicts resulting from patent applications and patents of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If others obtain patents with conflicting claims, we may need to obtain licenses to these patents or to develop or obtain alternative technology.

We may not be able to obtain any licenses or other rights to patents, technology or know-how from third parties necessary to conduct our business as described in this report and such licenses, if available at all, may not be available on commercially reasonable terms. Any failure to obtain such licenses could delay or prevent us from developing or commercializing our drug candidates or proposed product candidates, which would harm our business. Litigation or patent interference proceedings may be necessarily brought against third parties, as discussed below, to enforce any of our patents or other proprietary rights or to determine the scope and validity or enforceability of the proprietary rights of such third parties.

If our or our licensors' patent positions do not adequately protect our product candidates or any future products, others could compete with us more directly, which would harm our business.

Our commercial success will depend in part on our and our licensors' ability to obtain additional patents and protect our existing patent positions, particularly those patents for which we have secured exclusive rights, as well as our ability to maintain adequate protection of other intellectual property for our technologies, product candidates and any future products in the US and other countries. If we or our licensors do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our product candidates and delay or render impossible our achievement of profitability. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the US, and we may encounter significant problems in protecting our proprietary rights in these countries.

The patent positions of biotechnology and pharmaceutical companies, including our own patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. We and our licensors will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we or our licensors were the first to make the inventions covered by each of our pending patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' pending patent applications will result in issued patents;

- any of our or our licensors' patents will be valid or enforceable;
- any patents issued to us or our licensors and collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are patentable; or
- the patents of others will not have an adverse effect on our business.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing product candidates to market and harm our ability to operate.

Our commercial success will depend in part on our ability to manufacture, use, sell and offer to sell our product candidates and proposed product candidates without infringing patents or other proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to our product candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our or our licensors' existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding the patentability of our inventions relating to our product candidates or the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have our patents declared invalid, we may incur substantial monetary damages; encounter significant delays in bringing our product candidates to market; or be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses.

If our patent and other intellectual property protection is inadequate, our sales and profits could suffer or competitors could force our products completely out of the market.

Patents which prevent the manufacture or sale of our products may be issued to others. We may have to license those patents and pay significant fees or royalties to the owners of the patents in order to keep marketing our products. This would cause profits on sales to suffer.

We have been granted patents or licensed patents in the US, but patent applications that have been, or may in the future be, filed by us may not result in the issuance of additional patents. The scope of any patent issued may not be sufficient to protect our technology. The laws of foreign jurisdictions in which we intend to sell our products may not protect our rights to the same extent as the laws of the US.

In addition to patent protection, we also rely on trade secrets, proprietary know-how and technology advances. We enter into confidentiality agreements with our employees and others, but these agreements may not be effective in protecting our proprietary information. Others may independently develop substantially equivalent proprietary information or obtain access to our know-how. Litigation, which is expensive, may be necessary to enforce or defend our patents or proprietary rights and may not end favorably for us. We may also choose to initiate litigation against other parties who we come to believe are infringing these patents. If such litigation is unsuccessful or if the patents are invalidated or canceled, we may have to write off the related intangible assets and such an event could significantly reduce our earnings. Any of our licenses, patents or other intellectual property may be challenged, invalidated, canceled, infringed or circumvented and may not provide any competitive advantage to us.

If the Company is required to impair their long-lived assets, the Company's financial condition and results could be negatively affected.

If we are unable to further successfully develop products using our patents that were purchased, the Company may experience events which could cause our long-lived assets to be impaired. If we evaluate our long-lived assets and deem that there is an impairment, under current accounting standards, the Company will be required to write down the assets. Any write-down would have a negative effect on our consolidated financial statements. During the year ended June 30, 2018, the Company incurred an impairment charge of approximately \$1,691,000 due to the shutdown of its manufacturing facility.

Risks Related to Our Common Stock

Investors may experience dilution if we issue additional shares of common stock.

In general, stockholders do not have preemptive rights to any common stock issued by us in the future. Therefore, stockholders may experience dilution of their equity investment if we issue additional shares of common stock in the future. This includes shares issuable under equity incentive plans, or if we issue securities that are convertible into shares of our common stock. Given that we will require additional capital, we intend to raise funds in the future by issuing common stock that will cause dilution to our stockholders. We also have significant outstanding warrants to purchase common stock as well as a stock option pool available to employees, which if exercised, would cause dilution to our stockholders.

There is a limited trading market for our common stock, which could make it difficult to liquidate an investment in our common stock, in a timely manner.

Our common stock is currently traded on the OTCQB. Because there is a limited public market for our common stock, investors may not be able to liquidate their investment whenever desired. We cannot assure that an active trading market for our common stock will ever develop and the lack of an active public trading market means that investors may be exposed to increased risk. In addition, if we failed to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect its liquidity.

With a limited trading market for our common stock, the trading price can be impacted by naked short selling.

Our stock price has been under downward pressure for over a year and we have been puzzled as to why there would be consistent downward pressure on our stock even in the face of positive news about the Company and our prospects. Following some investigation and with the assistance of outside advisors, we believe we are the target of naked short selling. Naked short selling is when an investor sells short shares that they do not possess and have not confirmed their ability to possess. If the trade associated with the short does not take place within the clearing time period and the short-seller does not tender shares to the buyer, the trade is considered a “failure to deliver.”

Naked short selling, a practice that is prohibited by the SEC's Regulation SHO, reduces the value of companies and shareholders' investments by artificially pushing a company's stock price down. For smaller companies like ours that are looking to raise working capital, it makes the process difficult. Upon tracking our trading activity, we have determined that approximately 44% of our daily trading volume is short selling and we believe that the short sellers have been lax at complying with Regulation SHO since early 2013. There are no assurances that we will be able to curb the naked short selling of our stock.

If securities analysts do not publish research or reports about our business or if they downgrade us or our sector, the price of our common stock could decline.

The trading market for our common stock will depend in part on research and reports that industry or financial analysts publish about us or our business. We do not control these analysts. Furthermore, if one or more of the analysts who cover us downgrades us or the industry in which we operate or the stock of any of our competitors, the price of our common stock will likely decline. If one or more of these analysts ceases coverage altogether, we could lose visibility, which could also lead to a decline in the price of the common stock.

We cannot ensure that our common stock will be listed on a securities exchange, which may adversely affect your ability to dispose of our common stock in a timely fashion.

We plan to seek listing of our common stock on the NYSE MKT or NASDAQ exchange as soon as reasonably practicable. In 2011, the NYSE MKT and the NASDAQ amended their listings to restrict the ability of companies that have completed reverse mergers to list their securities on such exchanges. In order to become eligible to list their securities on such exchange, reverse merger companies must have had their securities traded on an over-the-counter (OTC) market for at least one year, maintained a certain minimum closing price for no less than 30 of the most recent 60 days prior to the filing of an initial listing application and prior to listing, and timely filed with the SEC all required reports since consummation of the reverse merger, including one annual report containing audited financial statements for a full fiscal year commencing after the date of the filing of the Form 8-K containing the Company's Form 10 information. To date the Company has not met all of the filing requirements above and may not be able to satisfy the initial listing standards of the NYSE MKT or NASDAQ exchanges in the foreseeable future or at all. Even if we are able to list our common stock on such exchange, we may not be able to maintain a listing of the common stock on such stock exchange.

The market price and trading volume of our common stock may be volatile, which may adversely affect its market price.

The market price of our common stock could be subject to significant fluctuations due to factors such as:

- actual or anticipated fluctuations in our financial condition or results of operations;
- limited trading activity;
- success or failure of our operating strategies and our perceived prospects; realization of any of the risks described in this section; failure to be covered by securities analysts or failure to meet the expectations of securities analysts;
- decline in the stock prices of peer companies; and

discount in the trading multiple of our common stock relative to that of common stock of certain of our peer companies due to perceived risks associated with our smaller size.

As a result, shares of our common stock may trade at prices significantly below the price an investor paid to acquire them. Furthermore, declines in the price of our common stock may adversely affect the Company's ability to conduct future offerings or to recruit and retain key employees.

Our common stock may be considered a "penny stock."

Trades of our common stock are subject to Rule 15c-9 promulgated by the SEC under the Exchange Act, which imposes certain requirements on broker-dealers who sell securities subject to the rule to persons other than established customers and accredited investors. For transactions covered by the rule, broker-dealers must make a special suitability determination for purchasers of the securities and receive the purchaser's written agreement to the transaction prior to sale. The SEC also has other rules that regulate broker-dealer practices in connection with transactions in "penny stocks." Penny stocks generally are equity securities with a price of less than \$5.00 (other than securities listed on a national securities exchange, provided that current price and volume information with respect to transactions in that security is provided by the exchange or system). The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result of the foregoing, investors may find it difficult to sell their shares.

We have no current plan to pay dividends on our common stock and investors may lose the entire amount of their investment.

We have no current plans to pay dividends on our common stock. Therefore, investors will not receive any funds absent a sale of their shares. We cannot assure investors of a positive return on their investment.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not required for smaller reporting companies.

ITEM 2. PROPERTIES

Our corporate headquarters are located at 1450 Infinite Drive, Louisville, Colorado.

On May 5, 2014, we entered into a lease agreement for the lease of 27,000 square feet of office, lab and clean room space in Louisville, Colorado. We have subsequently subleased a portion of this facility.

ITEM 3. LEGAL PROCEEDINGS

On March 31, 2017, Alpha Venture Capital Partners, L.P., a stockholder, filed a derivative complaint. In September 2017, the Company settled with the plaintiff's lawyer to pay certain legal expenses. In the year ended June 30, 2018, the Company made payments of \$250,000 for these expenses.

There were no additional legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is currently quoted on the OTCQB of the OTC Markets Group under the trading symbol "RZLT." The OTCQB is an inter-dealer quotation and trading system and only market makers can apply to quote securities on the OTCQB. Trading in our common stock on the OTCQB has been limited and sporadic and the quotations set forth below are not necessarily indicative of actual market conditions. Further, these prices reflect inter-dealer prices without retail mark-up, mark-down, or commission, and may not necessarily represent actual transactions.

The following table sets forth the high and low last reported sale price information for our common stock for the fiscal quarters:

	Common Stock	
	High	Low
First quarter 2017	\$ 1.45	\$ 0.81
Second quarter 2017	\$ 2.00	\$ 0.63
Third quarter 2017	\$ 1.10	\$ 0.82
Fourth quarter 2017	\$ 1.25	\$ 0.96
First quarter 2018	\$ 1.20	\$ 0.86
Second quarter 2018	\$ 1.18	\$ 0.65
Third quarter 2018	\$ 0.99	\$ 0.45
Fourth quarter 2018	\$ 0.63	\$ 0.36

Holdings

As of October 12, 2018 there were of record 363 holders of common stock.

Dividends

We have never paid cash dividends and intend to employ all available funds in the development of our business. We have no plans to pay cash dividends in the near future. If we issue in the future any preferred stock or obtain financing from a bank, the terms of those financings may contain restrictions on our ability to pay dividends for so long as the preferred stock or bank financing is outstanding.

Unregistered Sale of Equity Securities

In connection with the convertible note financing completed in April 2018, we agreed to issue warrants to purchase a total of 11,685,177 shares of common stock. All these warrants were fully vested as of June 30, 2018. The warrants have an exercise term of five years.

Equity Compensation Plan Information

To date, the Board has issued options to purchase 24,615,333 of shares to current employees and directors under the 2013, 2014, 2015 and 2016 Non Qualified Stock Option Plans. On August 21, 2017, the Board reduced the number of shares to be issued by the 2016 plan by 15,000,000 shares of common stock in the form of stock options. Consequently, 15,400,000 of the issued options were cancelled in August 2017.

ITEM 6. SELECTED FINANCIAL DATA.

Not required for smaller reporting companies.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations of contain forward-looking statements which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report. We assume no obligation to update forward-looking statements or the risk factors. You should read the following discussion in conjunction with Rezolute's financial statements and related notes.

Our stated strategy has been to build a metabolic focused biopharmaceutical company by in-licensing compelling compounds that we believe clearly target different diseases where there is an unmet need. In December 2017, we completed the latest phase of this strategy by in-licensing RZ358, a fully human monoclonal antibody that is currently in Phase 2 clinical development. RZ358 is being developed to treat congenital hyperinsulinism, a devastating ultra-orphan pediatric disease.

We believe that RZ358 complements our two other metabolic pipeline opportunities including: (i) our plasma kallikrein inhibitor, RZ402, which is a late stage preclinical program that offers the potential of an oral therapy to treat diabetic macular edema, the leading cause of blindness in adults in the US, and (ii) our super-long-acting basal insulin, AB101, which is currently in Phase 1 clinical development to assess the safety and tolerability, pharmacokinetics and pharmacodynamics of AB101 in patients with diabetes mellitus.

For fiscal and calendar year 2019, we have the following objectives to advance our development strategy: (i) initiate a Phase 2b clinical study for RZ358 in the US and Europe, (ii) complete the necessary toxicology studies for RZ402 to enable the filing of an IND and initiation of clinical studies, and (iii) complete the Phase 1 study for AB101 and explore partnership opportunities. In order to meet these objectives, we need to raise additional capital through an equity financing ("Financing").

Throughout calendar year 2018, we have met with a variety of large and mid-size health care funds ("Funds") to unveil the Rezolute story with RZ358 as our lead pipeline program. Many of these Funds have expressed interest in Rezolute and more than 10 Funds have conducted extensive due diligence on our programs and prospects involving many meetings and hundreds of hours of review and analysis.

By June 2018, it became readily apparent that with few exceptions, Funds were evaluating our prospects based solely upon RZ358. A few Funds did diligence and expressed interest in RZ402; however, given that RZ402 is preclinical, it has generally not been prioritized relative to RZ358. In addition, none of the Funds have expressed any interest in AB101. In fact, there has been universal consensus that we should continue with our AB101 strategy of completing our ongoing Phase 1 study for the program and then seek to out-license the program or terminate it depending upon the Phase 1 study results. Importantly, no Fund has expressed a willingness to provide capital for us to continue to advance AB101 beyond the first study.

Funds have also been clear that they believe that Rezolute needs to raise at least \$40 million in order to fund the Company through the completion of our planned Phase 2b study for RZ358. As a result, notwithstanding our initial desire to raise approximately \$20-25 million and then conduct additional financings based upon the achievement of clinical milestones, we are now targeting a \$40 million raise.

Further, while some Funds either declined to consider an investment in Rezolute or declined to invest following their diligence, by August 2018 various Funds concluded that they would be interested in investing in Rezolute as part of a syndicate on the condition that at least one Fund serve as the lead investor to prepare a term sheet and related documents. In the second half of August 2018, we received a term sheet from one potential investor (the "Lead Investor"); however, we did not believe that the terms were in the best interests of the Company and its shareholders and continued evaluating alternatives.

Another Fund declined to serve as lead investor in Rezolute or to participate in a syndicate as part of the Financing; nonetheless, this Fund suggested that we consider a strategic business combination with one of their existing portfolio companies (the "Portfolio Company"). In the second half of September 2018, we engaged in a diligence process with the Portfolio Company culminating in our receipt of a term sheet proposal from the Portfolio Company for a strategic transaction. Following discussions between the companies on October 11, 2018, we concluded that a transaction with the Portfolio Company was not the best option for Rezolute and its shareholders.

We have continued discussions with the Lead Investor through the first half of October 2018 and have concluded that finalizing a term sheet with that Fund whereby they would invest \$7 million in the Financing was the best path forward for the Company—particularly given that other Funds that have completed their diligence have expressed interest in following the Lead Investor as part of a syndicate to raise \$40 million.

Our objective is to finalize a non-binding term sheet with the Lead Investor and to then prepare definitive documentation for the Financing while building the syndicate. We believe that it will take several months to complete the Financing particularly if we concurrently up-list onto a national exchange as part of the transaction. In the interim, we will need to secure additional bridge funding given our low cash position.

While no assurance can be given that: (i) we will execute a term sheet with the Lead Investor; (ii) we will be able to negotiate a purchase agreement that is satisfactory to all parties; (iii) we will be able to generate enough interest from other Funds to raise the full \$40 million; (iv) that we will be able to raise additional bridge financing to continue operations pending the completion of the Financing, we believe that this Financing strategy is the best option for the Company and its shareholders. Our inability to either secure additional bridge funding or

complete the Financing would materially and adversely impact our ability to continue as a going concern.

Significant Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to the useful lives of depreciable assets and measure of any impairment, the fair value of share-based payments and warrants, fair value of derivative instruments, complex debt and equity financing, debt extinguishment, the valuation allowance of deferred tax assets due to continuing and expected future operating losses and the estimates of probability and potential magnitude of contingent liabilities. Management bases its estimates and judgments on historical experience and on various factors that are believed to be reasonable under the circumstance, 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. Actual results may differ from these estimates under different assumptions or conditions. The methods, estimates, and judgments used by us in applying these most critical accounting policies have a significant impact on the results we report in our consolidated financial statements.

Patents

Costs of establishing patents consisting of legal fees paid to third parties and related costs are currently expensed as incurred. We will continue this practice unless we can demonstrate that such costs add economic value to our business, in which case we will capitalize such costs as part of intangible assets. The primary consideration in making this determination is whether or not we can demonstrate that such costs have, in fact, increased the economic value of our intellectual property, which will not be considered until regulatory approval and successful commercialization of a drug candidate.

Research and Development

Research and development costs are expensed as incurred. These costs consist primarily of expenses for personnel engaged in the design and development of product candidates, license fees and expenses paid in connection with license agreements with third parties, the scientific research necessary to produce commercially viable applications of our proprietary drugs, early stage clinical testing of product candidates, and development equipment and supplies, facilities costs and other related overhead.

Stock-Based Compensation

We account for stock-based payments by recognizing compensation expense based upon the estimated fair value of the awards on the date of grant. We determine the estimated grant date fair value of options using the Black-Scholes option pricing model and recognize compensation costs ratably over the vesting period using the straight-line method. Common stock issued in exchange for services is recorded at fair value of the common stock at the date which we became obligated to issue the shares. The value of the shares is expensed over the requisite service period.

Derivatives

We account for our derivative liabilities by recording the fair value of such instruments and embedded features at inception. The fair value of our derivatives is calculated using either the Black-Scholes pricing model or a Lattice Model. Embedded derivative instruments are bifurcated and assessed, along with free-standing instruments such as warrants, on their issuance date and measured at their fair value for accounting purposes. The Company uses the Black-Scholes option pricing formula. Upon conversion of a note where the embedded conversion option has been bifurcated and accounted for as a derivative liability, the Company records the shares at fair value, relieves all related notes, derivatives and debt discounts and recognizes a net gain or loss on debt extinguishment. Changes in the fair value in subsequent periods are recorded to derivative gains or losses for the period.

Income Taxes

We use the asset and liability method of accounting for income taxes. Under this method, we recognize deferred assets and liabilities based on the differences between the tax basis of assets and liabilities and their reported amounts in the financial statements that will result in taxable or deductible amounts in future years, as well as for our net operating loss carryforwards. We establish a valuation allowance for all deferred tax assets for which there is uncertainty regarding realization.

Results of Operations

The Company recorded net losses of \$29,861,776 and \$20,277,132 for the years ended June 30, 2018 and 2017, respectively.

Revenues - We are a clinical stage company and have not yet generated any revenues.

Expenses – Research and development costs included salaries, benefits and other staff-related costs; third party licensing fees; consultants and outside costs; material manufacturing costs; and facilities and other costs. Research and development costs for the years ended June 30, 2018 and 2017 were \$17,279,548 and \$12,094,734, respectively. The increase was mainly due to the Company's license expense pertaining to RZ358 for approximately \$5,502,000, clinical trial costs for the AB101 Phase I trial of approximately \$1,627,000 and \$771,000 of expenses to obtain the PKI portfolio. The remainder of the expenses were attributable various salaries, benefits and other facility costs.

General and administrative costs as of June 30, 2018 and 2017 were \$11,454,658 and \$8,229,314, respectively. The increase was mainly due to an increase of approximately \$200,000 of employee bonuses, of which \$175,000 was related to a one time bonus for initiation of the AB101 Phase 1 study. Upon completion of an analysis of the Company's tangible long-lived assets, it was determined certain leasehold improvements had minimal probability of recoverability. Based on this evaluation, the Company recorded an impairment charge related to leasehold improvements of approximately \$1,691,000 in the year ended June 30, 2018. The Company did not record any impairment in the year ended June 30, 2017. The remaining increase was attributable to salaries, benefits and other staff related costs, and a \$663,017 loss on sale of assets, offset partially by a decrease in professional fees.

Other (Expense) Income - \$1,550,000.

The Company recorded interest expense of approximately \$689,188 and \$1,600 as of June 30, 2018 and 2017, respectively. The increase is attributable to convertible notes, bearing an interest rate between 12% and 15%, which were issued in February and April 2018. Additional increase is attributable to the amortization of debt issuance costs and debt discount costs, which are recorded through interest expense. The convertible notes will continue to bear interest at 15% due to an event of default. The debt discounts will become fully amortized to interest expense upon maturity in January 2019.

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 which raised additional capital, built out the manufacturing suite and then sold the assets, produced material for our lead product candidate under good laboratory practices (GLP), conducted studies using the GLP material, and conducted research and development 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 are continuing to evaluate raising additional capital in the near future to maintain the current operating plan. We cannot assure you that we will secure such financing or that it will be adequate to execute our business strategy. Even if we obtain this 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.

Our stated strategy has been to build a metabolic focused biopharmaceutical company by in-licensing compelling compounds that we believe clearly target different diseases where there is an unmet need. In December 2017, we completed the latest phase of this strategy by in-licensing RZ358, a fully human monoclonal antibody that is currently in Phase 2 clinical development. RZ358 is being developed to treat congenital hyperinsulinism, a devastating ultra-orphan pediatric disease.

We believe that RZ358 complements our two other metabolic pipeline opportunities including: (i) our plasma kallikrein inhibitor, RZ402, which is a late stage preclinical program that offers the potential of an oral therapy to treat diabetic macular edema, the leading cause of blindness in adults in the US, and (ii) our super-long-acting basal insulin, AB101, which is currently in Phase 1 clinical development to assess the safety and tolerability, pharmacokinetics and pharmacodynamics of AB101 in patients with diabetes mellitus.

For fiscal and calendar year 2019, we have the following objectives to advance our development strategy: (i) initiate a Phase 2b clinical study for RZ358 in the US and Europe, (ii) complete the necessary toxicology studies for RZ402 to enable the filing of an IND and initiation of clinical studies, and (iii) complete the Phase 1 study for AB101 and explore partnership opportunities. In order to meet these objectives, we need to raise additional capital through an equity financing (“Financing”).

Throughout calendar year 2018, we have met with a variety of large and mid-size health care funds (“Funds”) to unveil the Rezolute story with RZ358 as our lead pipeline program. Many of these Funds have expressed interest in Rezolute and more than 10 Funds have conducted extensive due diligence on our programs and prospects involving many meetings and hundreds of hours of review and analysis.

By June 2018, it became readily apparent that with few exceptions, Funds were evaluating our prospects based solely upon RZ358. A few Funds did diligence and expressed interest in RZ402; however, given that RZ402 is preclinical, it has generally not been prioritized relative to RZ358. In addition, none of the Funds have expressed any interest in AB101. In fact, there has been universal consensus that we should continue with our AB101 strategy of completing our ongoing Phase 1 study for the program and then seek to out-license the program or terminate it depending upon the Phase 1 study results. Importantly, no Fund has expressed a willingness to provide capital for us to continue to advance AB101 beyond the first study.

Funds have also been clear that they believe that Rezolute needs to raise at least \$40 million in order to fund the Company through the completion of our planned Phase 2b study for RZ358. As a result, notwithstanding our initial desire to raise approximately \$20-25 million and then conduct additional financings based upon the achievement of clinical milestones, we are now targeting a \$40 million raise.

Further, while some Funds either declined to consider an investment in Rezolute or declined to invest following their diligence, by August 2018 various Funds concluded that they would be interested in investing in Rezolute as part of a syndicate on the condition that at least one Fund serve as the lead investor to prepare a term sheet and related documents. In the second half of August 2018, we received a term sheet from one potential investor (the “Lead Investor”); however, we did not believe that the terms were in the best interests of the Company and its shareholders and continued evaluating alternatives.

Another Fund declined to serve as lead investor in Rezolute or to participate in a syndicate as part of the Financing; nonetheless, this Fund suggested that we consider a strategic business combination with one of their existing portfolio companies (the “Portfolio Company”). In the second half of September 2018, we engaged in a diligence process with the Portfolio Company culminating in our receipt of a term sheet proposal from the Portfolio Company for a strategic transaction. Following discussions between the companies on October 11, 2018, we concluded that a transaction with the Portfolio Company was not the best option for Rezolute and its shareholders.

We have continued discussions with the Lead Investor through the first half of October 2018 and have concluded that finalizing a term sheet with that Fund whereby they would invest \$7 million in the Financing was the best path forward for the Company—particularly given that other Funds that have completed their diligence have expressed interest in following the Lead Investor as part of a syndicate to raise \$40 million.

Our objective is to finalize a non-binding term sheet with the Lead Investor and to then prepare definitive documentation for the Financing while building the syndicate. We believe that it will take several months to complete the Financing particularly if we concurrently up-list onto a national exchange as part of the transaction. In the interim, we will need to secure additional bridge funding given our low cash position.

While no assurance can be given that: (i) we will execute a term sheet with the Lead Investor; (ii) we will be able to negotiate a purchase agreement that is satisfactory to all parties; (iii) we will be able to generate enough interest from other Funds to raise the full \$40 million; (iv) that we will be able to raise additional bridge financing to continue operations pending the completion of the Financing, we believe that this Financing strategy is the best option for the Company and its shareholders. Our inability to either secure additional bridge funding or complete the Financing would materially and adversely impact our ability to continue as a going concern.

Net Cash Used in Operating Activities

During the year ended June 30, 2018, our operating activities used approximately \$14.1 million in cash. The use of cash was \$15.2 million lower than the net loss due to non-cash charges for stock-based compensation, impairment of long-lived assets, loss on sale of assets, derivative expenses, amortization and depreciation as well as other non-cash activities. Net cash used in operating activities also included a \$4,570,000 million outflow of equity issued to XOMA in connection with the license agreement, a \$602,200 outflow of a loss on extinguishment of debt, an \$80,100 decrease in other assets, a \$53,433 decrease in deferred lease asset and cash provided by a \$824,453 increase in accounts payable and accrued expenses and a \$105,296 decrease in the deferred lease liability.

During the year ended June 30, 2017, our operating activities used approximately \$13.3 million in cash. The use of cash was \$7.0 million lower than the net loss due to non-cash charges for stock-based compensation, derivative expenses, amortization and depreciation as well as other non-cash activities. Net cash used in operating activities also included a \$68,762 increase in other assets and cash provided by a \$112,347 increase in accounts payable and accrued expenses and a \$109,856 decrease in the deferred lease liability.

Net Cash Used in Investing Activities

Net cash provided by investing activities during the year ended June 30, 2018 was \$1,731,684. During the year, the Company received proceeds of \$1,550,000 from a sale of fixed assets, received \$187,500 as a return of the security deposit on the lease of the facility and purchased \$5,816 of fixed assets for the facility.

Net cash used in investing activities during the year ended June 30, 2017 was \$195,383. During the year, the Company purchased \$407,949 of fixed assets for the facility, received \$187,500 as a return of the security deposit on the lease of the facility and received \$25,046 of a sublease deposit.

Net Cash from Financing Activities

Net cash provided by financing activities during the year ended June 30, 2018 was \$9,540,730. During the year, the Company received proceeds from an equity issuance of \$4,500,000 and proceeds from notes payable issued of \$5,340,000 and paid out issuance costs of \$299,270.

Net cash provided by financing activities during the year ended June 30, 2017 was \$13,931,367. During the year, the Company received proceeds from an equity issuance of \$14,637,689 and paid out issuance costs of \$683,194. The Company also made lease payments of \$23,128.

Liquidity and Capital Resources

As of June 30, 2018, we have approximately \$1.6 million in cash on hand and working deficit of approximately \$4.2 million. During the year ended June 30, 2018, we closed on a convertible note transaction in which we issued notes that will convert at a price set in a qualified financing event and we also closed on an equity transaction in which we issued straight shares of common stock.

The Company received net proceeds of approximately \$9.5 million (net) from the transactions above. Additionally, on June 22, 2018, the Company completed a sale of laboratory, including manufacturing assets, and certain leasehold improvements to an independent company for proceeds of \$1,550,000.

As previously discussed, the Company is seeking additional funding of approximately \$40 million to cover operating expenses, continue clinical trials of RZ358, bringing RZ402 through an IND filing, continuing clinical trials of AB101 and continuing research and development of our product pipeline through the calendar year end 2019. Due to the Company's low cash balance, in the interim, we will have to seek additional bridge financing. There is no guarantee that the Company will be able to bridge the Company until the Financing closes and our inability to do so would materially and adversely impact our ability to continue as a going concern.

Going Concern

The continuation of our business is dependent upon obtaining further financing and achieving a break even or profitable level of operations in our business. The issuance of additional equity securities or convertible notes payable and any warrants by us could result in a significant dilution in the equity interests of our current or future stockholders. Obtaining commercial loans, assuming those loans would be available, will increase our liabilities and future cash commitments. There are no assurances that we will be able to obtain additional financing through private placements and/or bank financing or other means necessary to support our working capital requirements. To the extent that funds generated from operations and any private placements, public offerings and/or bank financing are insufficient, we will have to raise additional working capital. No assurance can be given that additional financing will be available, or if available, will be on terms acceptable to us. These conditions raise substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

We had no off-balance sheet transactions.

Contractual Obligations

The following table summarizes our contractual obligations at June 30, 2018.

	Total	Less than 1 year	1-3 Years	3-5 years	Over 5 years
Operating lease obligations	\$ 2,692,437	\$ 747,953	\$ 1,375,120	\$ 569,364	\$ -
Less: Operating subleases income	(788,788)	(398,712)	(390,076)		
Net total obligations	<u>1,903,649</u>	<u>349,241</u>	<u>985,044</u>	<u>569,364</u>	<u>-</u>

Subsequent Events

The Company has considered subsequent events through the date of issuance of this Report on Form 10-K, and has determined no additional disclosure is necessary, other than those disclosed in the footnotes.

Recently Issued Accounting Pronouncements

See Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K regarding the impact of certain accounting pronouncements on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS.

Not required for smaller reporting companies.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our Financial Statements and Supplementary data are incorporated by reference to Item 15 part IV at page F-1 of this annual report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures” as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of the end of the period covered by this Annual Report, we carried out an evaluation, under the supervision and with the participation of senior management, including our chief executive officer (our principal executive officer) and our chief financial officer (our principal financial officer), of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rules 13a-15(b) and 15d-15(b). Based upon this evaluation, the chief executive officer and chief financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this Annual Report were not effective at the reasonable assurance level.

Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting has been designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Our internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of our assets; provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are being made only in accordance with authorization of our management and directors; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting at June 30, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013 Internal Control—Integrated Framework. Based on that assessment under those criteria, our management has determined that, at June 30, 2018, 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) we have not segregated duties as one employee can initiate and complete transactions in the general ledger system, (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 review from within the Company and (4) the Company did not have effective review controls over financial reporting over the financial statements and related disclosures in accordance with U.S. GAAP and SEC rules and regulation. We do not believe that these control weaknesses resulted in deficient financial reporting as the chief executive officer and chief financial officer were aware of their responsibilities under the SEC reporting requirement and personally certified the financial reports.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to the exemption provided to issuers that are not "large accelerated filers" nor "accelerated filers" under the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Changes in internal controls over financial reporting

During the period covered by this Annual Report, there were two material changes in our internal control over financial reporting. On May 10, 2018, the Company hired a chief financial officer. On June 26, 2018, the Company's chief accounting officer's employment ended. Other than these changes, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

See Item 5 of this annual report on Form 10-K for a description of our unregistered sales of securities during our fiscal year ended June 30, 2018. Such description is incorporated herein by reference.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item will be included in the Proxy Statement which will be filed with the Securities and Exchange Commission no later than 120 days after the end of our fiscal year ended June 30, 2018, and is incorporated herein by reference.

In addition, on May 10, 2018, Dr. Keith Vendola was hired by the Company as the Chief Financial Officer. Dr. Vendola, age 46, previously served as Vice President of Competitive Strategy and Chief of Staff at Coherus BioSciences while the market cap exceeded \$1 billion. In this role, he interacted extensively with Wall Street and executed multiple financings. In addition, he has served in senior finance and corporate development roles at a variety of pharmaceutical companies and as an investment banker within the healthcare groups of Banc of America Securities (now Bank of America Merrill Lynch) and Chase (now JPMorgan Chase). As an executive and investment banker, he has contributed to many transactions and helped companies raise over \$850 million.

Dr. Vendola received an M.B.A. in finance from Northwestern's Kellogg School of Management, M.D. from Dartmouth Medical School and B.A. in psychology from the College of the Holy Cross, where he graduated with honors. He completed an executive education program at Harvard Business School focused on strategic negotiations as well as a research fellowship in the Developmental Endocrinology Branch of the National Institutes of Health, where he was an author on multiple papers.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be included in the Proxy Statement which will be filed with the Securities and Exchange Commission not later than 120 days after the end of our fiscal year ended June 30, 2018, and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be included in the Proxy Statement which will be filed with the Securities and Exchange Commission not later than 120 days after the end of our fiscal year ended June 30, 2018, and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE.

The information required by this item will be included in the Proxy Statement which will be filed with the Securities and Exchange Commission not later than 120 days after the end of our fiscal year ended June 30, 2018, and is incorporated herein by reference.

pH Pharma Collaboration & Services Agreements

Dr. Hoyoung Huh was previously an officer and Director of the Company. As of April 4, 2018, Dr. Huh was appointed to serve as the Vice Chairman of the Board of Directors.

Review, Approval or Ratification of Transactions with Related Persons

We rely on our Board to review related party transactions on an ongoing basis to prevent conflicts of interest. Our Board reviews a transaction in light of the affiliations of the director, officer or employee and the affiliations of such person's immediate family. Transactions are presented to our Board for approval before they are entered into or, if this is not possible, for ratification after the transaction has occurred. If our Board finds that a conflict of interest exists, then it will determine the appropriate remedial action, if any. Our Board approves or ratifies a transaction if it determines that the transaction is consistent with the best interests of the Company.

Director Independence

Because our common stock is not currently listed on a national securities exchange, we have used the definition of "independence" of the NASDAQ Stock Market to determine whether our current director or our new directors are independent. We have determined that as of the date of this Annual Report David Welch, Samir Patel, Tae Hoon Kim, and Gil Labrucherie would qualify as "independent" in accordance with the published listing requirements of The NASDAQ Stock Market and for purposes of Section 16 of the Exchange Act. NASDAQ Listing Rule 5605(a)(2) provides that an "independent director" is a person other than an officer or employee of the Company or any other individual having a relationship which, in the opinion of our Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

The NASDAQ listing rules provide that a director cannot be considered independent if:

- the director is, or at any time during the past three years was, an employee of the Company;
- the director or a family member of the director accepted any compensation from the Company in excess of \$120,000 during any period of twelve consecutive months within the three years preceding the independence determination (subject to certain exclusions, including, among other things, compensation for board or board committee service);

- a family member of the director is, or at any time during the past three years was, an executive officer of the Company;
- the director or a family member of the director is a partner in, controlling stockholder of, or an executive officer of an entity to which the Company made, or from which the Company received, payments in the current or any of the past three fiscal years that exceed 5% of the recipient's consolidated gross revenue for that year or \$200,000, whichever is greater (subject to certain exclusions);
- the director or a family member of the director is employed as an executive officer of an entity where, at any time during the past three years, any of the executive officers of the Company served on the compensation committee of such other entity; or
- the director or a family member of the director is a current partner of the Company's outside auditor, or at any time during the past three years was a partner or employee of the Company's outside auditor, and who worked on the company's audit.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item will be included in the Proxy Statement which will be filed with the Securities and Exchange Commission not later than 120 days after the end of our fiscal year ended June 30, 2018, and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements

The following documents are filed as part of this Form 10-K, as set forth on the Index to Financial Statements found on page F-1.

- Report of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of June 30, 2018 and 2017
- Consolidated Statements of Operations for the years ended June 30, 2018 and 2017
- Consolidated Statements of Stockholders' Equity for the years ended June 30, 2018 and 2017
- Consolidated Statements of Cash Flows for the years ended June 30, 2018 and 2017
- Notes to Consolidated Financial Statements

(a)(2) Financial Statement Schedules

Not Applicable.

(a)(3) Exhibits

EXHIBIT INDEX

Exhibit No.	Description
2.1	Share Exchange and Reorganization Agreement, January 31, 2013 (incorporated by reference to the Company's Form 8-K filing on February 6, 2013)
2.2	Plan of Conversion, dated January 10, 2013 (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filing on January 11, 2013)
3.1	Articles of Conversion, dated January 10, 2013 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filing on January 11, 2013)
3.2	Certificate of Conversion, dated January 10, 2013 (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K filing on January 11, 2013)
3.3	Certificate of Incorporation, dated January 10, 2013 (incorporated by reference to Exhibit 3.3 of the Company's Form 8-K filing on January 11, 2013)
3.4	Delaware Bylaws, dated January 10, 2013 (incorporated by reference to Exhibit 3.4 of the Company's Form 8-K filing on January 11, 2013)
3.5	Certificate of Amendment to the Certificate of Incorporation, dated April 30, 2014 (incorporated by reference to Exhibit 3.5 of the Company's Form S-1 filing on May 20, 2014)
3.6	Certificate of Amendment to the Certificate of Incorporation, dated November 28, 2017 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filing on November 29, 2017)
3.7	Certificate of Designation dated December 7, 2015 (incorporated by reference on Exhibit 3.1 of the Company's Form 8-K on December 10, 2016)
3.8	Amended and Restated Bylaws, dated November 28, 2017 (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K filing on November 29, 2017)
3.9	Certificate of Ownership and Merger, dated December 6, 2017 (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filing on December 7, 2017)
4.1	Form of Konus Warrant (incorporated by reference to Exhibit 4.5 of the Company's Form 8-K filing on April 1, 2014)
4.2	Form of Warrant (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K filing on April 1, 2014)

- [4.3](#) [Form of Bridge Warrant \(incorporated by reference to Exhibit 4.2 of the Company's Form 8-K filing on January 16, 2014\)](#)
- [4.4](#) [Form of Conversion Warrant \(incorporated by reference to Exhibit 4.3 of the Company's Form 8-K filing on April 1, 2014\)](#)
- [4.5](#) [Form of Compensation Warrant \(incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q filing on May 14, 2014\)](#)
- [4.6](#) [Form of Warrant \(incorporated by reference to the Company's Form 8-K filing on December 4, 2014\)](#)
- [4.7](#) [Form of Financing Warrant \(incorporated by reference to the Company's Form 8-K filing on January 5, 2015\)](#)
- [4.8](#) [Form of Warrant \(incorporated by reference to the Company's Form 8-K filing on April 6, 2015\)](#)
- [4.9](#) [Form of Financing Warrant \(incorporated by reference to the Company's Form 8-K filing on April 6, 2015\)](#)
- [4.10](#) [Form of Agent Warrant \(incorporated by reference to the Company's Form 8-K filing on December 10, 2015\)](#)
- [4.11](#) [Form of Warrant \(incorporated by reference to the Company's Form 8-K filing on June 29, 2016\)](#)
- [4.12](#) [Form of Agent Warrant \(incorporated by reference to the Company's Form 8-K filing on June 29, 2016\)](#)
- [4.13](#) [Form of Financing Warrant \(incorporated by reference to the Company's Form 8-K filing on April 3, 2018\)](#)
- [10.1](#) [Asset Purchase Agreement with PR Pharmaceuticals \(incorporated by reference to the Company's Form 8-K filing on February 6, 2013\)](#)
- [10.2](#) [Asset Purchase Agreement \(incorporated by reference to the Company's Form 8-K filing on November 10, 2014\)](#)
- [10.3](#) [Employment Agreement with Nevan Elam, dated June 18, 2012 \(incorporated by reference to the Company's Form 8-K filing on February 6, 2013\)](#)
- [10.4](#) [Amended and Restated Employment Agreement with Nevan Elam, dated March 26, 2014 \(incorporated by reference to Exhibit 10.4 of the Company's Form 8-K filing on April 1, 2014\)](#)
- [10.5](#) [Second Amended and Restated Employment Agreement with Nevan Elam, dated February 23, 2015 \(incorporated by reference to the Company's Form 8-K filing on February 24, 2015\)](#)
- [10.6](#) [Employment Agreement with Sankaram Mantripragada, dated April 1, 2012 \(incorporated by reference to the Company's Form 8-K filing on February 6, 2013\)](#)
- [10.7](#) [Amended and Restated Employment Agreement with Sankaram Mantripragada, dated March 26, 2014 \(incorporated by reference to Exhibit 10.3 of the Company's Form 8-K filing on April 1, 2014\)](#)
- [10.8](#) [Second Amended and Restated Employment Agreement with Sankaram Mantripragada, dated February 23, 2015 \(incorporated by reference to the Company's Form 8-K filing on February 24, 2015\)](#)
- [10.9](#) [Consulting Agreement with Hoyoung Huh, dated July 1, 2012 \(incorporated by reference to the Company's Form 8-K filing on February 6, 2013\)](#)
- [10.10](#) [Termination Agreement with Hoyoung Huh, dated March 26, 2014 \(incorporated by reference to Exhibit 10.6 of the Company's Form 8-K filing on April 1, 2014\)](#)

- [10.11](#) [Employment Agreement with Hoyoung Huh, dated January 1, 2015 \(incorporated by reference to the Company's Form 8-K filing on January 8, 2015\)](#)
- [10.12](#) [Amended and Restated Employment Agreement with Hoyoung Huh, dated October 31, 2016 \(incorporated by reference to the Company's Form 8-K filing on November 4, 2016\)](#)
- [10.13](#) [Amended and Restated Employment Agreement with Morgan Fields, dated February 23, 2015 \(incorporated by reference to the Company's Form 8-K filing on February 24, 2015\)](#)
- [10.14](#) [Option Agreement with Steve Howe, dated January 30, 2013 \(incorporated by reference to the Company's Form 8-K filing on February 6, 2013\)](#)
- [10.15](#) [Option Agreement with Nevan Elam, dated January 30, 2013 \(incorporated by reference to the Company's Form 8-K filing on February 6, 2013\)](#)
- [10.16](#) [Option Agreement with Sankaram Mantripragada, dated January 30, 2013 \(incorporated by reference to the Company's Form 8-K filing on February 6, 2013\)](#)
- [10.17](#) [Option Agreement with Hoyoung Huh, dated January 30, 2013 \(incorporated by reference to the Company's Form 8-K filing on February 6, 2013\)](#)
- [10.18](#) [Subscription Agreement \(incorporated by reference to the Company's 8-K filing on January 16, 2014\)](#)
- [10.19](#) [Form of Bridge Note \(incorporated by reference to the Company's Form 8-K filing on January 16, 2014\)](#)
- [10.20](#) [Form of Note Conversion Letters \(incorporated by reference to the Company's Form 10-Q filing on February 13, 2014\)](#)
- [10.21](#) [Unit Subscription Agreement \(incorporated by reference to the Company's Form 8-K filing on April 1, 2014\)](#)
- [10.22](#) [AntriaBio, Inc. 2014 Stock and Incentive Plan \(incorporated by reference to Appendix B to the Company's Definitive Information Statement on Schedule 14C filed on April 10, 2014\)](#)
- [10.23](#) [AntriaBio, Inc. 2015 Non Qualified Stock Option Plan \(incorporated by reference to the Company's Form 8-K filing on February 24, 2015\)](#)
- [10.24](#) [AntriaBio, Inc. 2016 Non Qualified Stock Option Plan \(incorporated by reference to the Company's Form 8-K filing on November 4, 2016\)](#)
- [10.25](#) [AntriaBio, Inc. 2016 Non Qualified Stock Option Plan, as Amended \(incorporated by reference to the Company's Form 10-K on September 21, 2017\)](#)
- [10.26](#) [Nevan Elam Refresh Stock Option Agreement \(incorporated by reference to the Company's Form 8-K on December 29, 2016\)](#)
- [10.27](#) [Nevan Elam Prospective Refresh Stock Option Agreement \(incorporated by reference to the Company's Form 8-K on December 29, 2016\)](#)
- [10.28](#) [Hoyoung Huh Refresh Stock Option Agreement \(incorporated by reference to the Company's Form 8-K on December 29, 2016\)](#)
- [10.29](#) [Hoyoung Huh Prospective Refresh Stock Option Agreement \(incorporated by reference to the Company's Form 8-K on December 29, 2016\)](#)

- [10.30](#) [Morgan Fields Refresh Stock Option Agreement \(incorporated by reference to the Company's Form 8-K on December 29, 2016\)](#)
- [10.31](#) [Morgan Fields Prospective Refresh Stock Option Agreement \(incorporated by reference to the Company's Form 8-K on December 29, 2016\)](#)
- [10.32](#) [Sankaram Mantripragada Stock Option Agreement \(incorporated by reference to the Company's Form 8-K on December 29, 2016\)](#)
- [10.33](#) [Form of Stock Option Cancellation Agreement \(incorporated by reference to the Company's Form 10-Q filing on May 15, 2017\)](#)
- [10.34](#) [Lease Agreement \(incorporated by reference to the Company's Form 8-K filing on May 12, 2014\)](#)
- [10.35](#) [Lease Agreement with Elion \(incorporated by reference to the Company's Form 10-K on September 21, 2017\)](#)
- [10.36](#) [Sublease Agreement with Elion \(incorporated by reference to the Company's Form 10-K on September 21, 2017\)](#)
- [10.37](#) [Form of Subscription Agreement \(incorporated by reference to the Company's Form 8-K filing on January 5, 2015\)](#)
- [10.38](#) [Form of Subscription Agreement \(incorporated by reference to the Company's Form 8-K filing on April 6, 2015\)](#)
- [10.39](#) [Form of Purchase Agreement \(incorporated by reference to the Company's Form 10-Q filing on February 16, 2016\)](#)
- [10.40](#) [Collaboration Agreement \(incorporated by reference to the Company's Form 8-K filing on March 2, 2016\)](#)
- [10.41](#) [Form of Purchase Agreement \(incorporated by reference to the Company's Form 8-K filing on June 29, 2016\)](#)
- [10.42](#) [Form of Exchange Agreement \(incorporated by reference to the Company's Form 8-K filing on June 29, 2016\)](#)
- [10.43](#) [Placement Agent Agreement dated March 22, 2016 \(incorporated by reference to the Company's Form 10-K filing on September 28, 2016\)](#)
- [10.44](#) [Placement Agent Agreement dated April 11, 2016 \(incorporated by reference to the Company's Form 10-K filing on September 28, 2016\)](#)
- [10.45](#) [Form of Purchase Agreement \(incorporated by reference to the Company's Form 8-K filing on March 6, 2017\)](#)
- [10.46](#) [Development and License Agreement \(incorporated by reference to the Company's Form 8-K filing on August 7, 2017\)](#)
- [10.47](#) [Form of Purchase Agreement \(incorporated by reference to the Company's Form 8-k filing on December 26, 2017\)](#)
- [10.48](#) [Form of Registration Right Agreement \(incorporated by reference to the Company's Form 8-K filing on December 26, 2017\)](#)
- [10.49](#) [Form of Senior Secured Promissory Note \(incorporated by reference to the Company's Form 8-K filing on April 03, 2018\)](#)
- [21.1](#) [Listing of Subsidiaries*](#)
- [23.2](#) [Consent of Dorsey & Whitney, LLP \(incorporated by reference to Exhibit 5.1 of the Company's Form S-1 filing on January 29, 2018\)](#)
- [24.1](#) [Power of Attorney \(contained on signature page to the registration statement\)](#)
- [31.1](#) [Certification of Chief Executive Officer as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*](#)
- [31.2](#) [Certification of Chief Financial Officer as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*](#)

[32.1](#) [Certification of Chief Executive Officer as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*](#)

[32.2](#) [Certification of Chief Financial Officer as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*](#)

101 Interactive Data File (Form 10-K for the fiscal year ended June 30, 2018 furnished in XBRL)*

* Filed herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, the Registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

REZOLUTE, INC.

Date: October 15, 2018

By: /s/ Nevan Elam

Nevan Elam
Chief Executive Officer
(Principal Executive Officer)

Date: October 15, 2018

By: /s/ Keith Vendola

Keith Vendola
Chief Financial Officer
(Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this registration statement has been signed by the following persons in the capacities and on the dated indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Nevan Elam</u> Nevan Elam	Chief Executive Officer and Director	October 15, 2018
<u>/s/ Hoyoung Huh</u> Hoyoung Huh	Director	October 15, 2018
<u>/s/ David Welch</u> David F. Welch	Director	October 15, 2018
<u>/s/ Samir Patel</u> Samir Patel	Director	October 15, 2018
<u>/s/ Tae Hoon Kim</u> Tae Hoon Kim	Director	October 15, 2018
<u>/s/ Gil Labrucherie</u> Gil Labrucherie	Director	October 15, 2018

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
REZOLUTE, INC. AND SUBSIDIARIES**

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Rezolute, Inc.
Louisville, Colorado

OPINION ON THE FINANCIAL STATEMENTS

We have audited the accompanying consolidated balance sheets of Rezolute, Inc. (the “Company”) as of June 30, 2018 and 2017, and the related consolidated statements of operations, stockholders’ (deficit) equity, and cash flows for each year in the two-year period ended June 30, 2018, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2018 and 2017, and the results of its operations and its cash flows for each year in the two-year period ended June 30, 2018, in conformity with accounting principles generally accepted in the United States of America.

GOING CONCERN UNCERTAINTY

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

BASIS FOR OPINION

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

To the Stockholders and Board of Directors
Rezolute, Inc.
Page 2

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EKS&H LLLP

Denver, Colorado
October 15, 2018

We have served as the Company's auditors since 2013.

Rezolute, Inc.
Consolidated Balance Sheets

	<u>June 30, 2018</u>	<u>June 30, 2017</u>
<u>Assets</u>		
Current assets		
Cash	\$ 1,645,872	\$ 4,486,538
Other current assets	361,915	442,015
Total current assets	<u>2,007,787</u>	<u>4,928,553</u>
Non-current assets		
Fixed assets, net	368,374	5,325,401
Intangible assets, net	37,030	44,322
Deferred lease asset	32,850	86,293
Deposits	56,841	244,341
Total non-current assets	<u>495,095</u>	<u>5,700,357</u>
Total Assets	<u>\$ 2,502,882</u>	<u>\$ 10,628,910</u>
<u>Liabilities and Stockholders' (Deficit) Equity</u>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,706,154	\$ 951,239
Accrued payroll	770,976	701,438
Convertible notes payable, net	3,434,611	10,000
Embedded derivative liability	73,904	-
Deferred lease liability, current portion	113,997	105,295
Interest payable	148,372	2,762
Warrant derivative liability	-	588
Total current liabilities	<u>6,248,014</u>	<u>1,771,322</u>
Non-current liabilities:		
Deferred lease liability, less current portion	190,577	304,575
Deposit liability	25,046	25,046
Total non-current liabilities	<u>215,623</u>	<u>329,621</u>
Total Liabilities	<u>6,463,637</u>	<u>2,100,943</u>
Commitments and Contingencies (Note 10)		
Shareholders' (deficit) equity:		
Preferred stock, \$0.001 par value; 20,000,000 shares authorized; none issued and outstanding	-	-
Common stock, \$0.001 par value, 200,000,000 shares authorized; 62,166,309 and 49,228,640 shares issued and outstanding, June 30, 2018 and June 30, 2017	62,168	49,230
Additional paid-in capital	90,160,815	72,800,699
Accumulated deficit	(94,183,738)	(64,321,962)
Total stockholders' (deficit) equity	<u>(3,960,755)</u>	<u>8,527,967</u>
Total Liabilities and Stockholders' (Deficit) Equity	<u>\$ 2,502,882</u>	<u>\$ 10,628,910</u>

See accompanying notes to consolidated financial statements

Rezolute, Inc.
Consolidated Statements of Operations

	Year	
	Ended June 30,	
	2018	2017
Operating expenses		
<i>Research and development</i>		
Compensation and benefits	5,603,671	\$ 7,001,151
Consultants and outside costs	651,155	762,670
Material manufacturing costs	1,162,368	2,596,809
Clinical trial costs	1,627,534	-
License costs	6,272,505	-
Facilities and other costs	1,962,315	1,734,104
	<u>17,279,548</u>	<u>12,094,734</u>
<i>General and administrative</i>		
Compensation and benefits	6,683,490	5,569,426
Professional fees	762,389	1,100,480
Investor relations	317,052	327,556
General and administrative	1,337,319	1,231,852
Impairment of long-lived assets	1,691,391	-
Loss on sale of fixed assets	663,017	-
	<u>11,454,658</u>	<u>8,229,314</u>
Total operating expenses	<u>28,734,206</u>	<u>20,324,048</u>
Loss from operations	<u>(28,734,206)</u>	<u>(20,324,048)</u>
Other (expense) income		
Interest income	1,000	-
Rent income	136,127	37,144
Interest expense	(689,188)	(1,595)
Loss on extinguishment of debt	(602,193)	-
Derivative gains	26,684	11,367
Total other (expense) income	<u>(1,127,570)</u>	<u>46,916</u>
Net loss	<u>\$ (29,861,776)</u>	<u>\$ (20,277,132)</u>
Warrant modification deemed dividend	-	(3,406,932)
Net loss attributable to common stock	<u>\$ (29,861,776)</u>	<u>\$ (23,684,064)</u>
Net loss per common share - basic and diluted	<u>\$ (0.53)</u>	<u>\$ (0.57)</u>
Weighted average number		
of common shares outstanding - basic and diluted	<u>55,654,934</u>	<u>41,296,741</u>

See accompanying notes to consolidated financial statements

Rezolute, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)

	<u>Common Stock, \$0.001 Par Value</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in Capital</u>	<u>Deficit</u>	<u>Stockholders' Equity (Deficit)</u>
Balance at June 30, 2016	35,110,916	\$ 35,114	\$ 52,782,569	\$ (44,044,830)	\$ 8,772,853
Stock-based compensation	-	-	6,005,670		6,005,670
Fair value of warrants issued	-	-	5,434,987		5,434,987
Deemed dividend on warrant modification	-	-	(3,406,932)	-	(3,406,932)
Issuance of common stock, net of issuance costs of \$1,436,273	14,059,374	14,058	11,924,946		11,939,004
Conversion of note payable into common stock	58,350	58	59,459		59,517
Net loss for the year ended June 30, 2017	-	-	-	(20,277,132)	(20,277,132)
Balance at June 30, 2017	49,228,640	\$ 49,230	\$ 72,800,699	\$ (64,321,962)	\$ 8,527,967
Stock-based compensation	-	-	5,095,415		5,095,415
Warrant issuances	-	-	3,267,639	-	3,267,639
Issuance of common stock, net of issuance costs of \$60,000	4,500,000	4,500	4,435,500	-	4,440,000
Issuance of common stock to XOMA, Inc.	8,093,000	8,093	4,561,907	-	4,570,000
Commitment fee for issuance of common stock	344,669	345	(345)	-	-
Net loss for the year ended June 30, 2018	-	-	-	(29,861,776)	(29,861,776)
Balance at June 30, 2018	62,166,309	\$ 62,168	\$ 90,160,815	\$ (94,183,738)	\$ (3,960,755)

See accompanying notes to consolidated financial statements

Rezolute, Inc.
Consolidated Statements of Cash Flows

	Year ended June 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (29,861,776)	\$ (20,277,132)
Amortization of intangible asset	7,292	7,292
Amortization of debt discount	505,465	-
Depreciation expense	1,058,435	1,106,878
Loss on sale of fixed assets	663,017	-
Impairment of long-lived assets	1,691,391	-
Stock-based compensation expense	5,095,415	6,005,670
Derivative gains	(26,096)	(11,367)
Warrant expense for consulting services	550,065	-
Warrant expense	(588)	12,564
Common stock issued pursuant to license agreement	4,570,000	-
Loss on extinguishment of debt	602,193	-
Changes in operating assets and liabilities:		
Decrease (increase) in other assets	80,100	(68,762)
Decrease (increase) in deferred lease asset	53,443	(86,293)
Increase in accounts payable and accrued expenses	824,453	112,347
Increase (decrease) in interest payable	179,407	(2,800)
Decrease in deferred lease liability	(105,296)	(109,856)
Net Cash Used In Operating Activities	(14,113,080)	(13,311,459)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	(5,816)	(407,929)
Proceeds from sale of equipment	1,550,000	-
Receipt of sublease deposit	-	25,046
Return of security deposit	187,500	187,500
Net Cash Provided by (Used In) Investing Activities	1,731,684	(195,383)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on lease payable	-	(23,128)
Proceeds from convertible notes payable	5,340,000	-
Proceeds from issuance of equity financing	4,500,000	14,637,689
Payment of debt placement agent compensation and issuance costs	(239,270)	-
Payment of equity placement agent compensation and issuance costs	(60,000)	(683,194)
Net Cash Provided by Financing Activities	9,540,730	13,931,367
Net (decrease) increase in cash	(2,840,666)	424,525
Cash - Beginning of Period	4,486,538	4,062,013
Cash - End of Period	<u>\$ 1,645,872</u>	<u>\$ 4,486,538</u>
SUPPLEMENTARY CASH FLOW INFORMATION:		
Cash Paid During the Period for:		
Taxes	\$ -	\$ -
Interest	\$ -	\$ -
Non-Cash Transactions:		
Warrant value recorded as debt discount	\$ 2,717,574	\$ -
Embedded derivative liability value recorded as debt discount	\$ 100,000	\$ -
Warrant value recorded as issuance costs	\$ -	\$ 753,079
Fixed assets acquired through accounts payable and accrued expenses	\$ -	\$ 39,680
Conversion of note payable into common stock	\$ -	\$ 50,000
Conversion of interest payable into common stock	\$ -	\$ 9,517
Fair value of warrant modifications recorded as a deemed dividend	\$ -	\$ 3,406,932

See accompanying notes to consolidated financial statements

Rezolute, Inc.
Notes to Consolidated Financial Statements
June 30, 2018

Note 1 Nature of Operations

These financial statements represent the consolidated financial statements of Rezolute, Inc. (“Rezolute”), and its wholly owned operating subsidiary, AntriaBio Delaware, Inc. (“Antria Delaware”). Rezolute and Antria Delaware are collectively referred to herein as the “Company”.

Note 2 Summary of Significant Accounting Policies

The principal accounting policies applied in the preparation of these financial statements are set out below.

Basis of Presentation - The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”).

Principals of Consolidation – These consolidated financial statements include the accounts of Rezolute, and its wholly owned subsidiary. All material intercompany transactions and balances have been eliminated.

Accounting Estimates - The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and the accompanying notes. Such estimates and assumptions impact, among others, the following: the useful lives of depreciable assets and measurement of any impairment, the fair value of share-based payments and warrants, fair value of derivative instruments, estimates of the probability and potential magnitude of contingent liabilities, debt extinguishment, the valuation allowance for deferred tax assets due to continuing and expected future operating losses and going concern. Actual results could differ from those estimates.

Risks and Uncertainties - The Company's operations may be subject to significant risk and uncertainties including financial, operational, regulatory and other risks associated with a clinical stage company, including the potential risk of business failure. See Note 3 regarding going concern matters.

Cash - In the statement of cash flows, cash includes cash in hand and other short-term highly liquid investments with original maturities of three months or less. The Company places its cash on deposit with financial institutions it believes to be of high quality. At times during the year and at June 30, 2018, such cash investments may be in excess of the Federal Deposit Insurance Corporation (“FDIC”) insurance limits.

Fixed Assets – Fixed assets are carried at cost, adjusted for any impairment, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives.

Intangible Assets – Costs of establishing patents, consisting of legal and filing fees paid to third parties, are expensed as incurred. The value of the current intangible asset is based on the asset values assigned in the asset acquisition, which are periodically reassessed for reasonableness, based on the Company’s planned use and any changes in legal or economic factors. The intangible assets are being amortized over 11 years which is the life of the patents at the time they were acquired. The amortization expense is expected to be approximately \$7,000 for each of the next five fiscal years.

Deposits – Deposits represent amounts paid as a security deposit on the lease of the facilities and is recorded at cost.

Convertible Notes Payable - Borrowings are recognized initially at the principal amount received. Borrowings are subsequently carried at amortized cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognized as interest expense in the statements of operation over the period of the borrowings using the effective interest method. The Company records any identified beneficial conversion feature (“BCF”) related to the issuance of a convertible note when issued. Beneficial conversion features that are contingent upon the occurrence of a future event are recorded when the contingency is resolved. The value of the BCF is recorded in the financial statements as a debt discount from the face amount of the note and such discount is amortized over the expected term of the convertible note (or to the conversion date of the note, if sooner) and is charged to interest expense. If convertible notes are issued in conjunction with warrants, the Company allocates the proceeds to each component using a relative fair value.

Debt Issue Costs - Costs associated with obtaining debt financing are deferred and amortized to interest expense using the effective interest method over the term of the related financing.

Research and Development Costs - Research and development costs are expensed as incurred and include salaries, benefits and other staff-related costs; consultants and outside costs; material manufacturing costs; and facilities and other related costs. These costs relate to research and development costs without an allocation of general and administrative expenses.

General and Administrative Expenses - Such costs are expensed in the period incurred.

Share-based Compensation – The Company has various share-based employee and non-employee compensation plans, which are described more fully in Note 8. The Company accounts for stock options granted to employees and non-employees by recognizing the costs resulting from all share-based payment transactions in the consolidated financial statements at their estimated fair values. The Company estimates the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model based on assumptions of expected volatility of its common stock, prevailing interest rates, an estimated forfeiture rate, and the expected term of the stock options, and the Company recognizes that cost as an expense ratably over the associated employee service period, which is generally the vesting period.

Impairment of Long-Lived Assets – The Company routinely performs an evaluation of the recoverability of the carrying value of our long-lived assets to determine if facts and circumstances indicate that the carrying value of assets or intangible assets may be impaired and if any adjustment is warranted. As of June 30, 2018, the Company’s evaluation identified there were facts and circumstances that indicated impairment of certain assets. The Company recorded an impairment charge of approximately \$1,691,000, as further discussed in Note 4.

Derivatives - We account for our embedded derivatives and liability warrants by recording the fair value. The fair value of the warrants is calculated using the Black-Scholes pricing model. The embedded derivatives’ fair value was calculated based on the payment obligation if exercised. We recorded the derivative expense at the inception of each instrument reflecting the difference between the fair value and the cash received. Changes in the fair value in subsequent periods are recorded as derivative gains or losses for the period.

Income Taxes – The Company accounts for income taxes under an asset and liability approach. This process involves calculating the temporary and permanent differences between the carrying amounts of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes and net of loss carry-forward. The temporary differences result in deferred tax assets and liabilities, which would be recorded on the Company’s balance sheets in accordance with ASC 740, which established financial accounting and reporting standards for the effect of income taxes. The Company must assess the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent the Company believes that recovery is not likely, the Company must establish a valuation allowance. Changes in the Company’s valuation allowance in a period are recorded through the income tax provision on the statements of operations.

The Company follows ASC 740 (formerly known as FIN No. 48, *Accounting for Uncertainty in Income Taxes*). ASC 740 clarifies the accounting for uncertainty in income taxes recognized in an entity’s financial statements and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under ASC 740, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, ASC 740 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As a result of the implementation of ASC 740, the Company recognized no material adjustment in the liability for unrecognized income tax benefits. The Company reports tax related interest and penalties as a component of interest expense.

Segment Reporting – Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer and the board of directors that makes strategic decisions. The Company operates one segment.

Income (Loss) Per Common Share – Basic income (loss) per common share is calculated by dividing the net income (loss) available to the common shareholders by the weighted average number of common shares outstanding during that period. Diluted earnings per share reflects the effects of dilutive instruments including stock options and warrants, by dividing income available to common shareholders, adjusted for the effects of dilutive convertible securities, by the weighted average number of shares of common shares outstanding during the period and all additional common shares that would have been outstanding had all potential dilutive common shares been issued. The convertible notes issued in April 2018 would have a dilutive impact to earnings per share, but as the conversion feature was not resolved at the date of the balance sheet, they are not included in the dilutive calculation.

Although there were common stock equivalents of 57,106,492 and 39,454,065 shares outstanding at June 30, 2018 and 2017, respectively, consisting of stock options and warrants; they were not included in the calculation of earnings per share because they would have been anti-dilutive.

Fair Value of Financial Instruments - The Company follows ASC 820, *Fair Value Measurements and Disclosures*, which provides a framework for measuring fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The standard also expands disclosures about instruments measured at fair value and establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

- Level 1: Quoted prices for identical assets and liabilities in active markets;
- Level 2: Quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets; and
- Level 3: Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

The carrying amounts of financial instruments including cash, accounts payable and accrued expenses, approximated fair value as of June 30, 2018 and 2017 due to the relatively short maturity of the respective instruments. The fair value of the convertible notes payable approximates the face value of \$4,140,000 due to the one-year term.

The warrant derivative liability recorded as of June 30, 2018 and 2017 is recorded at an estimated fair value based on a Black-Scholes pricing model. The warrant derivative liability is a level 3 fair value instrument with the entire change in the balance recorded through earnings. See significant assumptions in Note 8. The following table sets forth a reconciliation of changes in the fair value of financial instruments classified as level 3 in the fair value hierarchy:

Balance as of June 30, 2017	\$ (588)
Total unrealized gains (losses):	
Included in earnings	588
Balance as of June 30, 2018	<u>\$ -</u>

The embedded derivative liability is recorded at an estimated fair value based on the present value of the probability of the weighted exercise of the payment obligation. The embedded derivative liability is a level 3 fair value measurement with the entire change in the balance recorded through earnings each reporting period. The significant inputs to the calculation are a term of one year and a weighted probability of 95%. Refer to Note 6 for further discussion. The following table sets forth a reconciliation of changes in the fair value of financial instruments classified as level 3 in the fair value hierarchy:

Value Recorded at issuance	100,000
Total unrealized gains (losses):	
Included in earnings	(26,096)
Balance as of June 30, 2018	<u>\$ 73,904</u>

Recently Issued Accounting Pronouncements - In January 2016, the FASB issued ASU 2016-01, *Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. ASU 2016-01 will be effective for us starting on July 1, 2018, and early adoption is not permitted. We are currently evaluating the impact that the standard will have on our consolidated financial statements.

In February 2018, the FASB issued ASU No. 2018-03, *Technical Corrections and Improvements to Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, that clarifies the guidance in ASU No. 2016-1, *Financial Instruments-Overall (Subtopic 825-10)* related to: Equity Securities without a Readily Determinable Fair Value-Discontinuation, Equity Securities without a Readily Determinable Fair Value- Adjustments, Forward Contracts and Purchased Options, Presentation Requirements for Certain Fair Value Option Liabilities, Fair Value Option Liabilities Denominated in a Foreign Currency and Transition Guidance for Equity Securities without a Readily Determinable Fair Value. The Company is currently in the process of assessing the impact of this ASU on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. This update requires organizations to recognize lease assets and lease liabilities on the balance sheet and also disclose key information about leasing arrangements. This ASU is effective for annual reporting periods beginning on or after December 15, 2018, and interim periods within those annual periods. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered after, the date of initial application, with an option to use certain transition relief. We will be required to adopt ASU 2016-02 starting on July 1, 2019. We are currently evaluating the impact the adoption of this ASU will have on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The update will affect all entities that issue share-based payment awards to their employees and is effective for annual periods beginning after December 15, 2016 for public entities. The areas for simplification in ASU 2016-09 involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. We adopted the ASU starting on July 1, 2017 and there was a minimal impact on our consolidated financial statements.

In May 2017, the FASB issued ASU 2017-9, *Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting*. The update includes guidance on what changes to share-based payment awards would require modification accounting and is effective for annual periods after December 15, 2017. We expect to adopt the ASU 2017-9 on July 1, 2018. We do not expect the adoption of the new provisions to have a material impact on our financial condition or results of operations.

In July 2017, the FASB issued Accounting Standards Update (“ASU”) No. 2017-11, “Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features, II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. ASU 2017-11 revises the guidance for instruments with down round features in Subtopic 815-40, *Derivatives and Hedging – Contracts in Entity’s Own Equity*, which is considered in determining whether an equity-linked financial instrument qualifies for a scope exception from derivative accounting. An entity still is required to determine whether instruments would be classified in equity under the guidance in Subtopic 815-40 in determining whether they qualify for that scope exception. If they do qualify, freestanding instruments with down round features are no longer classified as liabilities. ASU 2017-11 is effective for annual and interim periods beginning December 15, 2018, and early adoption is permitted, including adoption in an interim. ASU 2017-11 provides that upon adoption, an entity may apply this standard retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the opening balance of retaining earnings in the fiscal year and interim period adoption. The Company is currently in the process of assessing the impact of this ASU on its consolidated financial statements.

Subsequent Events – The Company has considered subsequent events through the date of issuance of this Report on Form 10-K, and has determined no additional disclosure is necessary, other than those disclosed in the footnotes.

Note 3 Going Concern

As reflected in the accompanying financial statements, the Company has a net loss of \$29,861,776 and net cash used in operations of \$14,113,080 for the year ended June 30, 2018, and a stockholders’ deficit of \$3,960,755 and an accumulated deficit of \$94,183,738 at June 30, 2018. In addition, the Company is in the clinical stage and has not yet generated any revenues. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

The Company expects that its current cash resources as well as expected lack of operating cash flows will not be sufficient to sustain operations for a period greater than one year from the filing date of these financial statements. The ability of the Company to continue its operations is dependent on Management’s plans, which include continuing to raise equity and debt based financing. There is no assurance that the Company will be successful in accomplishing this objective on terms acceptable to the Company.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a

going concern.

Note 4 Fixed Assets

The following is a summary of fixed assets and accumulated depreciation:

	Useful Life	June 30, 2018	June 30, 2017
Furniture and fixtures	5 - 7 years	\$ 118,450	\$ 118,450
Lab equipment	3 - 15 years	738,415	3,946,040
Leasehold Improvements	5 - 7 years	29,296	3,247,038
		886,161	7,311,528
Less: accumulated depreciation and amortization		(517,787)	(1,986,127)
		<u>\$ 368,374</u>	<u>\$ 5,325,401</u>

Depreciation expense was \$1,058,435 and \$1,106,878 for the years ended June 30, 2018 and 2017, respectively.

On June 22, 2018, the Company completed a sale of certain laboratory assets, including manufacturing assets, and leasehold improvements to an independent company for proceeds of \$1,550,000. The sale of assets resulted in the Company recognizing a loss on the sale of long lived assets for \$663,017.

Additionally, during the year ended June 30, 2018, the Company entered into discussions regarding the sublease of its manufacturing and laboratory space in Louisville, Colorado. The Company also had a strategic shift in April 2018, resulting in the manufacturing plant being shut down and a restructuring plan being implemented. This shift was to focus on finding a partner for continued development of AB101 and developing RZ358 with external manufacturing organizations. As the Company was completing its analysis of long-lived assets, an evaluation of the Company's leasehold improvements was conducted to evaluate the recoverability of assets carrying value. Upon completion of this impairment analysis, the Company concluded it would not be able to recover future benefits from leasehold improvements with a net book value of \$1,691,391 due to factors discussed above. As such the Company recorded an impairment charge for this amount in June 2018. There were no impairment charges recorded in the year ended June 30, 2017.

Note 5 Related Party Transactions

During the year ended June 30, 2018, the Company incurred investor relation expenses of \$33,322 and general and administrative expenses of \$67,726 for services performed by related parties of the Company and included in the statement of operations. During the year ended June 30, 2017, the Company incurred investor relation expenses of \$113,175 and general and administration expenses of \$13,829 for services performed by related parties of the Company and included in the statement of operations. As of June 30, 2018 and 2017, there were \$0 and \$25,200, respectively, related party expenses recorded in accounts payable and accrued expense.

Note 6 Convertible Notes Payable

Historical Note

As of June 30, 2018, the Company had one historical convertible note outstanding with a balance of \$10,000, which consists of notes which were not converted at the time of an equity transaction in 2017. As of June 30, 2018, this outstanding convertible note has matured, and payments were due. This convertible note which has not been repaid or converted continues to accrue interest at a rate of 8%.

Q3 2018 Notes

On February 26, 2018, the Company issued a secured convertible promissory note for gross proceeds of \$500,000. The note bears interest at a rate of 15% per annum and expires one year from issuance. The note contains an optional conversion feature in which if the Company raises \$10 million then, at the investor's option, the notes would convert into the financing at a 20% discount of the financing terms. With the promissory note, the investor also received warrants to purchase 500,000 shares of common stock which expire five years from date of issuance. The exercise price for these warrants was set on of June 29, 2018 at \$0.52 per share. The note also contains an embedded derivative liability for the acceleration of the maturity date as discussed in Note 2, which states a \$25,000 penalty plus all unpaid interest to be accrued will be paid if note is paid prior to maturity. The embedded derivative liability of \$100,000 is reflected as a debt discount. The embedded derivative liability is amortized into interest expense over the life of the note.

During the quarter ended March 31, 2018, the Company issued two secured convertible promissory notes for gross proceeds of \$700,000. The notes bore interest at a rate of 12% per annum and expire one year from issuance or 10 days after the closing of a financing of at least \$10 million. The notes included a default interest rate provision, in which the stated interest rate will increase to 15% during an event of default. Subsequent to June 30, 2018, the stated interest rate has increased to 15% as the quarterly interest payment is past due. The notes contained an optional conversion feature in which if the Company raises \$20 million then, at the investor's option, the notes would convert into the financing at a 20% discount of the financing terms. This conversion feature was a contingent beneficial conversion feature that was not calculated as a separate derivative until the contingent event has occurred. With the promissory note, the investor also received warrants to purchase 350,000 shares of common stock equal to one-half of the principal amount of the note. The warrants had an exercise price of \$1.00 per share and are exercisable for five years from date of issuance.

The above two notes and related warrants to purchase shares of stock were modified on April 3, 2018 with four changes. The first being the optional conversion was amended to an automatic conversion in the event of a qualified financing. Second, the maturity date on both were amended to January 31, 2019 or if the Company successfully offers and sells at least \$15 million of its securities in a single equity financing (a "Qualified Financing"), then the outstanding principal and interest due shall automatically be converted at the closing of the Qualified Financing at a 20% discount to the terms set forth in such Qualified financing. Third, the warrants issued were modified to a number of shares set by the principal amount divided by \$0.41, which was set on June 29, 2018. Finally, the exercise price was amended from \$1.00 to 120% the average closing price of the 10 days preceding July 1, 2018, or \$0.52.

As the debt issued in January and February 2018 was modified to mirror the terms of the April 3, 2018 financing closing, the Company completed a modification or extinguishment evaluation. As the future cash flows of the instruments fair value changed an amount greater than 10% and debt extinguishment accounting was applied. Accordingly, the net book value of the original note payable, including the unamortized debt discount of \$626,797 was removed and the fair value of the modified notes payable and warrants was recorded as \$683,737 and \$545,257, respectively. This resulted in the Company recording a loss on the extinguishment of debt of \$602,193.

Q4 2018 Notes

On April 3, 2018 and April 11, 2018, the Company closed on a series of Senior Secured Promissory Notes with gross proceeds of \$4.1 million, which had cash issuance costs of approximately \$239,000. The notes also include warrants to purchase common stock with the number of shares and exercise price to be determined at the at the close of the next financing or based on the average trading prices prior to July 1, 2018. As the Company did not complete a financing event prior to July 1, 2018, the warrant conversion share price was set based on the average closing price of the 20 trading days preceding July 1, 2018, or \$0.41. The exercise price was set at 120% of the average closing price of the 10 trading days preceding July 1, 2019, or \$0.52. As discussed in Note 8, the warrants had a fair value of \$134,000. The notes bear interest at 12% per annum, with a 15% default interest rate provision, and mature on January 31, 2019 or if the Company successfully offers and sells at least \$15 million of its securities in a single equity financing, then the outstanding principal and interest due shall automatically be converted at the closing of the Qualified Financing at a 20% discount to the terms set forth in such Qualified Financing. The notes contained a mandatory conversion feature, in which the notes will convert into shares at the close of a qualified financing. This conversion feature is a contingent beneficial conversion feature that is not calculated as a separate derivative until the contingent event has occurred. The notes include a default interest rate provision, in which the stated interest rate will increase to 15% during an event of default.

With the promissory notes issued in April 2018, each investor also received warrants to purchase an adjustable number of shares of common stock at an adjustable exercise price. The number of shares was to be set at the conversion price of the convertible notes or if no Qualified Financing occurs prior to July 1, 2018, the shares are set by the average closing stock price for the 20-day period preceding July 1, 2018. The exercise price is to be determined at 120% of the conversion price of the Convertible note if a financing occurs or 120% of the average closing stock price of the Company for 10 days prior to July 1, 2018. As no qualifying financing event had occurred prior to July 1, 2018, the number of warrants to purchase common stock was fixed as of June 30, 2018, based on the preceding 20-day average stock price, and 11,685,176 of warrants to purchase shares of common stock were issued. The exercise price of the shares was also fixed at \$0.52, which is 120% of the 10-day closing price for the period preceding July 1, 2018.

The value of the notes and warrants is determined using the relative fair value. The fair value of the promissory notes and warrants was \$7,186,883 and \$177,893, resulting in relative fair values \$2,319,000 allocated to notes and \$1,821,000 allocated to warrants. As of June 30, 2018, the outstanding balance of the secured convertible promissory notes was \$4,840,000, with a current debt discount outstanding of approximately \$2,120,611 and unamortized debt issuance costs of approximately \$265,000.

Note 7 Shareholders' Equity (Deficit)

Common Stock

The Company is authorized to issue 200,000,000 shares of \$0.001 par-value common stock. All shares of the Company's common stock have equal rights and privileges with respect to voting, liquidation and dividend rights. Each share of common stock entitles the holder thereof to:

- a. One non-cumulative vote for each share held of record on all matters submitted to a vote of the stockholders;
- b. To participate equally and to receive any and all such dividends as may be declared by the Board of Directors out of funds legally available therefore; and
- c. To participate pro rata in any distribution of assets available for distribution upon liquidation.

Stockholders have no pre-emptive rights to acquire additional shares of common stock or any other securities. Common shares are not subject to redemption and carry no subscription or conversion rights.

Preferred Stock

The Company is authorized to issue 20,000,000 shares of Preferred Stock with each share having a par value of \$0.001.

During the year ended June 30, 2017, the Company closed private placement transactions in which the Company issued 5,783,184 units to accredited investors. Each investor was issued either Class A Units or Class B units of the Company. Each Class A Unit received one share of common stock and one-half of one common share purchase warrant. If the investor had previously invested in the Company they were eligible for a Class B Unit which received one share of common stock and one common share purchase warrant. Each common share purchase warrant is exercisable at \$1.65 per share and will expire 60 months following the issuance. As of June 30, 2017, the Company received net proceeds of approximately \$5.2 million after the placement agent compensation and issuance costs paid of \$683,194 and \$516,550 of warrant expense recorded as issuance costs.

The Company also entered into a private placement transaction during 2017 and 2018 in which the Company issued common stock to accredited investors at an offering price of \$1.00 per share. During the years ended June 30, 2018 and 2017, the Company received net proceeds of approximately \$12.6 million after the placement agent compensation of \$246,671 of warrant expense recorded as issuance costs, as there was no placement agent compensation.

Additionally, during 2018 the Company closed a private placement transaction in which the Company issued 4,500,000 shares of common stock to accredited investors at an offering price of \$1.00 per share. The Company received net proceeds of \$4.44 million after the placement agent compensation of \$60,000.

Lincoln Park Transaction

On December 22, 2017, we entered into the Lincoln Park Purchase Agreement pursuant to which Lincoln Park has agreed to purchase from us up to an aggregate of \$10.0 million of the Company's common stock (subject to certain limitations) from time to time over the 36-month term of the agreement. We also entered into a registration rights agreement with Lincoln Park pursuant to which the Company filed with the Securities and Exchange Commission (the "SEC") the registration statement to register for resale under the Securities Act of 1933, as amended, or the Securities Act, the shares of common stock that have been or may be issued to Lincoln Park under the Purchase Agreement.

As a result, on December 22, 2017, 344,669 newly issued shares of the Company's common stock, equal to three percent of the \$10 million availability, were issued to Lincoln Park as consideration for Lincoln Park's commitment to purchase shares of the Company's common stock under the agreement.

Under the terms and subject to the conditions of the Lincoln Park Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$10.0 million worth of shares of the Company's common stock. Such future sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company's option, over the 36-month term of the agreement.

As contemplated by the Lincoln Park Purchase Agreement, and so long as the closing price of the Company's common stock exceeds \$0.40 per share, then the Company may direct Lincoln Park, at its sole discretion to purchase up to 65,000 shares of its common stock on any business day, provided that five business day has passed since the most recent purchase. The price per share for such purchases will be equal to the lower of: (i) the lowest sale price on the applicable purchase date and (ii) the arithmetic average of the three (3) lowest closing sale prices for the Company's common stock during the twelve (12) consecutive business days ending on the business day immediately preceding such purchase date (in each case, to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction that occurs on or after the date of the purchase agreement). The maximum amount of shares subject to any single regular purchase increases as the Company's share price increases, subject to a maximum of \$500,000.

In addition to regular purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the purchase agreement. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the purchase agreement if it would result in Lincoln Park beneficially owning more than 9.99% of its common stock. There are no trading volume requirements or restrictions under the purchase agreement nor any upper limits on the price per share that Lincoln Park must pay for shares of common stock.

The Lincoln Park Purchase Agreement and the registration rights agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the right to terminate the purchase agreement at any time, at no cost or penalty. During any “event of default” under the purchase agreement, all of which are outside of Lincoln Park’s control, Lincoln Park does not have the right to terminate the purchase agreement; however, the Company may not initiate any regular or other purchase of shares by Lincoln Park, until such event of default is cured. In addition, in the event of bankruptcy proceedings by or against the Company, the purchase agreement will automatically terminate.

Actual sales of shares of common stock to Lincoln Park under the purchase agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. Lincoln Park has no right to require any sales by the Company, but is obligated to make purchases from the Company as it directs in accordance with the purchase agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the Company’s shares.

XOMA Equity Issuance

As the closing of the debt financing in April 2018 was considered to be the initial closing for the Common Stock purchase agreement, on April 3, 2018, the Company issued approximately 7 million shares of Common Stock to XOMA as well as approximately 1.1 million shares for \$4,570,000 related to the interim financing which reduce the amount of shares to be issued upon the closing of a Qualified financing, as discussed in Note 10.

Other

The Company has not declared or paid any dividends or returned any capital to common stock shareholders as of June 30, 2018 and 2017.

Note 8 Stock-Based Compensation

Options

On October 31, 2016, the Board adopted the AntriaBio, Inc. 2016 Non Qualified Stock Option Plan which allows the Company to issue up to 35,000,000 shares of common stock in the form of stock options. Due to a shareholder settlement the 2016 Non Qualified Stock Option Plan was amended on August 21, 2017 to reduce the number of shares to be issued to 15,000,000 shares of common stock in the form of stock options. The Board had issued options to purchase 28,995,000 of these shares to current employees and directors as of June 30, 2017, of which 4,360,000 were cancelled before their terms were established and 11,090,000 were additionally cancelled by the Board during the year ended June 30, 2017. The Company had 1,550,000 of the cancelled stock options that had begun vesting prior to the cancellation and with the cancellation the Company recorded \$1,199,847 of unrecognized stock compensation expense. Due to a shareholder settlement we agreed to among other things (i) cancel certain options granted to certain members of the board of directors and our executive officers, (ii) reduce the number of options issuable under the 2016 plan, (iii) include an amendment to the Company’s Bylaws at the Company’s next annual meeting and (iv) implement certain corporate governance changes. The proposed settlement was conditioned upon, among other things, approval by the Chancery Court.

The Company granted 255,000 of 2016 Non Qualified Stock Option Plan options to current employees and directors of the Company during the year ended June 30, 2018. The options have an exercise price from \$1.00 to \$1.15 per share. The options expire no later than ten years from the date of the grant. The options vest on a monthly basis over 48 months, except for 75,000 of the options which do not begin to vest until specific events have occurred and then begin to vest over 48 months and 60,000 of the options that all vest at the end of the consulting contract. Some options are subject to a one year cliff and all options have an exercise price based on the fair value of the common stock on the date of grant.

The Company has computed the fair value of all options granted that have begun vesting using the Black-Scholes option pricing model. The options that require specific events before they begin to vest are valued at the grant date, however; have not been recorded as the specific event is not probable of occurring. In order to calculate the fair value of the options, certain assumptions are made regarding components of the model, including the estimated fair value of the underlying common stock, risk-free interest rate, volatility, expected dividend yield and expected option life. Changes to the assumptions could cause significant adjustments to valuation. The Company estimated a volatility factor utilizing comparable published volatility of several peer companies. Due to the small number of option holders, the Company has estimated a forfeiture rate of zero as the value of each option holder is calculated individually. The Company estimates the expected term based on the average of the vesting term and the contractual term of the options. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity.

Rezolute has computed the fair value of all options granted during the year ended June 30, 2018 using the following assumptions:

Expected volatility	84%
Risk free interest rate	2.0 - 2.21%
Expected term (years)	7
Dividend yield	0%

Rezolute has computed the fair value of all options granted during the year ended June 30, 2017 using the following assumptions:

Expected volatility	74 - 80%
Risk free interest rate	1.46% - 2.43%
Expected term (years)	7
Dividend yield	0%

Stock option activity is as follows:

	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life</u>
Outstanding, June 30, 2016	8,947,418	\$ 2.73	
Granted	24,725,000	\$ 1.19	
Cancelled	(12,256,667)	\$ 1.51	
Forfeited	(125,000)	\$ 1.12	
Outstanding, June 30, 2017	21,290,751	\$ 1.65	7.7
Granted	255,000	\$ 1.08	
Forfeited	(1,880,505)	\$ 1.62	
Expired	(250,000)	\$ 4.50	
Outstanding, June 30, 2018	<u>19,415,246</u>	\$ 1.55	7.8
Exercisable at June 30, 2018	<u>11,398,855</u>	\$ 1.92	6.4

Stock options outstanding at June 30, 2018 are summarized in the table below:

<u>Range of Exercise Prices</u>	<u>Number of Options Outstanding</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Lives</u>
\$1.00 - \$1.99	12,908,287	\$ 1.20	6.5
\$2.00 - \$2.99	3,778,208	\$ 2.06	7.3
\$3.00 - \$4.50	2,728,751	\$ 3.14	2.2
	<u>19,415,246</u>	\$ 1.64	5.3

Stock-based compensation expense related to the fair value of stock options was included in the statement of operations as research and development - compensation and benefits expense of \$982,468 and \$1,790,851 for the years ended June 30, 2018 and 2017, respectively and as general and administrative – compensation and benefits expense of \$4,112,947 and \$4,214,819 for the years ended June 30, 2018 and 2017, respectively. The unrecognized stock-based compensation expense at June 30, 2018 is \$5,058,172. Rezolute determined the fair value as of the date of grant using the Black-Scholes option pricing method and expenses the fair value ratably over the vesting period.

Warrants

Rezolute issued warrants to agents and security holders in conjunction with the closing of various financings, note conversions, and private placements as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding, June 30, 2016	28,964,376	\$ 2.11	3.1
Warrants issued in private placements	3,248,184	\$ 1.65	
Warrantes issued to placement agent	786,150	\$ 1.54	
Warrants issued for consulting services	250,000	\$ 1.00	
Warrants expired	<u>(452,262)</u>	\$ 2.39	
Outstanding, June 30, 2017	32,796,448	\$ 1.71	3.7
Warrants issued for consulting services	650,000	\$ 1.03	
Warrants issued in debt financing	12,185,176	\$ 0.54	
Warrants issued to placement agent	289,000	\$ 0.54	
Warrants expired	<u>(285,407)</u>	\$ 2.43	
Outstanding, June 30, 2018	<u><u>45,635,217</u></u>	\$ 1.37	3.4

Year Ended June 30, 2018

The Company issued warrants to purchase 100,000 shares of common stock at a price of \$1.00 per share in connection with a consulting agreement. The Company also issued warrants to purchase 50,000 shares of common stock at a price of \$1.00 per share in connection with investor services. The Company issued warrants to purchase 500,000 shares of common stock at a price of \$1.04 per share in connection with a consulting agreement. The Company issued warrants to purchase 350,000 shares of common stock at a price of \$1.00 per share in connection with the issuance of convertible notes. The Company issued also warrants to purchase 500,000 shares of common stock at a price to be determined at a future date in connection with the issuance of convertible notes at a price of \$0.52 per share. The warrants to purchase 350,000 shares of common stock were modified as of April 3, 2018, in connection with the issuance of the promissory notes discussed in Note 6

The Company issued warrants to purchase shares of common stock in connection with the April 3, 2018 and April 11, 2018 interim financing closings. The number of shares was to be set at the time of a qualified financing. If no qualified financing event had occurred prior to July 1, 2018, the number of shares was to be set based on the average closing price of the 20-day period preceding July 1, 2018. The exercise price of the warrants was to be set at 120% of a qualified financing event or 120% of the average closing price of the 10-day period prior to July 1, 2018.

As the Company had not completed a qualified financing as of July 1, 2018, which was not a trading day, the number of warrants to purchase shares of common stock and the exercise price of these warrants were fixed on June 29, 2018, the last trading day of the period. The number of shares issued amounted to 11,685,177, with an exercise price of \$0.52.

The warrants issued for the 11,685,177 shares of common stock were accounted for as equity at the date of issuance. The fair value of the warrants was valued at \$3,770,028 and was recorded based on relative fair value through equity and as a debt discount, as discussed in Note 6.

The Company issued warrants to purchase 289,000 shares of common stock at an exercise price to be determined at 120% of the share price of a qualified financing if it occurs prior to July 1, 2018 or the exercise price will be 120% of the average closing price of the Company's share price for the ten trading days prior to July 1, 2018, which had an exercise price of \$0.52.

These warrants were valued using the Black-Scholes option pricing model on the date of issuance. In order to calculate the fair value of the warrants, certain assumptions were made regarding components of the model, including the closing price of the underlying common stock, risk-free interest rate, volatility, expected dividend yield, and warrant term. Changes to the assumptions could cause significant adjustments to valuation. Rezolute estimated a volatility factor utilizing a comparable published volatility of several peer companies. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. The Black-Scholes valuation methodology was used because that model embodies all of the relevant assumptions that address the features underlying these instruments.

The Lattice pricing model was used to determine the fair value of the warrants to purchase 289,000 shares of common stock on the day they were issued. The Lattice model accommodates the probability of changes in the exercise price as outlined in the warrant agreement. Under the terms of the warrant agreement, the exercise price of the warrant will be 120% of the share price of a qualified financing if it occurs prior to July 1, 2018 or the exercise price will be 120% of the average closing price of the Company's share price for the ten trading days prior to July 1, 2018. The estimated fair value was derived using the lattice model, due to the unknown exercise price at date at issuance, with the following assumptions

Significant assumptions for the warrants issued for the year ended June 30, 2018 used in both the Black-Scholes option pricing model and the Lattice model were as follows:

Expected volatility	24% -96%
Risk free interest rate	0.45% - 2.91%
Warrant term (years)	0 - 7
Dividend yield	0%

Significant assumptions for the warrants issued for the year ended June 30, 2017 were as follows:

Expected volatility	24-110%
Risk free interest rate	0.45% - 2.35%
Warrant term (years)	0-7
Dividend yield	0%

Note 9 Income Taxes

Taxing jurisdictions related to income taxes are the United States Federal Government, the State of Colorado and the State of California. The provision for income taxes is as follows:

	Year Ended June 30,	
	2018	2017
Current tax benefit		
Federal	\$ -	\$ -
State	-	-
	<u>\$ -</u>	<u>\$ -</u>
Deferred tax benefit		
Federal	1,410,582	5,542,631
State	(1,326,566)	618,192
Change in valuation allowance	<u>(84,016)</u>	<u>(6,160,823)</u>
Total tax expense	<u>\$ -</u>	<u>\$ -</u>

Deferred taxes are a result of differences between income tax accounting and GAAP with respect to income and expenses. The following is a summary of the components of deferred taxes recognized in the financial statements as of June 30, 2018 and 2017:

	As of June 30,	
	2018	2017
Deferred tax assets		
Net operating loss carryforward	\$ 15,563,220	\$ 15,358,843
Start-up and organizational expenses	333,868	540,221
Stock-based compensation	4,161,916	5,111,766
Fixed assets	514,878	-
Other	467,372	529,096
Total deferred tax assets	<u>21,041,254</u>	<u>21,539,926</u>
Deferred tax liabilities		
Fixed assets	-	349,346
Federal benefit for state deferred taxes	798,221	863,531
Total deferred tax liabilities	<u>798,221</u>	<u>1,212,877</u>
Valuation allowance	<u>(20,243,033)</u>	<u>(20,327,049)</u>
Net deferred taxes	<u>-</u>	<u>-</u>

The valuation allowance was established because the Company had not reported earnings in order to support the recognition of the deferred tax asset. The Company has net operating loss carryforwards of approximately \$60,700,000 for federal and state income tax purposes. Federal and state net operating loss carryforwards, to the extent not used, will expire starting in 2031. Under provisions of the Internal Revenue Code, substantial changes in the Company's ownership may result in limitations on the amount of net operating loss carryforwards that can be utilized in future years. As of June 30, 2018, approximately \$6,281,000 of the net operating loss carryforwards are subject to IRS limitations. The Company is no longer subject to income tax examinations for federal income taxes before 2013 and for Colorado before 2012.

The Tax Cuts and Jobs Act of 2017 (the "Act") was enacted on December 22, 2017 and significantly revises tax law. The Act reduces the U.S. federal corporate tax rate from 35% to 21%, effective requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously deferred and includes a variety of other changes. Consequently, we recorded a provisional decrease of approximately \$8.9 million. This reduction was fully offset by a corresponding change in the valuation allowance recorded against the deferred tax assets.

The income tax provision differs from the amount of income tax determined by applying the U.S. federal income tax rate of 27.5% to pretax income for the following periods, due to the following:

	Year Ended June 30,	
	2018	2017
Computed "expected" tax expenses (benefit)	\$ (8,078,305)	\$ (6,894,226)
Change in income taxed From:		
State Taxes net of Federal Benefit	(984,553)	(617,139)
Permanent Difference	12,406	18,150
Return To provision	-	(205,794)
Stock option expiration	644,780	1,538,186
Tax Cuts and Jobs Act	8,489,688	-
Change in valuation allowance	(84,016)	6,160,823
	<u>\$ -</u>	<u>\$ -</u>

Note 10 Commitments and Contingencies

Lease Commitments

In May 2014, the Company entered into a lease of approximately 27,000 square feet of office, laboratory and clean room space to be leased for seventy-two months. The lease requires monthly payments of \$28,939 adjusted annually by approximately 3% plus triple net expenses monthly of \$34,381 adjusted annually. The Company also made a security deposit of \$750,000 which is held by the landlord, of which \$562,500 has been returned to the Company and the remaining balance will be returned gradually over the next several years.

On March 17, 2017, the Company entered into a lease of approximately 20,000 square feet of office space to be leased for eighty-two months. The lease requires monthly payments of \$28,425 adjusted annually plus triple net expenses monthly of \$28,410 adjusted annually. The Company also made a security deposit of \$56,851 which will be returned at the end of the lease.

On March 17, 2017, the Company sub-leased their original approximately 10,000 square feet of office space to another company. The sublease is for eighty-two months unless the Company is unable to extend its current lease then the sub-lease will expire on March 31, 2020. The Company is to receive monthly payments of \$12,523 adjusted annually plus triple net expenses monthly of \$12,828 adjusted annually. The Company also received a security deposit of \$25,046 which will be returned at the end of the lease.

On July 1, 2018 the Company sub-leased approximately 4,100 square feet of office space and 6,770 square feet of clean room and lab space to other companies. The Company is to receive monthly payments of approximately \$30,300 for this sublease through the conclusion of the lease.

Additionally, the Company sub-leased approximately 3,200 square feet of lab space to another company. The Company is to receive monthly payments of approximately \$8,000 for this space through the conclusion of the lease.

As of June 30, 2018, minimum rental commitment under the leases is as follows:

Year Ending June 30,	Operating Leases	Sub-lease Income	Total
2019	747,953	(398,712)	349,241
2020	688,892	(390,076)	298,816
2021	338,392	-	338,392
2022	347,836	-	347,836
2023	357,279	-	357,279
Thereafter	212,085	-	212,085
	\$ 2,692,437	\$ (788,788)	\$ 1,903,649

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 Program”). The Company desires to use the PKI Program to develop, file, manufacture, market and sell products for diabetic macular edema and other human therapeutic indications. The Company was required to make an upfront payment of \$750,000, which was expensed to research and development license expense, payable within five (5) days of the date the parties execute the License Agreement and then various milestone payments ranging from \$1 million to \$10 million when milestone events occur up to an aggregate of \$36 million. The Company would also be required to pay royalty payments of 2% of sales for any products that use the PKI Program up to an aggregate of \$10 million.

On December 6, 2017, the Company entered into a License Agreement and Common Stock Purchase Agreement (collectively “Transaction Documents”) with XOMA LLC (“XOMA”) pursuant to which the Company acquired the exclusive rights to develop and commercialize XOMA 358 (now RZ358) for an orphan indication, Congenital Hyperinsulinism. The Company is responsible for all development, regulatory, manufacturing and commercialization activities associated with RZ358. Pursuant to the Transaction Documents, the Company is required to pay XOMA \$6 million and to issue XOMA \$12 million of the Company’s common stock based upon the Company’s financing activities in 2018. The Company would be required to issue additional shares and a put option to XOMA if certain financing activities did not occur in 2018, as more fully described in the agreements. The Company also has a required development spend every year related to RZ358. The Company is also required to make certain clinical, regulatory and annual net sales milestone payments of up to \$222 million in the aggregate. The Company is also obliged to pay XOMA royalties ranging from the high single digits to the mid-teens based upon annual net sales of RZ358. Finally, under the terms of the License Agreement, the Company is required to pay XOMA a low single digit royalty on sales of the Company’s other products.

On March 30, 2018, the Company amended the License Agreement and Common Stock Purchase Agreement. The License Agreement was amended to add terms specifying the financial responsibility for certain tasks related to the technology transfer. The Purchase Agreement was amended as follows: (1) adjusted the total shares due upon the Initial Closing (as defined in the Purchase Agreement) from \$5 million in value to 7,000,000 shares; (2) increase the shares due upon a Qualified Financing (as defined in the Purchase Agreement) from \$7 million in value to \$8.5 million in value; and (3) increase the shares due upon the 2019 Closing (as defined in the Purchase Agreement) from \$7 million in value to \$8.5 million in value.

On April 3, 2018, the Company closed on a debt financing which was considered the initial closing for the Common Stock Purchase Agreement and the initial seven million shares were issued to XOMA as well as approximately 1.1 million interim financing shares which reduce the shares to be issued upon a Qualified Financing.

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 June 30, 2018, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the results of our operations. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholders, is an adverse party or has a material interest adverse to our interest.

Reduction in Force

On April 5, 2018, the Company did a reduction of the workforce based on the changing needs of the Company. The Company reduced its workforce by 30 employees and recorded the expense on that date for the severance payouts of approximately \$575,000 that were due to all employees that were impacted.

Subsidiaries of the Registrant

Name of Entity	Jurisdiction of Incorporation	Holder of Stock
AntriaBio Delaware, Inc.	United States	Rezolute, Inc.

CERTIFICATION⁽¹⁾

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), Nevan Elam, Chief Executive Officer of Rezolute, Inc. (the “Company”), hereby certifies that, to the best of his knowledge:

1. The Company’s annual report on Form 10-K for the fiscal year ended June 30, 2018, to which this Certification is attached as Exhibit 32.1 (the “Periodic 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 Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In witness whereof, the undersigned have set their hands hereto as of the 15th of October 2018.

/s/ Nevan Elam

Nevan Elam
Chief Executive Officer

- (1) This certification accompanies the annual report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Rezolute, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Rezolute, Inc. and will be retained by Rezolute, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.
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CERTIFICATION⁽¹⁾

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), Keith Vendola, Chief Financial Officer of Rezolute, Inc. (the “Company”), hereby certifies that, to the best of his knowledge:

1. The Company’s annual report on Form 10-K for the fiscal year ended June 30, 2018, to which this Certification is attached as Exhibit 32.2 (the “Periodic 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 Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In witness whereof, the undersigned have set their hands hereto as of the 15th of October 2018.

/s/ Keith Vendola

Keith Vendola
Chief Financial Officer

- (1) This certification accompanies the annual report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Rezolute, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Rezolute, Inc. and will be retained by Rezolute, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.
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