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

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2023

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

For the Transition Period from to

Commission File Number **001-39683**

REZOLUTE, INC.

(Exact Name of Company as Specified in its Charter)

Nevada	**27-3440894**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
275 Shoreline Drive, Suite 500 **Redwood City, California**	**94065**
(Address of principal executive offices)	(Zip Code)
Registrant's telephone number, including area code:	**(650) 206-4507**

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

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

Securities registered pursuant to Section 12(g) of the Act: **None**

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 Company was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☑	Smaller reporting company ☑
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of December 31, 2022, the last business day of the registrants most recently completed second fiscal quarter, the aggregate market value of the registrant's voting stock held by non-affiliates, was approximately $63,584,000, based on the last reported sales price of $2.07 as quoted on the Nasdaq Capital Market on such date.

The registrant had 36,827,567 shares of its $0.001 par value common stock outstanding as of September 8, 2023.

DOCUMENTS INCORPORATED BY REFERENCE

None

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended June 30, 2023 ("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:

- Expectations regarding clinical development and the timing of clinical trials in the United States and outside of the United States;
- projected operating or financial results, including anticipated cash flows to be used in operating activities;
- expectations regarding capital expenditures, research and development expense and other payments;
- our beliefs and assumptions relating to our liquidity position, including our ability to obtain additional financing;
- our ability to obtain regulatory approvals for clinical trials and our drug candidates; and
- our future dependence on third party manufacturers or strategic partners to manufacture any of our pharmaceutical drugs and diagnostics that receive regulatory approval, and our ability to identify strategic partners and enter into license, co-development, collaboration or similar arrangements.

Any or all of our forward-looking statements may turn out to be wrong. They can be affected by inaccurate assumptions or by known or unknown risks, uncertainties and other factors including, but not limited to, the risks described in "*Risk Factors*" in Part I, Item 1A of this Annual Report.

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, the accuracy of our forward-looking statements cannot 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 business developing therapies for metabolic diseases related to chronic glucose imbalance.

Summary of Clinical Assets

RZ358

Our lead clinical asset, RZ358, is a potential treatment for congenital hyperinsulinism ("HI"), an ultra-rare pediatric genetic disorder characterized by excessive production of insulin by the pancreas. If untreated, the elevated insulin levels in patients suffering with congenital HI can induce extreme hypoglycemia (low blood sugar) events, increasing the risk of neurological and developmental complications, including persistent feeding problems, learning disabilities, recurrent seizures, brain damage or even death. There are no FDA approved therapies for all forms of congenital HI and the current standard of care treatments are suboptimal. The current treatments used by physicians include glucagon, diazoxide, somatostatin analogues and pancreatectomy.

RZ358 is an intravenously administered human monoclonal antibody that binds to a unique site (allosteric) on the insulin receptor in insulin target tissues, such as in the liver, fat, and muscle. The antibody down modulates insulin's binding, signaling, and action to maintain glucose levels in a normal range thereby counteracting the effects of elevated insulin in the body. RZ358 shows dose dependent pharmacokinetics with a half- life greater than two weeks which has the potential for twice or even once monthly dosing. Therefore, we believe that RZ358 is ideally suited as a potential therapy for conditions characterized by excessive insulin levels, and it is being developed to treat hyperinsulinism and low blood sugar. As RZ358 acts downstream from the beta cells, it has the potential to be universally effective at treating congenital HI caused by any of the underlying genetic defects.

In the fourth quarter of 2023, we plan to initiate a pivotal Phase 3 clinical study of RZ358 for the treatment of hypoglycemia in participants with congenital HI (the "sunRIZE" study) outside of the U.S. The sunRIZE study is a randomized, double-blind, placebo-controlled, parallel arm evaluation of RZ358 in participants with congenital HI who are not adequately responding to standard of care medical therapies. Topline results from the study are anticipated to be available in the first half of 2025. The Phase 3 study follows the Company's multinational Phase 2b study ("RIZE") conducted in participants 2 years of age and older who were failing medical therapies. The RIZE study demonstrated that RZ358 was generally safe and well-tolerated, as well as highly effective in improving hypoglycemia.

We have concluded our pre-Phase 3 regulatory and scientific advice meetings with Regulatory Authorities outside of the U.S. and have reached agreement on the design of the Phase 3 study that will include participants 3 months of age and older. In the U.S., we had similar interactions with the U.S. Food and Drug Administration ("FDA") culminating in a meeting held with the agency on May 24, 2023 (as confirmed by meeting minutes received from FDA on June 22, 2023), and FDA has maintained an existing age restriction of 12 years of age and older on RZ358 clinical studies, and imposed dose level restrictions based on historical rat toxicology findings. We believe that the FDA restrictions make it infeasible to include the U.S. in the Phase 3 study at this time, since that the pediatric population with congenital HI has the greatest therapeutic need. We are pursuing some additional nonclinical studies that may potentially address FDA's concerns, in parallel with the initiation and advancement of the Phase 3 study outside of the U.S. Please see *Management's Discussion and Analysis of Financial Condition and Results of Operation's* on this Form 10-K for more information on our plans.

The sunRIZE study will evaluate the safety and efficacy of RZ358 in participants with congenital HI who are unable to achieve control of low blood sugars (<70 mg/dL) with available medical therapies ("hypoglycemia"). The study will determine the ability of RZ358 to correct hypoglycemia as assessed by (i) hypoglycemia events using self-monitored blood glucose ("SMBG") and (ii) time in hypoglycemia using continuous glucose monitoring ("CGM") over 24 weeks of treatment.

The study will also measure the levels of RZ358 and its effects on other important blood and clinical markers of hypoglycemia, as well as quality of life measures. The primary and key secondary efficacy endpoints are the following:

Primary efficacy endpoint:

- Change in average weekly occurrence of hypoglycemia events as measured by SMBG after 24 weeks

Key secondary efficacy endpoint:

- Change in average daily percent time in hypoglycemia as measured by CGM after 24 weeks

Approximately 56 participants between 3 months and 45 years of age are intended to be enrolled. Participants between 1 and 45 years of age (approximately 48 participants) will be enrolled in a randomized, double-blind, placebo-controlled fashion to receive RZ358 or placebo at dose levels of 5 or 10 mg/kg while on standard of care. Infant participants between 3 months and 1 year of age (approximately 8 participants) will be enrolled in open label fashion to receive RZ358 at a starting dose level of 5 mg/kg, which may be increased to 10 mg/kg at the discretion of the investigator. Participants will receive RZ358 as an intravenous infusion every 2 weeks over an initial 4-week loading period (3 doses), followed by monthly doses over an additional 16-week maintenance period (4 doses), for a total of 7 doses over the total 24-week treatment period. Following the study period, participants may proceed into an open-label extension program where investigators shall be permitted to: (i) adjust the dose between 5 and 10 mg/kg; (ii) adjust the dosing frequency between 2 and 4 weeks; and (iii) wean or stop other background hypoglycemia therapies.

In summary, the study will be comprised of the following treatment groups:

- Participants ≥1 year old: 5 mg/kg (n = 16)
- Participants ≥1 year old: 10 mg/kg (n = 16)
- Participants ≥1 year old: placebo (n = 16)
- Infant Participants: starting at 5 mg/kg (n = 8)

RZ402

Our second clinical asset, RZ402, is an oral plasma kallikrein inhibitor ("PKI") being developed as a potential therapy for the chronic treatment of diabetic macular edema ("DME"). DME is a vascular complication of diabetes and a leading cause of blindness in the U.S. and elsewhere. Chronic exposure to high blood sugar levels can lead to inflammation, cell damage, and the breakdown of blood vessel walls. Specifically, in DME, retinal blood vessels at the back of the eye become porous and permeable leading to the unwanted infiltration of fluid into the macula. This fluid leakage creates distorted vision, and if left untreated, blindness.

Currently available treatments for DME include anti-vascular growth factor (anti-VEGF) injections into the eye or laser surgery. RZ402 is designed to be a once daily oral therapy for the treatment of DME and unlike the anti-VEGF therapies, RZ402 targets the Kallikrein-Kinin System to address inflammation and vascular leakage. We believe that systemic exposure through oral delivery is critical to target the retinal microvasculature at the back of the eye. Further, as an oral therapy, RZ402 has the potential to substantially change the therapeutic paradigm for patients suffering with DME by providing a convenient, self-administered treatment option to encourage earlier initiation of therapy, adherence to prescribed treatment guidelines, and improved overall outcomes.

In December 2022, we initiated a Phase 2 multi-center, randomized, double-masked, placebo-controlled, parallel-arm study to evaluate the safety, efficacy, and pharmacokinetics of RZ402 administered as a monotherapy over a 12-week treatment period in participants with DME who are naïve to, or have received limited anti-VEGF injections. The study population is comprised of DME patients with mild to moderate non-proliferative diabetic retinopathy. Eligible participants are being randomized equally, to one of three RZ402 active treatment arms at doses of 50, 200, and 400 mg, or a placebo control arm, to receive study drug once daily for 12 weeks, before completing a four-week follow-up. The study is expected to enroll up to approximately 100 patients overall, across approximately 25 investigational sites in the United States. The principal endpoints of the trial include (i) changes in central subfield thickness of the macula, as measured by Spectral Domain Ocular Coherence Tomography, (ii) changes in visual acuity as measured by the early treatment diabetic retinopathy scale, (iii) the repeat dose pharmacokinetics of RZ402 in patients with DME, and (iv) the safety and tolerability of RZ402. We expect to announce topline results from the study in the first quarter of calendar year 2024.

Intellectual Property

Our success depends on an intellectual property portfolio that supports our future revenue streams and also erects barriers to our competitors. We are maintaining and building our patent portfolio through filing new patent applications; prosecuting existing applications; and licensing patents and patent applications. Furthermore we seek to protect our ownership of know-how, trade secrets and trademarks through an active program of legal mechanisms including registrations, assignments, confidentiality agreements, material transfer agreements, research collaborations and licenses. While we have confidence in our agreements and security measures, either may be compromised, and we may not have adequate remedies. In addition, our trade secrets may otherwise become known or independently discovered by competitors.

U.S. patents, as well as most foreign patents, are generally effective for 20 years from the date the earliest application was filed. U.S. patents that were issued on applications filed before June 8, 1995, may be effective until 17 years from the issue date, if that is later than the 20-year date. In some cases, the patent term may be extended to recapture a portion of the term lost during regulatory review of the claimed therapeutic or, in the case of the U.S., because of U.S. Patent and Trademark Office (USPTO) delays in prosecuting the application. In the U.S., under the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), a patent that covers a drug approved by the FDA may be eligible for patent term extension (for up to five years, but not beyond a total of 14 years from the date of product approval) as compensation for patent term lost during the FDA regulatory review process. The duration and extension of the term of foreign patents varies in accordance with local law. In the EU, Supplementary Protection Certificates, or SPCs, are available to extend a patent term up to five years to compensate for patent protection lost during regulatory review. Although all EU Member States must provide SPCs, SPCs must be applied for and granted on a country-by-country basis. Limited exceptions apply to the protection conferred by the SPC.

As further described in the "XOMA License Agreement" section below, we hold a worldwide, exclusive license from XOMA to patents covering the RZ358 molecule, including 37 issued patents worldwide and in the U.S. (3 U.S.) and pending patent applications with claims directed to compositions of matter and methods of use in therapy. These patents expire between 2030 to 2036. We also are pursuing patent applications relating to formulations of the clinical product candidate. In addition, for certain of our product candidates we also expect to have further exclusivity in the form of data and marketing exclusivity under pharmaceutical regulatory laws, including for example, potentially up to 12 years of exclusivity from the date of first BLA approval of our product candidates.

We also hold a worldwide, exclusive license from ActiveSite to patents covering the RZ402 molecule, certain prodrug forms of RZ402, and uses (as further described in the "ActiveSite License Agreement" section below), including 9 issued international patents and 7 issued U.S. patents. We have additional patents (2 U.S.) and pending patent applications (3 U.S. and 29 international) with claims directed to formulations, solid forms of RZ402, methods of preparing RZ402, and methods of use in therapy. These patents are expected to expire between 2040 and 2043. We also expect to be granted further exclusivity in the form of data and marketing exclusivity under pharmaceutical regulatory laws in various jurisdictions.

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 other companies developing therapies for HI that are potential competitors to RZ358, including, Eiger Biopharmaceuticals, Hanmi Pharmaceuticals, and Zealand Pharma.

There are also companies developing therapies for DME that are potential competitors to our PKI including Curacle, KalVista, Ocuphire Pharma, Oxurion and Verseon.

Government Regulation

Regulation by governmental authorities in the U.S. 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 (as defined below) 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.

In addition, we are 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 $43.8 million and $32.5 million in research and development expenses for the fiscal years ended June 30, 2023 and 2022, respectively. For further discussion of activities related to our RZ358 and RZ402 product candidates, please refer to the discussion above. For further discussion of our research and development expenses, please refer to the discussion under the caption *Results of Operations* under Item 7 of this Annual Report.

Human Capital Management

Employees

As of June 30, 2023, we had 51 full time employees, of which 38 employees were engaged in research and development, manufacturing, clinical operations, regulatory and quality activities and 13 employees were engaged in administrative functions. Of the 51 employees, all were located in the United States. We have a number of employees who hold Ph.D. degrees and other advanced degrees. None of our employees are covered by a collective bargaining agreement, and we have experienced no work stoppages nor are we aware of any employment circumstances that are likely to disrupt work at any of our facilities. As part of our measures to attract and retain personnel, we provide a number of benefits to our full-time employees, including health insurance, life insurance, retirement plans, paid holiday and vacation time. In addition, we grant stock options to certain key employees as added incentive to remain in our employment. We believe that we maintain good relations with our employees.

Diversity and Inclusion

Diversity and inclusion are priorities for us. We believe that a rich culture of inclusion and diversity enables us to create, develop and fully leverage the strengths of our workforce. In furtherance of our commitment to inclusion and diversity, on May 30, 2023 we adopted an equity and inclusion policy.

Human Resources, Hiring and Professional Development

The development, attraction and retention of employees is critical to our success. We work diligently to attract the best talent from a diverse range of sources in order to meet the current and future demands of our business. We leverage both formal and informal programs to identify, foster and retain top talent.

Business Ethics

Our Code of Business Conduct and Ethics is designed to ensure that the conduct of our business is consistent with the highest standards of business ethics. Our Code of Business Conduct and Ethics serves as a critical tool to help employees recognize and report unethical conduct, while preserving our culture of excellence. Our Board of Directors, management and staff are provided with training regarding our Code of Business Conduct and Ethics. On May 30, 2023, we adopted an amended and restated Code of Business Conduct and Ethics. The purpose of amending and restating the prior code was to improve its readability and clarify certain areas of importance, including with respect to compliance with laws, accounting and auditing matters, conflicts of interest, insider trading, confidentiality obligations and the reporting of violations of our Code of Business Conduct and Ethics.

Corporate Information

We were incorporated in Delaware in 2010 and we re-incorporated in Nevada in June 2021. We maintain an executive office located at 275 Shoreline Drive, Suite 500, Redwood City, CA 94065 and our phone number is (650) 206-4507. Our website is located at www.rezolutebio.com. We file annual, quarterly, current reports, proxy statements and other information with the Securities and Exchange Commission ("SEC"). The SEC maintains a website that contains our public filings and other information regarding the Company, at www.sec.gov. 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 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 Product Development and Commercialization

Any delays in the commencement or completion, or termination or suspension, of our future clinical trials, if any, could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining approval from the government authorities or professional bodies with authority to grant regulatory approval for our drug candidates in a particular country, such as the European Medicines Agency ("EMA"), the Food and Drug Administration of the U.S. Department of Health and Human Services ("FDA") and analogous authorities in other jurisdictions outside of the United States ("Regulatory Authorities"), we must conduct extensive clinical studies to demonstrate safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. Any delays in the commencement or completion of our ongoing, planned or future clinical trials could significantly increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. We do not know whether our planned trials will begin on time or at all, or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- Regulatory Authorities disagreeing as to the design or implementation of our clinical trials or with our recommended dose for any of our pipeline programs;
- obtaining Regulatory Authority authorization to commence a trial or reaching a consensus with such Regulatory Authorities on trial design;

- identifying and activating investigators and clinical trial sites to conduct trials;
- obtaining approval from one or more independent institutional review board ("IRB") or Ethics Committee ("EC") at each clinical trial site before each trial may be initiated;
- IRBs/ECs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- failing to manufacture or obtain sufficient quantities of drug candidate, or, if applicable, combination therapies for use in clinical trials;
- patients failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- patients choosing an alternative treatment, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- patients experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selecting or being required to use clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our drug candidates, or any of their components, including without limitation, our own facilities being ordered by Regulatory Authorities to temporarily or permanently shut down due to violations of current good manufacture practices, regulations or other applicable requirements, or infections or cross-contaminations in the manufacturing process;
- lack of stability of our clinical trial material or any quality issues that arise with the clinical trial material;
- any changes to our manufacturing process that may be necessary or desired;
- our, or our third-party contractors, not performing data collection or analysis in a timely or accurate manner or improperly disclosing data prematurely or otherwise in violation of a clinical trial protocol;
- any third-party contractors becoming debarred or suspended or otherwise penalized by Regulatory Authorities or other government or regulatory bodies for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications;
- a clinical trial being suspended or terminated by us, by the IRBs/ECs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by Regulatory Authorities, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by Regulatory Authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the product under investigation, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial; or
- changes in regulatory requirements and policies and our need to amend clinical trial protocols to comply with these changes and potentially resubmit our clinical trial protocols to IRBs/ECs for reexamination.

Delays in initiating a new phase of clinical trials resulting from action by FDA or any other Regulatory Authority would delay the approval obtainment and commercialization of our product candidates and our ability to generate revenue, which would have an adverse effect on our business. For example, as discussed in the *Management's Discussion and Analysis of Financial Condition and Results of Operations* section of this Annual Report on Form 10-K, the FDA has re-imposed a human drug exposure limit equating to repeat doses of approximately 3 mg/kg per week, a limit which was previously removed during the RIZE study (the "New Restrictions"). As is customary in pediatric drug development, there is a progression of the inclusion of younger participants as a program advances through different stages and continues to demonstrate a good safety profile and a prospect of benefit for children based on previous stages; and the Company's progression to include younger participants is dampened by the imposition of the New Restrictions by the FDA. The Company and FDA have discussed potential solutions that could enable removal of the New Restrictions and as a result, the Company is pursuing some additional nonclinical studies to potentially address FDA's concerns, in parallel with the initiation and advancement of the Phase 3 ("sunRIZE") study outside of the U.S. It is possible that the Company may not satisfy FDA's nonclinical concerns, which will cause further delays and negatively impact the Company's development plans for congenital hyperinsulinism ("HI") in the U.S.

The clinical hold in the U.S. on RZ358 may impact our development plans and may impact our ability to access the capital markets.

Our most advanced product candidate, RZ358, is currently under clinical hold in the U.S. It may take considerable time and expense to respond to the New Restrictions that have been placed on RZ358 by the FDA, and no assurance can be given that the FDA will remove the New Restrictions or that we will receive FDA approval for RZ358, in which case our business and prospects will likely suffer material adverse consequences.

In May 2023, based on historical rat toxicology found during an early RZ358 development program, the FDA affirmed its decision to impose the New Restrictions after the Company completed its multinational Phase 2b RIZE study conducted in participants 2 years of age and older, which consisted of the age restriction of 12 years and above for U.S. patients, and to re-impose impose a human drug exposure limit equating to repeat doses of approximately 3 mg/kg per week, a limit which was previously removed during the RIZE study. The New Restrictions delay the Company's progression to include younger participants and consequentially delay the sunRIZE study in the U.S.

A clinical hold for RZ358 and sunRIZE continues to be in place in the U.S., and we do not know whether or when the clinical hold for the development of RZ358 will be lifted. However, we currently expect to commence the sunRIZE study outside of the U.S. as we have concluded our pre-sunRIZE regulatory and scientific advice meetings with Regulatory Authorities outside of the U.S. and have reached agreements on the design of the sunRIZE study that will include participants 3 months of age and older. Positive or promising results from clinical trials of RZ358 conducted in jurisdictions outside of the U.S. may not be predictive of similar results, or may not be replicated, in clinical trials within the U.S. Accordingly, even if we continue to observe the lack of adverse liver findings in the sunRIZE study outside of the U.S., it is not guaranteed that the FDA will accept such findings and lift the New Restrictions which could impact our development plans or ability to file for approval or market RZ358 in the U.S.

It may take a considerable period of time, the length of which is not certain at this time, and expense for us to fully address FDA's concerns, if at all. Even if we are able to fully respond to the FDA's questions, the FDA may subsequently make additional requests that we would need to fulfill prior to the lifting of the New Restrictions. It is possible that we will be unable to fully address the FDA's concerns and as a result the New Restrictions may never be lifted, and we may never be able to begin the sunRIZE study or complete our clinical trials of RZ358 in the U.S. Many of the factors that cause, or lead to, a delay in the commencement or completion of the sunRIZE study may also ultimately lead to the denial of regulatory approval from the FDA for RZ358. If we don't receive regulatory approval from the FDA for RZ358 our ability to raise capital and the terms of such raise could be impacted.

If we are unable to commercialize RZ358, need to limit the scope of our RZ358 program, or experience significant delays in development, our business, results of operations, financial condition, and our prospects will be adversely affected.

Results of preclinical testing or earlier clinical studies or approval from a Regulatory Authority for the next phase of clinical trials 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 our clinical studies produce promising results or a Regulatory Authority provided approval for the next phase of clinical trials, there is no assurance that such results will be replicated or exceeded in later clinical studies. A number of companies in the biotechnology 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 our clinical studies will demonstrate adequate efficacy and safety to justify the continuing advancement of a program. If later stage clinical studies, such as the sunRIZE study to be conducted outside of the U.S., do not produce favorable results, our ability to achieve regulatory approval for 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 or other Regulatory Authority approval for our product candidates.

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 IRB/EC, 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 are exposed to additional risks as we conduct the sunRIZE study outside of the U.S. and may not be successful in meeting the study's primary endpoint.

We are initiating and advancing the sunRIZE study outside of the U.S. The sunRIZE study may not produce positive results and meet its primary endpoint outside of the U.S. We may need to commence and complete additional clinical trials that satisfy the specified primary endpoint criteria in order to obtain necessary regulatory approvals from the EMA for RZ358. It is possible that we may not observe the lack of adverse liver findings in the sunRIZE study outside of the U.S., which could potentially impact the FDA's decision regarding the New Restrictions. Conducting clinical trials outside the U.S. also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- potential political or economic instability in the jurisdictions where we initiate clinical trials;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

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 Authorities have reviewed and approved the applications for such product candidates. We cannot assure that the Regulatory Authorities 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 Regulatory Authority policy during the period of product development, clinical studies and regulatory review.

Even if U.S. 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-approval 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-approval requirement. Even if the FDA or a foreign Regulatory Authority 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 Regulatory Authorities also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including substantial monetary penalties and withdrawal of product approval.

If we or a Regulatory Authority 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 Authority 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 Authority 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 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 the 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 Authorities 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 Authority 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 U.S., 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 U.S. 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, one or more IRBs/ECs at clinical trial sites, a Data Safety Monitoring Board or the FDA or other Regulatory Authority to terminate a clinical study or require that we repeat it or conduct additional 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 Authorities 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.

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 aspects of our 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.

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. In addition, third-party suppliers that we engage may be adversely impacted by COVID-19.

It is possible that our raw material suppliers may not be able to sell these raw materials at the times we need them or on commercially reasonable terms due to forces outside of our control including, but not limited to, inflation and global conflicts. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Our third-party manufacturers and suppliers may encounter delays in providing their services as a result of supply chain constraints. 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.

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.

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.

Risks Related to Our Business

We could be negatively impacted and unable to raise capital on favorable terms or generate revenue if we are not successful with the sunRIZE study outside of the U.S. and if the FDA does not lift the New Restrictions on RZ358.

RZ358 is our lead clinical asset. We have expended considerable resources and efforts on the development of RZ358. As we continue to pursue the development of RZ358, there is no guarantee that we will be able to successfully complete clinical trials for RZ358 outside of the U.S. or that the FDA will lift the New Restrictions imposed on RZ358 within the U.S. If we do not receive positive results from the sunRIZE study outside of the U.S. or if the FDA continues to impose the New Restrictions by such time, our ability to raise additional capital, if at all, on favorable terms may be impeded by our inability to advance the development of our product candidates.

Changes in financial accounting standards or policies have affected, and in the future may affect, our reported financial condition or results of operations; there are inherent limitations to our system of internal controls; changes in corporate governance policies and practices may impact our business.

We prepare our consolidated financial statements in conformity with GAAP. The preparation of our financial statements in accordance with GAAP requires that we make estimates and assumptions that affect the recorded amounts of assets, liabilities and net income during the reporting period. A change in the facts and circumstances surrounding those estimates could result in a change to our estimates and could impact our future operating results. GAAP is subject to interpretation by the Financial Accounting Standards Board (“FASB”), the SEC and various bodies formed to interpret and create accounting policies. A change in those policies can have a significant effect on our reported results and may affect our reporting of transactions which are completed before a change is announced. In general, changes to accounting rules or challenges to our interpretation or application of the rules by regulators may have a material adverse effect on our reported financial results or on the way we conduct business.

Our system of internal and disclosure controls and procedures was designed to provide reasonable assurance of achieving its objectives. However, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been or will be detected. As a result, there can be no assurance that our system of internal and disclosure controls and procedures will be successful in preventing all errors, theft and fraud, or in informing management of all material information in a timely manner.

Finally, corporate governance, public disclosure and compliance practices continue to evolve based upon continuing legislative action, SEC rulemaking and policy positions taken by large institutional stockholders and proxy advisors. As a result, the number of rules, regulations and standards applicable to us may become more burdensome to comply with, could increase scrutiny of our practices and policies by these or other groups and increase our legal and financial compliance costs and the amount of time management must devote to governance and compliance activities. For example, the SEC has recently proposed rules requiring that issuers provide significantly increased disclosures concerning cybersecurity matters and the impact of climate changes on their business and has adopted rules requiring public companies to adopt more stringent executive compensation clawback policies. Increasing regulatory burdens and corporate governance requirements could also make it more difficult for us to attract and retain qualified members of our Board of Directors and qualified executive officers.

We have a history of losses and may not achieve profitability in the future. We will need substantial additional capital to fund our operations. If we fail to obtain additional capital, we will be unable to sustain operations.

We incurred net losses of $51.2 million and $41.1 million for the fiscal years ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $261.0 million. Cash used in our operating activities amounted to $44.5 million and $39.6 million for the fiscal years ended June 30, 2023 and 2022, respectively. We expect that the amount of cash used in our operating activities will continue to increase for the next several years. As of June 30, 2023, we had cash and cash equivalents of $16.0 million and investments in marketable debt securities of $102.3 million that is expected to provide us with adequate capital resources to fund planned activities at least through the third quarter of calendar year 2025.

Since our inception, we have not generated meaningful revenue. We expect to continue to incur operating losses for the foreseeable future as we develop and commercialize our product candidate pipeline, and we expect to need additional capital from external sources before we will be able to begin generating revenue, if ever. If we are unable to raise additional capital, we may have to significantly delay, scale back or discontinue one or more of our 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 on terms that are less favorable than might otherwise be available. If we are unable to secure additional capital, we may be required to 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 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 for our 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.

We may not be able to use a significant portion of our net operating loss carryforwards, which could adversely affect our profitability.

Federal and state laws impose substantial restrictions on the utilization of net operating loss ("NOL") carryforwards in the event that certain ownership changes occur as defined in Section 382 of the Internal Revenue Code ("IRC"). Due to our financing activities, we experienced ownership changes that have resulted in significant limitations on the future use of our NOL carryforwards. As of June 30, 2023, we have US federal NOL carryforwards of approximately $153.2 million, of which $33.4 million will expire without any opportunity for utilization due to the limitations set forth in IRC Section 382. Assuming that further IRC Section 382 ownership changes do not occur, the remaining $119.8 million of NOL carryforwards consist of approximately (i) $17.1 million that never expire and are currently available to offset taxable income, (ii) $7.9 million that are currently available to offset taxable income but if not utilized will expire in 2031 through 2035, (iii) $13.4 million that becomes available through 2038 and that expire by June 30, 2038 if not utilized, and (iv) $81.4 million that never expire. With respect to $81.4 million of NOL carryforwards that never expire, this amount will become available in varying annual amounts for an aggregate of approximately $15.6 million through fiscal year 2038, and $1.2 million annually thereafter. It is possible that any future ownership changes could result in further limitations on the use of our NOL carryforwards or other tax attributes, which could adversely affect our future financial position, profitability and cash flows.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 ("Section 404"), and the related rules of the SEC which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. Effective April 27, 2020, the SEC adopted amendments to the "accelerated filer" and "large accelerated filer" definitions in Rule 12b-2 under the Securities and Exchange Act of 1934. The amendments exclude from the "accelerated filer" and "large accelerated filer" definitions an issuer that is eligible to be a smaller reporting company and that had annual revenues of less than $100 million in the most recent fiscal year for which audited financial statements are available. We determined that our Company does not meet the accelerated or large accelerated filer definitions as of June 30, 2023. For so long as we remain a smaller reporting company and a non-accelerated filer, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies, including, but not limited to, not being required as a non-accelerated filer to comply with the auditor attestation requirements of Section 404(b). An independent assessment by our independent registered public accounting firm of the effectiveness of internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Although we have determined that our internal control over financial reporting was effective as of June 30, 2023, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

We intend to seek regulatory approval in foreign countries for all of our potential products prior to commercialization. Pharmaceutical therapies are subject to rigorous preclinical testing and clinical trials and other pre-market approval requirements by Regulatory Authorities in foreign countries. 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.

We could recognize losses on securities held in our securities portfolio, particularly if interest rates increase or economic and market conditions deteriorate.

As of June 30, 2023, the fair value of the investments in our marketable debt securities portfolio was approximately $102.3 million. Factors beyond our control can significantly influence the fair value of securities in our portfolio and can cause potential adverse changes to the fair value of these securities. For example, fixed-rate securities acquired by us are generally subject to decreases in market value when interest rates rise. Additional factors include, but are not limited to, rating agency downgrades of the securities or our own analysis of the value of the security, defaults by the issuer with respect to the underlying securities, and continued instability in the credit markets. Any of the foregoing factors could cause other-than-temporary impairment in future periods and result in realized losses. The process for determining whether impairment is other-than-temporary usually requires difficult, subjective judgments about the future financial performance of the issuer and any collateral underlying the security in order to assess the probability of receiving all contractual principal and interest payments on the security.

As of June 30, 2023, we had $351,000 in net unrealized losses in our marketable debt securities. Unrealized losses in our marketable debt securities portfolio may increase in the future due to the aforementioned economic factors. While our goal is to hold each security until maturity, that may not be possible in light of our policy to preserve capital and liquidity and because investment in securities with unrealized losses has a diminished utility as a source of liquidity prior to maturity. Selling securities with an unrealized loss would result in the realization of such losses, which could have an adverse effect on our financial condition and results of operations.

The collapse of certain banks and potentially other financial institutions may adversely impact us.

On March 10, 2023, Silicon Valley Bank (“SVB”) was shut down, followed on March 11, 2023 by Signature Bank and on May 1, 2023 by First Republic Bank whereby, the Federal Deposit Insurance Corporation was appointed as receiver for each of those banks. As a result, there have been reports of instability at other banks across the globe. Despite the steps taken to date by U.S. agencies to protect depositors, the follow-on effects of the events surrounding the failures of SVB, Signature Bank, and First Republic Bank and the pressure on other banks are unknown. Such effects could include failures of other financial institutions to which we face direct or more significant exposure, and the extent of the impacts relating to financial institution instability or failure is uncertain. Our investment portfolio did not and currently does not contain any securities of SVB, and we did not have any deposit accounts with SVB. We are monitoring the situation and intend to minimize any disruptions to our operations should they arise. However, there may be risks that we have not yet identified, and we cannot guarantee that we will be able to avoid negative consequences directly or indirectly from the foregoing events or other impacts on financial institutions.

Unfavorable global and regional economic, political and health conditions could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by global or regional economic, political and health conditions. Various macroeconomic factors could adversely affect our business, financial condition and results of operations, including changes in inflation, interest rates and overall economic conditions and uncertainties, including those resulting from political instability, trade disputes between nations and the current and future conditions in the global financial markets. For example, beginning in fiscal year ended June 30, 2023, much of the world, including the U.S. and the E.U., began to experience inflation levels not seen in more than 30 years. As a result, prices for many of our inputs have risen, in some cases dramatically. If inflation stays at elevated levels or increases, we may not be able to mitigate the impact of the increased costs we will bear, which could have an impact on our results of operations and financial condition. A global financial crisis or global or regional political and economic instability, wars, terrorism, civil unrest, outbreaks of disease (for example, COVID-19), and other unexpected events, such as supply chain constraints or disruptions, could cause extreme volatility in the capital and credit markets and disrupt our business. Business disruptions could include, among others, disruptions to our commercial activities, including due to supply chain or distribution constraints or challenges, clinical enrollment, clinical site availability, patient accessibility, and conduct of our clinical trials, as well as temporary closures of the facilities of suppliers or contract manufacturers in the biotechnology supply chain. In addition, during certain crises and events, patients may prioritize other items over certain or all of their treatments and/or medications, which could have a negative impact on our commercial sales. A severe or prolonged economic downturn, political disruption or adverse health conditions could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

Certain Provisions of Nevada law may have anti-takeover effects.

Certain provisions of Nevada law applicable to us could also delay or make more difficult a merger, tender offer or proxy contest involving us, including Sections 78.411 through 78.444 of the Nevada Revised Statutes, which prohibit a Nevada corporation from engaging in any business combination with any "interested shareholder" (as defined in the statute) for a period of two years unless certain conditions are met. In addition, our senior management is entitled to certain payments upon a change in control.

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 (i) a fully human monoclonal antibody from XOMA Corporation ("XOMA") as well as (ii) a plasma kallikrein inhibitor portfolio from ActiveSite Pharmaceuticals ("ActiveSite") and in consideration for such licenses, we will owe milestone payments and royalties as 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.

U.S. patent applications filed after November 29, 2000 are confidential in the U.S. 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 Annual 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, patent office administrative proceedings or patent interference proceedings may be necessarily brought against us or 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.

In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise under our agreements, and we may be limited in our ability to use, make or sell these inventions. Litigation may be necessary to resolve these disputes, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

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 U.S. 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 U.S., 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. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and patent scope can be reinterpreted by the courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any patents, if issued, will provide sufficient protection from competitors. 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, future sales and profits may never materialize 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 United States, 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 United States.

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.

Risks Related to Our Common Stock

Exercise or conversion of warrants, stock options and other convertible securities will dilute shareholder's percentage of ownership.

In addition to pre-funded warrants ("PFWs"), we have issued stock options and other warrants to purchase shares of our common stock. In the future, we may grant additional stock options, warrants and convertible securities. The exercise, conversion or exchange of stock options, warrants and convertible securities will dilute the percentage ownership of our shareholders. The dilutive effect of the exercise or conversion of these securities may adversely affect our ability to obtain additional capital. The holders of these securities may be expected to exercise or convert such stock options, warrants and convertible securities at a time when we would be able to obtain additional equity capital on terms more favorable than such securities or when our common stock is trading at a price higher than the exercise or conversion price of the securities.

Our common stock may be delisted from the Nasdaq Capital Market if we fail to comply with continued listing standards.

Our common stock is currently traded on Nasdaq under the symbol "RZLT". If we fail to meet any of the continued listing standards of Nasdaq, our common stock could be delisted from Nasdaq. The continued listing standards include specifically enumerated criteria, such as: $1.00 minimum closing bid price (the "Share Price Condition"); shareholders' equity of at least $2.5 million; 500,000 shares of publicly-held common stock with a market value of at least $1 million; 300 round-lot shareholders; and compliance with Nasdaq's corporate governance requirements, as well as additional or more stringent criteria that may be applied in the exercise of Nasdaq's discretionary authority.

In order to obtain the initial listing of our shares for trading on the Nasdaq Capital Market in November 2020, we effected a reverse stock split in the ratio of 50 shares for 1 share in order to comply with the Share Price Criteria. If the trading price for our shares decreases below $1.00 per share in the future, Nasdaq could delist our shares if the trading price does not subsequently increase above $1.00 per share during prescribed periods and under prescribed conditions set forth in Nasdaq's listing rules.

Our stock price may be volatile.

The market price of our common stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including (i) limited trading activity on our common stock, (ii) positive or negative results achieved in our clinical activities, including regulatory determinations, (iii) our ability to obtain financing, (iv) additions or departures of key personnel, (v) the specific terms associated with new debt or equity financings, (vi) our ability to execute our business plan, (vii) loss of any strategic relationship, and (viii) economic and other external factors.

In addition, the securities markets have from time-to-time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our shareholders sell substantial amounts of our common stock in the public market upon the expiration of any statutory holding period or lockup agreements, under Rule 144, or issued upon the exercise of outstanding PFWs, stock options, warrants or other convertible securities, it could create a circumstance commonly referred to as an "overhang" and in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, also could make more difficult our ability to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. The shares of our restricted common stock will be freely tradable upon the earlier of: (i) effectiveness of a registration statement covering such shares and (ii) the date on which such shares may be sold without registration pursuant to Rule 144 (or other applicable exemption) under the Securities Act of 1933, as amended ("Securities Act").

Investor relations activities and supply and demand factors may affect the price of our common stock.

We expect to utilize various techniques such as non-deal road shows and investor relations campaigns in order to generate investor awareness. These campaigns may include personal, video and telephone conferences with investors and prospective investors in which our business practices are described. We may provide compensation to investor relations firms and pay for newsletters, websites, mailings and email campaigns that are produced by third parties based upon publicly-available information concerning us. We do not intend to review or approve the content of such analysts' reports or other materials based upon analysts' own research or methods. Investor relations firms should generally disclose when they are compensated for their efforts, but whether such disclosure is made or complete is not under our control. In addition, investors may, from time to time, also take steps to encourage investor awareness through similar activities that may be undertaken at the expense of the investors. Investor awareness activities may also be suspended or discontinued which may impact the trading market of our common stock.

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

We have never paid cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock for the foreseeable future. Accordingly, any income derived from our common stock would only come from a rise in the market price of our common stock, which is uncertain and unpredictable. We cannot assure investors of a positive return on their investment.

Changes in U.S. tax law could adversely affect our business.

Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, for the fiscal year ended June 30, 2023, we became subject to Internal Revenue Code Section 174 that requires capitalization of the vast majority of research and development costs whereas under prior tax law substantially all of these costs were deductible in the year incurred. Section 174 provides that such newly-capitalized costs may be amortized and become deductible over a period of 5 years for U.S. based costs and 15 years for foreign- based costs.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws or regulations may be enacted under existing or new tax laws. This could result in an increase in our tax liability or require changes in our business in order to mitigate any adverse effects of changes in tax laws.

Item 1B. Unresolved Staff Comments.

Not required for smaller reporting companies.

Item 2. Properties.

In January 2019, we entered into a lease for our headquarters location at 201 Redwood Shores Parkway, Suite 315, Redwood City, CA 94065. The leased space consists of approximately 3,500 square feet of office space and provides for monthly rent of approximately $21,000 through the expiration date in March 2022. Subsequently, we extended this lease on a month-to-month basis through October 2022, when the lease for our new headquarters location commenced.

In April 2022, we entered into a lease for a new headquarters location at 275 Shoreline Drive, Suite 500, Redwood City CA 94065. The leased space contains approximately 9,300 square feet of office space. The lease commenced in October 2022 and provides for average remaining monthly rent of approximately $53,000 through October 2027.

In November 2020, we entered into a lease in Bend, Oregon where the leased space consists of approximately 5,000 square feet of office space and provides for monthly rent of approximately $8,400 through the expiration date in February 2024.

We believe our current physical properties are sufficient and adequate to meet our current and projected requirements.

Item 3. Legal Proceedings.

For a discussion of the Company's legal proceedings, see "Notes to Consolidated Financial Statements - Commitments and Contingencies" in Part II. Item 8 on this Annual Report on Form 10-K, which is incorporated herein by reference.

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

Since November 9, 2020, our common stock has traded on Nasdaq under the symbol "RZLT".

Holders

As of September 8, 2023, there were 274 holders of record of our common stock. We believe the number of beneficial owners of our common stock is substantially greater than the number of record holders because a large portion of our outstanding common stock is held of record in broker "street names" for the benefit of individual investors.

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 foreseeable future.

Recent Sales of Unregistered Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

Information regarding our equity compensation plans as of June 30, 2023 is disclosed in Item 12 "*Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*" of this Annual Report on Form 10-K.

Item 6. [Reserved]

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 contains 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 the Cautionary Statement Regarding Forward-Looking Statements on page ii, the "Risk Factors" set forth in Item 1A, 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 our consolidated financial statements and related notes included in Item 8 of this Annual Report.

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

Executive Summary

Clinical Development

Our key objectives in the fourth quarter of 2023 are completing enrollment for the RZ402 Phase 2 study in DME to enable announcement of topline results in the first quarter of 2024, as well as initiation of the sunRIZE Phase 3 study for RZ358.

RZ358 Regulatory Status

As discussed in our disclosures on Current Reports on Form 8-K filed with the SEC, toxicology studies in rats and monkeys were conducted as part of the early RZ358 development program and in these studies, rats demonstrated a microvascular liver injury at potentially clinically relevant doses and exposures ("rat findings"). However, there were no adverse liver findings in monkeys at dose levels that were more than 10 times higher than doses that were toxic in rats, and more than 4 times higher than human doses evaluated in clinical studies. Based on the absence of liver toxicity in monkeys and the lack of adverse liver findings in closely monitored human trials, the Company believes that the toxicity is unique to rats and unlikely relevant to humans.

As is customary in pediatric drug development, there is a progression of the inclusion of younger participants as a program advances through different stages and continues to demonstrate a good safety profile and a prospect of benefit for children based on previous stages. After the completion of Phase 1 adult healthy volunteer studies for RZ358, Phase 2a single-dose proof of concept studies ("Phase 2a") were conducted in participants with congenital HI who were 12 years of age and older in countries governed by the Regulatory Authorities in the European Union and elsewhere in Europe. In the US, FDA restricted enrollment in Phase 2a to participants 18 years of age and older and, based on the rat findings, imposed a human drug exposure limit equating to repeat doses of approximately 3 mg/kg per week ("exposure cap").

Subsequently, in the RIZE study European Authorities and other regulatory bodies continued the expected downward age progression, lowering the age for study participants down from 12 years of age to 2 years of age and older. At the start of the RIZE study the clinical program in the US remained under the 18 years of age and older restriction as well as the exposure cap. However, in the first half of 2020, while the RIZE study was underway, we reached agreement with FDA to proceed with the RIZE study in the US at all dose levels (no exposure cap) and in younger participants (ages 12 and older). Following these developments, the study protocol was harmonized globally, other than a regional difference in the minimum permitted age (12 years and older in the US versus 2 years and older in all other geographies).

After the completion of the RIZE study, in the second half of 2022 and the first half of 2023, the Company conducted scientific advice meetings with the Regulatory Authorities in Europe which resulted in alignment with our proposed Phase 3 program including overall study design, dosing regimen, endpoints, sample size and patient population. Notably, with all available nonclinical (including the rat findings) and clinical information under review, European Authorities aligned with a further downward age progression whereby participants 3 months of age and older will be permitted to be enrolled in the Phase 3 study.

Prior to engaging FDA on Phase 3 planning in the US, we began interacting with the agency in the second half of 2022 to further liberalize the age restriction to achieve alignment with the parameters established by the European Authorities in the RIZE study. Over the course of these post-RIZE regulatory interactions with FDA, the agency revisited prior concerns regarding the rat findings and, despite the absence of new clinical or nonclinical data (other than the RIZE data), the agency decided to maintain the age restriction of 12 years and above and re-imposed the previous exposure cap which had been removed during the RIZE study (collectively, "New Restrictions"). In the second half of 2022 and the first half of 2023, we interacted with FDA to resolve the New Restrictions, particularly in the context of the advancement of the clinical program in the rest of the world. Nonetheless, FDA affirmed the New Restrictions at a meeting held with us on May 24, 2023.

We have concluded pre-Phase 3 regulatory and scientific advice meetings with Regulatory Authorities outside of the U.S. and have reached agreement on the design of the Phase 3 study that will include participants 3 months of age and older. We believe that the New Restrictions make it infeasible to include the U.S. in the Phase 3 study at this time, particularly given that the pediatric population with congenital HI has the greatest therapeutic need. We are evaluating potential nonclinical studies to address FDA's concerns in parallel with the initiation and advancement of the Phase 3 study outside of the U.S.

Specifically, in the fourth quarter of 2023, we plan to initiate the Phase 3 sunRIZE clinical study of RZ358 which will be a randomized, double-blind, placebo-controlled, parallel arm evaluation of RZ358 in participants with congenital HI who are not adequately responding to standard of care medical therapies. Topline results from the study are anticipated to be available in the first half of 2025.

RZ402

In December 2022, we initiated a Phase 2 multi-center, randomized, double-masked, placebo-controlled, parallel-arm study to evaluate the safety, efficacy, and pharmacokinetics of RZ402 administered as a monotherapy over a 12-week treatment period in participants with DME who are naïve to, or have received limited anti-VEGF injections. The study population is comprised of DME patients with mild to moderate non-proliferative diabetic retinopathy. Eligible participants are being randomized equally, to one of three RZ402 active treatment arms at doses of 50, 200, and 400 mg, or a placebo control arm, to receive study drug once daily for 12 weeks, before completing a four-week follow-up. The study is expected to enroll up to approximately 100 patients overall, across approximately 25 investigational sites in the United States. The principal endpoints of the trial include (i) changes in central subfield thickness of the macula, as measured by Spectral Domain Ocular Coherence Tomography, (ii) changes in visual acuity as measured by the early treatment diabetic retinopathy scale, (iii) the repeat dose pharmacokinetics of RZ402 in patients with DME, and (iv) the safety and tolerability of RZ402. We expect to complete enrollment in 2023 and to announce results from the study in the first quarter of 2024.

Investment in Marketable Debt Securities

In January 2023, our Board of Directors determined that it was in our best interest to diversify our cash position, which amounted to $146.7 million as of December 31, 2022. Accordingly, we reinvested an aggregate of $115.0 million of cash held in demand deposit accounts in a portfolio of marketable debt securities and an overnight money market mutual fund with the objective of achieving higher returns on investment.

Factors Impacting our Results of Operations

We have not generated any meaningful revenues since our inception in March 2010. Over the last several years, we have conducted private placements and public offerings to raise additional capital, adopted a licensing model to pursue development of product candidates, conducted pre-clinical and clinical trials, and conducted other research and development activities on our pipeline of product candidates.

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

Key Components of Consolidated Statements of Operations

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

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

Interest and other income. Interest and other income consist primarily of interest income earned on marketable debt securities and temporary cash investments, amortization of investment premiums and accretion of investment discounts.

Gain from change in fair value of derivative liabilities, net. We recognize derivative liabilities if we issue stock options and warrants but don't have sufficient authorized shares of common stock to accommodate all potential exercise. Under these circumstances, accounting as a derivative liability was required since the possibility existed that we could have been required to settle stock options and warrants in cash. Such derivative liabilities were recorded at fair value on the date that the deficiency occurred and subsequently adjusted to fair value at the end of each reporting period through the date the deficiency was cured. We also recognize liabilities for embedded derivatives that arose in connection with our legacy debt agreement. Derivative liabilities are adjusted to fair value at the end of each reporting period until the derivative liability contracts are settled, expire, or meet the conditions for equity classification. Changes in fair value are reflected as gains and losses in our consolidated statements of operations. Gains and losses reflected prior to the date a deficiency is cured are not subsequently reversed.

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

Underwriting discount on issuance of derivative. For derivative liabilities that were issued at a discount versus the grant date fair value of the financial instrument, an expense equal to the amount of the discount was recognized on the issuance date since the derivative liability would have been required to be settled at fair value.

Interest expense. The components of interest expense include the amount of interest payable in cash at the stated interest rate set forth in the debt agreement, and accretion of debt discounts and issuance costs ("DDIC") using the effective interest

method. DDIC arises from the issuance of debt instruments and other related contracts or agreements which possess certain terms and conditions resulting in additional financing costs arising from origination, exit and final fees, and other incremental and direct costs incurred to consummate the financing, among others.

Loss on extinguishment of loan agreement. When we repay our debt arrangements prior to the maturity date, we evaluate the terms to determine if the repayment should be accounted for as a troubled debt restructuring, a modification or an extinguishment. If we conclude that accounting as an extinguishment is required, the extinguishment charge includes the write-off of any unaccreted DDIC, prepayment premiums required under the debt agreement, and professional fees incurred to complete the transaction.

Critical Accounting Policies and Significant Judgments and Estimates

Overview

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of the consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

With respect to our significant accounting policies that are described in Note 1 to our consolidated financial statements included in Item 8 of this Annual Report, we believe that the following accounting policies involve a greater degree of judgment and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of operations.

Investments in Marketable Debt Securities

We account for our investments in marketable debt securities as available-for-sale securities whereby they are recorded in the consolidated balance sheet at fair value. Interest income consists of accrued interest earned based on the coupon rate of the security, plus the impact of accreting discounts and amortizing premiums to maturity using the straight-line method which approximates the interest method. Unrealized gains and losses due to subsequent changes in fair value of the investments are reported in shareholders' equity as a component of accumulated other comprehensive income (loss). The individual debt securities in our portfolio are subject to credit risk in the event of default by the issuers. We review the components of our portfolio of available-for-sale debt securities, using both quantitative and qualitative factors, to determine if declines in fair value below amortized cost have resulted from a credit-related loss or other factors. If declines in fair value are due to a deterioration of credit quality of the issuer, we recognize (i) a loss in other comprehensive income (loss) if the reduction in fair value is considered temporary, or (ii) a loss in the consolidated statement of operations if the reduction in fair value is considered other than temporary. For a decline in fair value that is solely due to changes in interest rates, impairment is not recognized if we have the ability and intent to hold the investment until maturity. The cost basis of any securities sold prior to maturity will be determined using the specific identification method.

Research and Development

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

Clinical Trial Accruals

Clinical trial costs are a component of research and development expenses. We accrue and charge to expenses clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with clinical research organizations and clinical trial sites. We determine our estimates through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Nonrefundable advance payments for goods and services that will be used or rendered in future research and development activities are deferred and recognized as expense in the period that the related goods are delivered, or services are performed.

Share-Based Compensation Expense

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

Gain from Change in Fair Value of Derivative Liabilities

We recognize derivative liabilities whenever we issue stock options and warrants but do not have sufficient authorized shares of common stock to accommodate all potential exercises. Under these circumstances, accounting as a derivative liability was required since the possibility existed that we could have been required to settle these financial instruments in cash. Such derivative liabilities were recorded at fair value on the date that the deficiency occurred and subsequently adjusted to fair value at the end of each reporting period through the date the deficiency was cured.

Changes in fair value are reflected as gains and losses in our consolidated statements of operations. Gains and losses reflected prior to the date a deficiency is cured are not subsequently reversed. We also recognize liabilities for embedded derivatives that arose in connection with a legacy debt agreement.

Results of Operations

Results of operations for the fiscal years ended June 30, 2023 and 2022 reflect net losses of approximately $51.8 million and $41.1 million, respectively. Our consolidated statements of operations for the fiscal years ended June 30, 2023 and 2022, along with the changes between fiscal years, are presented below (in thousands, except percentages):

			Changes	
	2023	2022	Amount	Percent
Operating expenses:				
Research and development:	$ 43,813	$ 32,486	$ 11,327	35 %
General and administrative:	12,177	9,357	2,820	30 %
Total operating expenses	55,990	41,843	14,147	34 %
Operating loss	(55,990)	(41,843)	(14,147)	34 %
Non-operating income (expense):				
Interest and other income	4,208	80	4,128	5,160 %
Gain (loss) from change in fair value of derivative liabilities	(5)	6,545	(6,550)	(100)%
Employee retention credit	—	231	(231)	(100)%
Underwriting discount on issuance of derivative	—	(2,495)	2,495	(100)%
Interest expense	—	(1,807)	1,807	(100)%
Loss on extinguishment of loan agreement	—	(1,771)	1,771	(100)%
Total non-operating income, net	4,203	783	3,420	437 %
Net loss	$ (51,787)	$ (41,060)	$ (10,727)	26 %

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

Revenue. As a clinical stage company, we did not generate any revenue for the fiscal years ended June 30, 2023 and 2022. We are at an early stage of development and do not currently have any commercial products. Our existing product candidates will require extensive additional clinical evaluation, regulatory review, significant marketing efforts and substantial investment before they generate any revenues. We do not expect to be able to market any of our product candidates for several years.

Research and Development Expenses. R&D expenses for the fiscal years ended June 30, 2023 and 2022 were as follows (in thousands, except percentages):

			Increase	
	2023	2022	Amount	Percent
Total R&D expenses	$ 43,813	$ 32,486	$ 11,327	35 %

The increase of $11.3 million was primarily attributable to an increase of $5.3 million in R&D compensation and benefits for our R&D workforce. Cash-based R&D compensation and benefits increased by $3.5 million from $8.2 million for the fiscal year ended June 30, 2022 to $11.7 million for the fiscal year ended June 20, 2023. This increase was primarily attributable to an increase in the average number of R&D employees from 26 to 36 and an increase in bonuses. R&D share-based compensation increased by $1.8 million from $1.4 million for the fiscal year ended June 30, 2022 to $3.2 million for the fiscal year ended June 30, 2023. This increase is primarily attributable to the expense related to stock options granted to employees in June 2022.

Additional increases of $4.3 million were incurred for our two clinical candidate programs, of which the RZ358 had an increase in spending of $1.1 million and the RZ402 program had an increase in spending of $3.2 million.

The increase in RZ358 program costs of $1.1 million primarily was driven by an increase of $3.1 million for higher spending for drug substance and drug product manufacturing and other development activities as we began manufacturing activities for a Phase 3 study where enrollment is planned to be initiated during the fiscal year ending June 30, 2024. This increase was partially offset by a $2.0 million reduction in milestone payments under our license agreement with XOMA. For the fiscal year ended June 30, 2022, we incurred a milestone payment due to XOMA upon dosing of the last patient in the Phase 2b clinical study. We did not incur any RZ358 milestone related costs during the fiscal year ended June 30, 2023.

The RZ402 program cost increase of $3.2 million was primarily attributable to a $3.0 million increase in milestone payments due under our license agreement with ActiveSite. In February 2023, we dosed the first patient in the RZ402 Phase 2 study, triggering a milestone payment due for $3.0 million to ActiveSite. There were no RZ402 related milestone costs incurred during the fiscal year ended June 30, 2022. In addition to the $3.0 million increase in milestone costs, there was a $1.9 million increase in clinical operation costs related to the ongoing Phase 2 study. These increases were partially offset by a decrease in preclinical, toxicology and other related costs of approximately $1.7 million.

In addition to the increases in R&D compensation and benefits and our clinical programs noted above for the fiscal year ended June 30, 2023, an increase of approximately $0.8 million was incurred related to facilities and employee related travel costs allocable to R&D due to the increased headcount as noted above.

General and Administrative Expenses. G&A expenses for the fiscal years ended June 30, 2023 and 2022 were as follows (in thousands, except percentages):

			Increase	
	2023	2022	Amount	Percent
Total G&A expenses	$ 12,177	$ 9,357	$ 2,820	30 %

The increase in G&A expenses of $2.8 million for the fiscal year ended June 30, 2023 was primarily attributable to an increase in G&A compensation and benefits related to our administrative workforce of $2.8 million. Cash-based G&A compensation and benefits increased by $1.1 million from $2.7 million for the fiscal year ended June 30, 2022 to $3.8 million for the fiscal year ended June 20, 2023. This increase was attributable to an increase in the average number of G&A employees from 9 to 12 and an increase in compensation related to bonuses. G&A share-based compensation increased by $1.8 million from $2.2 million for the fiscal year ended June 30, 2022 to $4.0 million for the fiscal year ended June 30, 2023. This increase is primarily attributable to the expense related to stock options granted to employees in June 2022.

Interest and other income. For the fiscal year ended June 30, 2023, we recognized $4.2 million of interest income compared to $0.1 million of interest income for the fiscal year ended June 30, 2022. This increase was primarily due to our decision in January 2023 to invest an aggregate of approximately $115.0 million in marketable debt securities and an overnight money market mutual fund that bear interest at a weighted average effective rate of approximately 5.0%, whereas our temporary cash investments as of June 30, 2022 provided for earnings that were less than 1.0%. This change in strategy midway through the fiscal year ended June 30, 2023 resulted in interest income of $1.2 million for the first half of the fiscal year and $3.0 million for the second half of the fiscal year.

Change in Fair Value of Derivative Liabilities. For the fiscal year ended June 30, 2022, we recognized a gain of $6.6 million that was primarily due to a reduction of $0.60 per share in our stock price, resulting in changes in fair value of the derivative liability related to our authorized share deficiency that arose when we entered into an underwriting agreement for issuance of the Class B PFWs on May 4, 2022. This authorized share deficiency existed until June 16, 2022 when our shareholders approved an increase in our authorized shares of common stock. Our stock price decreased from $3.80 per share on May 4, 2022, to $3.20 per share on June 16, 2022 when the authorized share deficiency was cured. For the fiscal year ended June 30, 2023 and 2022, we recognized losses from the change in fair value of embedded derivative liabilities of $5,000 and $20,000, respectively.

Employee Retention Credit. Employee retention credit income was $0.2 million for the fiscal year ended June 30, 2022. This income is a result of CARES Act benefits for the period of July 1, 2021 through September 30, 2021. For the fiscal year ended June 30, 2023, no income was recognized since governmental assistance was no longer available under the CARES Act.

Underwriting discount on issuance of derivative liability. For the fiscal year ended June 30, 2023, we did not recognize any expense related to underwriting discounts. For the fiscal year ended June 30, 2022, we recognized an expense of approximately $2.5 million for an underwriting discount related to the issuance of the Class B PFWs. The fair value of the Class B PFWs on the date of issuance amounted to $41.6 million and the Class B PFWs were sold to the underwriter for a discounted price of $39.1 million. Accordingly, an expense was recognized on the issuance date for the amount of the underwriting discount of $2.5 million.

Interest Expense. Interest expense was $1.8 million for the fiscal year ended June 30, 2022. Interest expense for the fiscal year ended June 30, 2022 was solely attributable to a loan agreement entered in April 2021 and consisted of (i) accretion of discount of $0.4 million, and (ii) interest expense of $1.4 million based on the contractual rate of approximately 8.9%. For the fiscal year ended June 30, 2023 we did not incur any interest expense due to the repayment of a loan agreement on June 30, 2022.

Loss on extinguishment of loan agreement. We incurred a loss on extinguishment of a loan agreement of approximately $1.8 million for the fiscal year ended June 30, 2022. This extinguishment loss was attributable to our exercise of the loan prepayment option that required a 2.00% prepayment penalty of $0.3 million and the unaccreted discount of $1.5 million was written off. We did not incur any losses on extinguishment for the fiscal year ended June 30, 2023.

Income Taxes. For the fiscal years ended June 30, 2023 and 2022, we did not recognize any income tax benefit due to our net losses and our determination that a full valuation allowance was required for our deferred income tax assets.

Liquidity and Capital Resources

Short-term Liquidity Requirements

As of June 30, 2023, we had cash and cash equivalents of $16.0 million, investments in marketable debt securities $102.3 million and working capital was approximately $99.7 million. We have incurred cumulative net losses of $261.0 million since our inception and as a clinical stage company we have not generated any meaningful revenue to date.

Accordingly, our primary source of liquidity has historically been from the completion of private placements and public offerings of our equity securities, as well as proceeds from the issuance of debt securities. For the fiscal years ended June 30, 2023 and 2022, we received net proceeds from the issuance of equity securities of $11.6 million and $165.2 million, respectively. As of June 30, 2022, we exercised the prepayment option under a loan agreement which used approximately $16.0 million of the funding from issuances of equity securities earlier in the fiscal year. The completion of these equity financings is the primary source of remaining cash and cash equivalents and investments in marketable debt securities as of June 30, 2023. For further information about the key terms and results of our debt and equity financing activities, please refer to the discussion above under the caption *Executive Summary*.

In April 2022 we entered into a lease agreement for a new corporate headquarters facility in Redwood City, California. This lease, which commenced in October 2022, provides for total base rent payments of approximately $2.9 million through the expected expiration of the lease in July 2027. Cash payments related to existing contractual obligations for the fiscal year ending June 30, 2024 include approximately (i) $0.7 million under all of our operating lease agreements, and (ii) a potential milestone payment to XOMA of $5.0 million that will be due upon dosing of the first patient in a Phase 3 clinical trial for RZ358 that we expect will occur in the next twelve months. Due to uncertainties in the timing associated with clinical trial activities, it is possible that the milestone payments to XOMA could be delayed beyond our the fiscal year ending June 30, 2024.

Based on our cash and cash equivalents balance of $16.0 million combined with our investment in marketable debt security balance of $102.3 million as of June 30, 2023, we believe we have adequate capital resources to meet all of our contractual obligations and conduct all planned activities to advance our clinical trials at least through the third quarter of calendar year 2025.

Long-term Liquidity Requirements

Our most significant long-term contractual obligations consist of additional clinical and regulatory milestone payments up to $35.0 million payable to XOMA and additional milestone payments up to $25.0 million payable to ActiveSite. Of this total, we expect that $5.0 million will be payable to XOMA during the fiscal year ended June 30, 2024 as discussed above under the caption *Short-term Liquidity Requirements*. The remaining $55.0 million is considered a long-term liquidity requirement. Due to uncertainties in the timing associated with clinical trial activities and regulatory approvals, there is even greater uncertainty in forecasting the timing of future clinical and regulatory milestone payments to XOMA and ActiveSite that may be required during the fiscal year ending June 30, 2025 and thereafter.

In addition to the clinical and regulatory milestone payments discussed above, upon the future commercialization of RZ358 and RZ402 we will be obligated to pay additional milestone payments and royalties based on the net sales of the related products sales-based and alternative indication regulatory approvals to XOMA and ActiveSite for an additional $202.5 million. These future milestones include $185.0 million in potential payments to XOMA and $17.5 million to ActiveSite for various sales-based milestones and alternative indication regulatory approvals. No assurance can be provided that commercialization will ever be achieved for either of RZ358 and RZ402, whereby none of these future payments may ever be required.

In addition to our licensing obligations, we also have long-term contractual obligations under existing operating lease agreements ranging between approximately $0.6 million to $0.7 million for each of the fiscal years ending June 30, 2025 through 2027. Based on our current forecast, we expect that our existing cash and cash equivalents will be sufficient to fund our contractual obligations and conduct all planned activities to advance our clinical trials at least through the third quarter of calendar year 2025. Therefore, we will need to obtain additional equity or debt financing in order to fund all of our long-term liquidity requirements.

Presented below is additional discussion about the ongoing requirements pursuant to our license agreements with XOMA and ActiveSite, along with additional information about our ongoing financing activities that impacted our liquidity and capital resources for the fiscal year ended June 30, 2023.

XOMA License Agreement

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

Upon the achievement of certain clinical and regulatory events, we will be required to make up to $37.0 million in aggregate milestone payments to XOMA. The first such milestone payment of $2.0 million was triggered upon enrollment of the last patient in our ongoing phase 2 clinical study in January 2022. The next milestone payment of $5.0 million will be due upon the enrollment of the first patient in a Phase 3 study, which we believe will occur in the next twelve months. Additionally, upon the future commercialization of RZ358, we will be required to pay royalties to XOMA based on the net sales of the related products, and milestone payments up to an additional $185.0 million if future annual sales related to RZ358 exceed targets ranging from $100.0 million to $1.0 billion. Through June 30, 2023, no events have occurred that would result in the requirement to make additional milestone payments and no royalties have been incurred.

ActiveSite License Agreement

In August 2017, we entered into a Development and License Agreement with ActiveSite ("ActiveSite License Agreement") pursuant to which we acquired the rights to ActiveSite's PKI portfolio. We are planning to use the PKI Program to develop, file, manufacture, market and sell products for diabetic macular edema and other therapeutic indications. The ActiveSite License Agreement requires various milestone payments ranging from $1.0 million to $10.0 million when milestone events occur, up to an aggregate of $46.5 million of aggregate milestone payments. The first milestone payment for $1.0 million was paid in December 2020 after completion of preclinical work and submission of an IND to the FDA for RZ402. The second milestone payment for $3.0 million became due upon dosing of the first patient

in a Phase 2 study in February 2023. Remaining milestone payments under the ActiveSite License Agreement for various clinical and regulatory milestones amount to $25.0 million and milestones after commercial success or alternative indication approvals amount to $17.5 million. We will also be required to pay royalties equal to 2.0% of any sales of products that use the PKI Program. Through June 30, 2023, no events have occurred that would result in the requirement to make additional milestone payments and no royalties have been incurred.

Cash Flows Summary

Presented below is a summary of our operating, investing and financing cash flows for the fiscal years ended June 30, 2023 and 2022 (in thousands):

	2023	2022	Change
Net cash provided by (used in):			
Operating activities	$ (44,481)	$ (39,616)	$ (4,865)
Investing activities	(101,464)	—	(101,464)
Financing activities	11,571	148,979	(137,408)

Cash Flows Used in Operating Activities

For the fiscal years ended June 30, 2023 and 2022, cash flows used in operating activities amounted to $44.5 million and $39.6 million, respectively. The key components in the calculation of our cash used in operating activities are as follows (in thousands):

	2023	2022	Change
Net loss	$ (51,787)	$ (41,060)	$ (10,727)
Non-cash expenses	7,655	8,331	(676)
Non-cash gains, net	(1,370)	(6,545)	5,175
Prepayment premium	—	300	(300)
Changes in operating assets and liabilities, net	1,021	(642)	1,663
Total	$ (44,481)	$ (39,616)	$ (4,865)

For the fiscal year ended June 30, 2023, our net loss was $51.8 million compared to $41.1 million for the fiscal year ended June 30, 2022. For further discussion about changes in our operating results for the fiscal years ended June 30, 2023 and 2022, please refer to *Results of Operations* above.

For the fiscal year ended June 30, 2023, our non-cash expenses of $7.7 million primarily consisted of share-based compensation expense of $7.3 million and non-cash lease expense of $0.4 million. For the fiscal year ended June 30, 2022, our non-cash expenses of $8.3 million primarily consisted of share-based compensation expense of $3.7 million, a discount on the issuance of the Class B PFWs derivate liability of $2.5 million, a loss on extinguishment of debt of $1.5 million, accretion of debt discount and issuance costs of $0.4 million, and non-cash lease expense of $0.2 million.

For the fiscal year ended June 30, 2023, non-cash gains consisted of discount accretion on investments in marketable debt securities of $1.4 million. For the fiscal year ended June 30, 2022, non-cash gains consisted of a gain of $6.5 million attributable to changes in fair value of the Class B PFW derivative liability related to a deficiency in our authorized shares that existed from May 4, 2022 until June 16, 2022.

For the fiscal year ended June 30, 2022, we paid a prepayment premium of $0.3 million in connection with the termination of the loan agreement. The cash payment for this amount is included as a financing cash outflow and as a component of our net loss. Accordingly, an adjustment is required to remove this amount from our operating cash outflows. A similar charge was not incurred for the fiscal year ended June 30, 2023.

For the fiscal year ended June 30, 2023, net changes in operating assets and liabilities increased operating cash flow by $1.0 million, primarily driven by an increase accounts payable and other accrued liabilities of $2.3 million, partially offset by an increase in prepaid expenses and other assets of $1.3 million that associated with prepayments for clinical trials and

manufacturing activities. For the fiscal year ended June 30, 2022, net changes in operating assets and liabilities reduced operating cash flow by $0.6 million, primarily driven by an increase in prepaid expenses and other assets of $0.9 million that was associated with to prepayments for clinical trials and manufacturing activities, partially offset by a decrease in other accrued liabilities of $0.2 million

Cash Flows Used in Investing Activities

For the fiscal year ended June 30, 2023, our net cash utilized in investing activities amounted to $101.5 million, primarily related to the purchase of $107.3 million of marketable debt securities offset by cash inflows provided by $6.0 million of marketable debt securities. Additionally, our investing activities used $0.2 million for the purchase of furniture and equipment primarily for use in our new office location in Redwood City, California. We did not have any cash flows from investing activities for the fiscal years ended June 30, 2022.

Cash Flows Provided by Financing Activities

Net cash provided by financing activities for the fiscal year ended June 30, 2023 amounted to $11.6 million. This amount consisted of proceeds of $12.3 million from the 2022 Private Placement. The total proceeds from the 2022 Private Placement of $12.3 million were partially offset by payments of $0.8 million for underwriting commissions and other costs related to this offering.

Net cash provided by financing activities for the fiscal year ended June 30, 2022 amounted to $149.0 million. This amount included (i) $50.7 million received from an underwritten offering of Units in October 2021 for the issuance of approximately 6.8 million shares of common stock at a purchase price of $6.50 per share and issuance of 1.7 million of PFWs at a purchase price of $6.49 per share, (ii) $5.0 million received from a registered direct offering related to the issuance of common stock in October 2021 for the purchase of approximately 0.8 million shares at a purchase price of $6.50 per share, (iii) $110.5 million of proceeds after underwriter discounts from the 2022 RDO in May 2022 for the purchase of approximately 18.0 million shares of common stock at a purchase price of $3.80 per share and purchase of an aggregate of approximately 12.9 Class A PFWs and Class B PFWs at a purchase price of $3.799 per share, and (iv) $2.7 million in gross proceeds for the issuance of common stock under the a purchase agreement and an agent equity distribution agreement. The total proceeds from equity financing activities amounted to $168.9 million and were partially offset by payments of $3.7 million related to financial advisory fees and other costs of equity financings, resulting in net cash proceeds from equity financing activities of $165.2 million.

For the fiscal year ended June 30, 2022, we used cash of $16.3 million related to our debt financing activities. Debt financing payments consisted of $0.3 million for payment of additional debt discount and issuance costs under our loan agreement, and $16.0 million for contractual payments required to terminate the loan agreement on June 30, 2022. The contractual payments included (i) repayment of the principal balance of the loan for $15.0 million, (ii) a prepayment fee equal to 2.00% of the outstanding principal balance for a total of $0.3 million, and (iii) a final fee equal to 4.75% of the aggregate amount of the term loan funded for a total of $0.7 million. The security interests and liens granted in April 2021 when we entered into the loan agreement were released on June 30, 2022.

Off-Balance Sheet Arrangements

During the fiscal years ended June 30, 2023 and 2022, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities, which were established for the purpose of facilitating off-balance sheet arrangements.

Recently Issued Accounting Pronouncements

See Note 1 to our consolidated financial statements included in Item 8 of this Annual Report regarding the impact of certain accounting pronouncements on our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Rezolute, Inc. (the "Company") as of June 30, 2023 and 2022, the related consolidated statements of operations, shareholders' equity, and cash flows for each of the years in the two-year period ended June 30, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of June 30, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

The Company's management is responsible for these financial statements. 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.

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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Plante & Moran, PLLC

We have served as the Company's auditor since 2013.
Cleveland, Ohio
September 14, 2023

REZOLUTE, INC.

Consolidated Balance Sheets
June 30, 2023 and 2022
(In Thousands, Except Per Share Amounts)

	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 16,036	$ 150,410
Investments in marketable debt securities	85,860	—
Prepaid expenses and other	3,014	1,694
Total current assets	104,910	152,104
Long-term assets:		
Investments in marketable debt securities	16,470	—
Right-of-use assets	2,054	152
Property and equipment, net	139	16
Deposits and other	148	148
Total assets	$ 123,721	$ 152,420
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 3,269	$ 1,132
Accrued liabilities:		
Compensation and benefits	883	—
Accrued clinical and other	507	1,222
Current portion of operating lease liabilities	541	108
Total current liabilities	5,200	2,462
Long term liabilities:		
Operating lease liabilities, net of current portion	1,937	80
Embedded derivative liabilities	412	407
Total liabilities	7,549	2,949
Commitments and contingencies (Notes 5 and 11)		
Shareholders' equity:		
Preferred stock, $0.001 par value; 400 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 100,000 shares authorized; issued and outstanding 36,827 and 33,582 shares as of June 30, 2023 and 2022, respectively	37	34
Additional paid-in capital	377,471	358,635
Accumulated other comprehensive loss	(351)	—
Accumulated deficit	(260,985)	(209,198)
Total shareholders' equity	116,172	149,471
Total liabilities and shareholders' equity	$ 123,721	$ 152,420

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

REZOLUTE, INC.

Consolidated Statements of Operations and Comprehensive Loss
For the Fiscal Years Ended June 30, 2023 and 2022
(In Thousands, Except Per Share Amounts)

	2023	2022
Operating expenses:		
Research and development	$ 43,813	$ 32,486
General and administrative	12,177	9,357
Total operating expenses	55,990	41,843
Operating loss	(55,990)	(41,843)
Non-operating income (expense):		
Interest and other income, net	4,208	80
Gain (loss) from change in fair value of derivative liabilities	(5)	6,545
Employee retention credit	—	231
Underwriting discount on issuance of derivative	—	(2,495)
Interest expense	—	(1,807)
Loss on extinguishment of loan agreement	—	(1,771)
Total non-operating income (expense), net	4,203	783
Net loss	(51,787)	(41,060)
Other comprehensive loss:		
Net unrealized loss on available-for-sale marketable debt securities	(351)	—
Comprehensive loss	$ (52,138)	$ (41,060)
Net loss per common share:		
Basic	$ (1.01)	$ (2.26)
Diluted	$ (1.01)	$ (2.32)
Weighted average number of common shares outstanding:		
Basic	51,187	18,197
Diluted	51,187	19,487

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

REZOLUTE, INC.

Consolidated Statements of Shareholders' Equity
For the Fiscal Years Ended June 30, 2023 and 2022
(In Thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balances, June 30, 2021	8,352	$ 8	$ 194,229	$ —	$ (168,138)	$ 26,099
Proceeds from issuance of equity securities for cash in 2022 Registered Direct Offering, net of discounts:						
Common stock	18,026	18	64,372	—	—	64,390
Class A pre-funded warrants	—	—	7,048	—	—	7,048
Gross proceeds from issuance of equity securities for cash in Underwritten Public Offering:						
Common stock	6,147	6	39,950	—	—	39,956
2021 pre-funded warrants	—	—	10,783	—	—	10,783
Gross proceeds from issuance of common stock for cash:						
In 2021 Registered Direct Offering	769	1	4,999	—	—	5,000
Under Equity Distribution Agreement	138	1	1,518	—	—	1,519
Under LPC Purchase Agreement	116	—	1,172	—	—	1,172
Underwriting commissions and other equity offering costs	—	—	(4,596)	—	—	(4,596)
Share-based compensation	—	—	3,685	—	—	3,685
Reclassification of Class B pre-funded warrant derivative liability to equity upon cure of authorized share deficiency	—	—	35,025	—	—	35,025
Commitment shares issued under LPC Purchase Agreement	34	—	450	—	—	450
Net loss	—	—	—	—	(41,060)	(41,060)
Balances, June 30, 2022	33,582	$ 34	$ 358,635	$ —	$ (209,198)	$ 149,471
Gross proceeds from issuance of equity securities for cash in 2022 Private Placement	3,245	3	12,327	—	—	12,330
Underwriting discounts and other equity offering costs	—	—	(759)	—	—	(759)
Share-based compensation	—	—	7,268	—	—	7,268
Net change in other accumulated comprehensive loss	—	—	—	(351)	—	(351)
Net loss	—	—	—	—	(51,787)	(51,787)
Balances, June 30, 2023	36,827	$ 37	$ 377,471	$ (351)	$ (260,985)	$ 116,172

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

REZOLUTE, INC.

Consolidated Statements of Cash Flows
For the Fiscal Years Ended June 30, 2023 and 2022
(In Thousands)

	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (51,787)	$ (41,060)
Share-based compensation expense	7,268	3,685
Non-cash lease expense	352	243
Loss from change in fair value of derivative liabilities	5	—
Accretion of discounts and amortization of premiums on marketable debt securities, net	(1,370)	—
Depreciation and amortization expense	30	13
Gain from change in fair value of derivative liabilities, net	—	(6,545)
Underwriting discount on issuance of derivative	—	2,495
Loss on extinguishment of Loan Agreement:		
Prepayment premium paid	—	300
Other	—	1,471
Accretion of debt discount and issuance costs	—	424
Changes in operating assets and liabilities:		
Increase in prepaid expenses and other assets	(1,320)	(860)
Increase (decrease) in accounts payable	2,136	(11)
Increase in accrued liabilities	205	229
Net Cash Used in Operating Activities	(44,481)	(39,616)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable debt securities	(107,311)	—
Proceeds from maturities of marketable debt securities	6,000	—
Purchase of property and equipment	(153)	—
Total Cash Used in Investing Activities	(101,464)	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Gross proceeds from issuance of common stock for cash:		
2022 Private Placement	12,330	—
2021 Registered direct offering	—	5,000
Under Equity Distribution Agreement	—	1,519
Under LPC Purchase Agreement	—	1,172
Gross proceeds from 2022 Registered Direct Offering, net of underwriting discounts:		
Issuance of common stock	—	64,390
Issuance of Class A pre-funded warrants	—	7,048
Issuance of Class B pre-funded warrants	—	39,094
Gross proceeds from 2021 Underwritten Offering:		
Common stock	—	39,956
2021 pre-funded warrants	—	10,783
Payment of commissions and other offering costs	(759)	(3,716)
Payment of debt discount and issuance costs	—	(254)
Prepayment of contractual obligations under Loan Agreement, including prepayment fee	—	(16,013)
Net Cash Provided by Financing Activities	11,571	148,979
Net (decrease) increase in cash, cash equivalents and restricted cash	(134,374)	109,363
Cash, cash equivalents and restricted cash at beginning of period	150,410	41,047
Cash, cash equivalents and restricted cash at end of period	$ 16,036	$ 150,410

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

REZOLUTE, INC.

Consolidated Statements of Cash Flows, Continued
For the Fiscal Years Ended June 30, 2023 and 2022
(In Thousands)

	2023	2022
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
Cash and cash equivalents, end of year	$ 16,036	$ 150,410
Restricted cash, end of year	—	—
Total cash, cash equivalents and restricted cash, end of year	$ 16,036	$ 150,410
SUPPLEMENTARY CASH FLOW INFORMATION:		
Cash paid for interest	$ —	$ 1,487
Cash paid for income taxes	—	—
Cash paid for amounts included in the measurement of operating lease liabilities	215	254
Operating lease liabilities incurred in exchange for right-of-use assets	2,204	—
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Reclassification of derivative liabilities to equity upon cure of authorized share deficiency	$ —	$ 35,025
Issuance of commitment shares for deferred offering costs subsequently charged to additional paid-in capital	—	450
Payables for deferred offering costs subsequently charged to additional paid-in capital	—	61

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

REZOLUTE, INC.
Notes to Consolidated Financial Statements

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

Nature of Operations

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

Consolidation

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

Basis of Presentation

The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

Comprehensive income (loss) is defined as net income (loss) plus other comprehensive income (loss). Other comprehensive income (loss) is comprised of revenues, expenses, gains, and losses that under GAAP are reported as separate components of shareholders' equity instead of net income (loss). For the fiscal year ended June 30, 2023, components of comprehensive loss included the Company's net loss and unrealized gains (losses) on investments in marketable debt securities. For the fiscal year ended June 30, 2022, the only component of comprehensive loss was the Company's net loss as the Company had no items constituting any other comprehensive income (loss).

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts in the consolidated financial statements and the accompanying notes. The Company bases its estimates and assumptions on current facts, historical experience, and various other factors that it believes are reasonable under the circumstances, to determine the carrying values of assets and liabilities that are not readily apparent from other sources. The Company's significant accounting estimates include, but are not necessarily limited to, determination if other than temporary impairment exists for marketable debt securities, the fair value of derivative liabilities, fair value of share-based payments and warrants, management's assessment of going concern, and clinical trial accrued liabilities. Actual results could differ from those estimates.

Risks and Uncertainties

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

Cash and Cash Equivalents

All highly liquid investments purchased with an original maturity of three months or less that are freely available for the Company's immediate and general business use are classified as cash and cash equivalents. Cash and cash equivalents

consist primarily of demand deposits with financial institutions, money market funds and corporate commercial paper purchased with a maturity of three months or less.

Investments in Marketable Debt Securities

Under the investment policy approved by the Company's Board of Directors, eligible investments in fixed income debt securities must be denominated and payable in U.S. dollars, including eligible corporate bonds, corporate commercial paper, U.S. government obligations, and money market funds. This investment policy only permits investments in the debt securities of issuers that meet stringent credit quality ratings on the date of the investment. The investment policy also places restrictions on the length of maturities and concentrations by type and issuer. The Company's investments are issued by financial institutions that management believes are of high credit quality. However, they are exposed to credit risk in the event of default by the issuers. The Company classifies investments in marketable debt securities that mature in less than one year as short-term assets. For investments that mature in more than one year, the investments are classified as long-term assets unless management intends to liquidate the investments to fund current operations before the scheduled maturity dates.

The Company accounts for its investments in marketable debt securities as available-for-sale securities whereby they are recorded in the consolidated balance sheet at fair value. Interest income is recognized in the consolidated statement of operations, consisting of accrued interest earned based on the coupon rate of the security, plus the impact of accreting discounts and amortizing premiums to maturity using the straight-line method which approximates the interest method. Unrealized gains and losses due to subsequent changes in fair value of the investments are reported in shareholders' equity as a component of accumulated other comprehensive income (loss). The Company reviews the components of its portfolio of available-for-sale debt securities, using both quantitative and qualitative factors, to determine if declines in fair value below amortized cost have resulted from a credit-related loss or other factors. If declines in fair value are due to a deterioration of credit quality of the issuer, the Company recognizes (i) a loss in other comprehensive income (loss) if the reduction in fair value is considered temporary, or (ii) a loss in the consolidated statement of operations if the reduction in fair value is considered other than temporary. For a decline in fair value that is solely due to changes in interest rates, impairment is not recognized if the Company has the ability and intent to hold the investment until maturity. The cost basis of any securities sold prior to maturity will be determined using the specific identification method.

Leases

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

Property and Equipment

Property and equipment consist solely of office furniture and equipment that is recorded at cost. Depreciation expense is calculated using the straight-line method over the estimated useful lives of the assets which range from 3 to 5 years. Maintenance and repairs are expensed as incurred.

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Notes to Consolidated Financial Statements

Debt Discounts and Issuance Costs

Debt discounts and issuance costs ("DDIC") incurred to obtain new debt financings or modify existing debt financings consist of incremental direct costs incurred for fees paid to the lender, professional fees and due diligence services. DDIC is presented as a reduction in the carrying value of the debt and is accreted to interest expense using the effective interest method.

Research and Development Costs

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

Clinical Trial Accruals

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with clinical research organizations and clinical trial sites. The Company determines the estimates through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Nonrefundable advance payments for goods and services that will be used or rendered in future research and development activities are deferred and recognized as expense in the period that the related goods are delivered, or services are performed.

Share-Based Compensation

The Company measures the fair value of employee and director services received in exchange for all equity awards granted, including stock options, based on the fair value of the award as of the grant date. The Company computes the fair value of stock options using the Black-Scholes-Merton ("BSM") option pricing model and recognizes the cost of the equity awards over the period that services are provided to earn the award, usually the vesting period. For awards granted which contain a graded vesting schedule, and the only condition for vesting is a service condition, compensation cost is recognized as an expense on a straight-line basis over the requisite service period as if the award was, in substance, a single award. The Company recognizes the impact of forfeitures in the period that the forfeiture occurs, rather than estimating the number of awards that are not expected to vest in accounting for share-based compensation. For stock options that are voluntarily surrendered by employees, all unrecognized compensation is immediately recognized in the period the options are cancelled.

For stock options with vesting that is dependent on achieving certain market, performance and service conditions ("Hybrid Options"), the Company recognizes compensation expense over the requisite service period beginning on the date when the performance condition is considered probable of occurrence. The Company determines the requisite service period as the longest of the derived, implicit and explicit vesting periods for each of the market, performance and service conditions, respectively. If the Hybrid Options do not ultimately become exercisable due to the failure of the option holder to achieve the requisite service period, any previously recognized compensation cost is reversed. However, if the Hybrid Options do not ultimately become exercisable due to the failure to achieve the market condition, previously recognized compensation cost will not be reversed.

Embedded Derivatives

When the Company enters into a financial instrument such as a debt or equity agreement (the "Host Contract"), the Company assesses whether the economic characteristics of any embedded features would meet the definition of a derivative instrument, and if so whether the features are considered clearly and closely related to the primary economic

characteristics of the Host Contract. When it is determined that (i) an embedded feature possesses economic characteristics that are not clearly and closely related to the primary economic characteristics of the Host Contract, and (ii) a separate, stand-alone instrument with the same terms would meet the definition of a financial derivative instrument and cannot be classified in shareholders' equity, then the embedded feature is bifurcated from the Host Contract and accounted for as a derivative liability. The estimated fair value of the derivative feature is recorded separately from the carrying value of the Host Contract, with subsequent changes in the estimated fair value recorded as a non-operating gain or loss in the Company's consolidated statements of operations.

Governmental Assistance

In response to the COVID-19 pandemic, the United States government designed programs to assist businesses in dealing with the financial hardships caused by the pandemic. The Company recognizes the right to receive governmental assistance payments in the period in which all necessary legal requirements have been met and other related conditions on which they depend are substantially met.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that are in effect when the differences are expected to be recovered or settled. Realization of deferred income tax assets is dependent upon future taxable income. A valuation allowance is recognized if it is more likely than not that some portion or all of a deferred income tax asset will not be realized based on the weight of available evidence, including expected future earnings.

The Company recognizes uncertain tax position in its financial statements when it concludes that a tax position is more likely than not to be sustained upon examination based solely on its technical merits. Only after a tax position passes the first step of recognition will measurement be required. Under the measurement step, the tax benefit is measured as the largest amount of benefit that is more likely than not to be realized upon effective settlement. This is determined on a cumulative probability basis. The full impact of any change in recognition or measurement is reflected in the period in which such change occurs. Interest and penalties related to income taxes are recognized in the provision for income taxes.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of outstanding shares of common stock and pre-funded warrants that are accounted for as equity instruments. Common shares associated with pre-funded warrants are included in the computation of both basic and diluted net loss per share since the exercise price is negligible and all of the pre-funded warrants are fully vested and exercisable. To the extent dilutive, during periods in which pre-funded warrants are accounted for as derivative liabilities, the calculation of diluted net loss per share is further adjusted to eliminate gains on changes in the fair value of such pre-funded warrants, net of related discounts upon issuance, and the related pre-funded warrant shares are included in the weighted average number of shares outstanding

Diluted net loss per share is computed using the treasury stock method by further giving effect to all potential shares of common stock, including stock options and warrants, to the extent dilutive.

For participating warrants that are entitled to participate in dividend to holders of shares of common stock, the Company applies the two-class method of allocating earnings if the impact is dilutive for the calculation of both basic and diluted net loss per share.

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Notes to Consolidated Financial Statements

Recent Accounting Pronouncements

Recently Adopted Accounting Standard. The following accounting standard was adopted in the fiscal year ended June 30, 2023:

In August 2020, FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity).* ASU 2020-06 reduces the number of accounting models for convertible debt instruments and convertible preferred stock, which results in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Additionally, ASU 2020-06 affects the diluted earnings per share calculation for instruments that may be settled in cash or shares and for convertible instruments and requires enhanced disclosures about the terms of convertible instruments and contracts in an entity's own equity. ASU 2020-06 allows entities to use a modified or full retrospective transition method and is effective for smaller reporting companies for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. The Company adopted this standard using the full retrospective transition method effective July 1, 2022. The adoption did not have any impact on the Company's consolidated financial statements.

Standards Required to be Adopted in Future Years. The following accounting standard is not yet effective but will be adopted effective on July 1, 2023:

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.* ASU 2016-13 amends the guidance on the impairment of financial instruments. This update adds an impairment model (known as the current expected credit losses model) that is based on expected losses rather than incurred losses. Under the new guidance, an entity recognizes, as an allowance, its estimate of expected credit losses. In November 2019, ASU 2016-13 was amended by ASU 2019-10, *Financial Instruments- Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)* whereby the effective date for ASU 2016-13 for smaller reporting companies is now required for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. ASU 2016-13 will be implemented during the fiscal quarter ending September 30, 2023 and will impact the Company's evaluation of impairment of investments in marketable debt securities. The Company does not expect the adoption of this accounting guidance will have a material impact on its consolidated financial statements.

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

NOTE 2 — LIQUIDITY

The Company is in the clinical stage and has not yet generated any revenues. For the fiscal year ended June 30, 2023, the Company incurred a net loss of $51.8 million and net cash used in operating activities amounted to $44.5 million. As of June 30, 2023, the Company had an accumulated deficit of $261.0 million, and the Company's capital resources consisted of cash and cash equivalents of $16.0 million, short-term investments in marketable debt securities of $85.9 million and long-term investments in marketable debt securities of $16.5 million.

As of June 30, 2023, the Company had total liabilities of $7.5 million, including total current liabilities of $5.2 million. As discussed in Note 5, the Company is subject to license agreements that provide for future contractual payments upon achievement of various milestone events. Pursuant to the XOMA License Agreement (as defined below), a $5.0 million milestone payment will be due upon dosing of the first patient in a Phase 3 clinical trial for RZ358. First patient dosing milestone for the RZ358 Phase 3 clinical trial is expected to occur within the next 12 months.

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Notes to Consolidated Financial Statements

Management believes the Company's cash and cash equivalents and investments in marketable securities will be adequate to meet the Company's contractual obligations and carry out ongoing clinical trials and other planned activities through September 2024, at a minimum.

NOTE 3 — INVESTMENTS IN MARKETABLE DEBT SECURITIES

The estimated fair value of investments in marketable debt securities are classified as follows in the consolidated balance sheet as of June 30, 2023 (in thousands):

	2023
Short-term investments	$ 85,860
Long-term investments	16,470
Total investments	$ 102,330

The Company only invests in liquid, high quality debt securities. However, all of these investments are subject to interest rate and credit risk that may result in fluctuations in the fair value of the investments. To minimize the exposure due to an adverse shift in interest rates, the Company generally invests in securities with expected maturities of two years or less and maintains a weighted average maturity of one year or less. As of June 30, 2023 investments in marketable debt securities with a fair value of $85.9 million are scheduled to mature during the 12-month period ending June 30, 2024 and substantially all of the remaining investments with a fair value of $16.5 million, are scheduled to mature during the 12-month period ending June 30, 2025.

During the fiscal year ended June 30, 2023, no securities classified as available-for-sale were sold and the only redemptions occurred were as a result of the maturity of the respective investments. During the fiscal year ended June 30, 2022, the Company did not have any investments in marketable debt securities.

Accrued interest receivable on all marketable debt securities amounted to $0.3 million which is included in other current assets in the accompanying consolidated balance sheet as of June 30, 2023.

The following table summarizes the unrealized gains and losses that result in differences between the amortized cost basis and fair value of the Company's marketable debt securities held as of June 30, 2023 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate commercial paper	$ 41,670	$ —	$ (73)	$ 41,597
Obligations of U.S. government agencies	26,565	—	(170)	26,395
U.S. Treasury obligations	10,416	2	(14)	10,404
Corporate notes and bonds	19,253	1	(14)	19,240
Asset-backed securities	4,777	—	(83)	4,694
Available-for-sale investments	$ 102,681	$ 3	$ (354)	$ 102,330

NOTE 4 — LEASES

In April 2022, the Company entered into a lease agreement for a new corporate headquarters in Redwood City, California. The space consists of approximately 9,300 square feet and provides for total base rent payments of approximately $2.9 million through the expected expiration of the lease in November 2027. Prior to occupancy, the landlord was required to make improvements to the facility that were completed in October 2022, triggering the commencement of the lease. The lease provided for a six-month rent abatement period beginning upon commencement of the lease term. In addition, the lease provided an allowance of approximately $0.1 million that was utilized by the Company for the purchase of furniture and equipment. The average base rent payable in cash over the 60-month lease term is approximately $48,000 per month.

Upon commencement of the lease, the Company recognized a right-of-use asset for approximately $2.3 million, and a related operating lease liability for approximately $2.2 million.

As of June 30, 2023 and 2022, the carrying values of all of the Company's right-of-use assets and operating lease liabilities were as follows (in thousands):

	2023	2022
Right-of-use assets	$ 2,054	$ 152
Operating lease liabilities:		
Current	$ 541	$ 108
Long-term	1,937	80
Total	$ 2,478	$ 188

For the fiscal years ended June 30, 2023 and 2022, operating lease expense was as follows (in thousands):

	2023	2022
Research and development	$ 453	$ 289
General and administrative	154	103
Total	$ 607	$ 392

As of June 30, 2023, the weighted-average remaining lease term under operating leases was 4.3 years, and the weighted-average discount rate used to determine the operating lease liabilities was 6.8%.

Future Lease Payments

Future payments under operating lease agreements as of June 30, 2023 are as follows (in thousands):

Fiscal year ending June 30,	
2024	$ 689
2025	627
2026	646
2027	666
Thereafter	224
Total lease payments	2,852
Less imputed interest	(374)
Present value of operating lease liabilities	$ 2,478

NOTE 5 —LICENSE AGREEMENTS

XOMA License Agreement

In December 2017, the Company entered into a license agreement ("XOMA License Agreement") with XOMA Corporation ("XOMA"), through its wholly-owned subsidiary, XOMA (U.S.) LLC, pursuant to which XOMA granted an exclusive global license to the Company to develop and commercialize XOMA 358 (formerly X358, now RZ358) for all indications.

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In January 2022, the Company was required to make a milestone payment under the XOMA License Agreement of $2.0 million that became due upon the dosing of the last patient in the Company's ongoing Phase 2b Clinical Trial for RZ358. Upon the achievement of certain clinical and regulatory events under the XOMA License Agreement, the Company will be required to make additional milestone payments to XOMA up to $35.0 million. After the clinical and regulatory milestones, the Company will be required, upon the future commercialization of RZ358, to pay royalties to XOMA based on the net sales of the related products and additional milestone payments to XOMA up to $185.0 million related to annual net sales amounts. There have been no events that would result in any royalty payments owed under the XOMA License Agreement to date. The next milestone payment of $5.0 million will be due upon dosing of the first patient in a Phase 3 clinical trial for RZ358.

ActiveSite License Agreement

In August 2017, the Company entered into a Development and License Agreement (the "ActiveSite License Agreement") with ActiveSite Pharmaceuticals, Inc. ("ActiveSite") pursuant to which the Company acquired the rights to ActiveSite's Plasma Kallikrein Inhibitor program ("PKI Portfolio"). The Company is initially using the PKI Portfolio to develop an oral PKI therapeutic for diabetic macular edema (RZ402) and may use the PKI Portfolio to develop other therapeutics for different indications. The ActiveSite Development and License Agreement requires various milestone payments up to $46.5 million if all milestone events are achieved. The first milestone payment for $1.0 million was paid in December 2020 after clearance was received for an Initial Drug Application, or IND, filed with the U.S. Food and Drug Administration ("FDA"). The second milestone payment of $3.0 million was paid in February 2023 after dosing of the first patient in a Phase 2 clinical trial for RZ402. The next milestone payment of $5.0 million will be due upon the first dosing of a patient in a Phase 3 clinical trial. The Company is also required to pay royalties equal to 2.0% of any sales of products that use the PKI Portfolio. There have been no events that would result in any royalty payments owed under the ActiveSite License Agreement to date.

NOTE 6 — EMBEDDED DERIVATIVE LIABILITY

On April 14, 2021, the Company entered into a $30.0 million Loan and Security Agreement (the "Loan Agreement") with SLR Investment Corp. ("SLR") and certain other lenders (collectively, the "Lenders"). The Lenders agreed to loan up to $30.0 million but the actual amount borrowed by the Company amounted to $15.0 million. The maturity date of the outstanding borrowings was April 1, 2026 (the "Maturity Date"), but the Company elected to repay the entire amount and terminated the Loan Agreement on June 30, 2022. Accordingly, the Company paid a total of $16.0 million consisting of the outstanding principal of $15.0 million, the Final Fee of $0.7 million and the prepayment fee of $0.3 million. As of June 30, 2022, a loss on extinguishment of the Loan Agreement of $1.8 million was recognized for the unaccreted discount of $1.5 million and the 2.00% prepayment penalty of $0.3 million.

Concurrently with the execution of the Loan Agreement, the Company entered into an exit fee agreement (the "Exit Fee Agreement") that provides for a fee of 4.00% of the funded principal balance for a total of $0.6 million in the event certain transactions (defined as "Exit Events") occur prior to April 13, 2031. The Exit Fee was not impacted by termination of the Loan Agreement discussed above. The Company is accounting for the Exit Fee Agreement as an embedded derivative liability with an estimated fair value of $0.4 million as of June 30, 2023 and 2022. Exit Events include, but are not limited to, sales of substantially all assets, certain mergers, change of control transactions, and issuances of common stock that result in new investors owning more than 35% of the Company's shares. Fair value of embedded derivatives is assessed at the end of each reporting period with changes in fair value recognized as a nonoperating gain or loss.

NOTE 7 — DERIVATIVE LIABILITY FOR AUTHORIZED SHARE DEFICIENCIES

As discussed in Note 8, the Company completed an underwritten offering in May 2022 that resulted in the issuance of 10,947,371 Class B pre-funded warrants ("Class B PFWs") for gross proceeds of approximately $41.6 million or $3.80 per share. Exercisability of the Class B PFWs was subject to the Company's ability to obtain shareholder approval for an

increase in authorized shares. Since the ability to obtain shareholder approval was outside the Company's control, liability classification was required beginning on the date of issuance of the Class B PFWs on May 4, 2022.

The fair value of approximately $41.6 million related to the Class B PFWs on the date of issuance was accounted for as a derivative liability beginning on May 4, 2022. As discussed in Note 8, the Company's shareholders approved an increase in authorized shares from 40.0 million shares to 100.0 million shares on June 16, 2022. Upon receipt of shareholder approval for the authorized share increase, fair value of the derivative liability had decreased to $35.0 million or $3.20 per share, which resulted in a gain of $6.6 million. This gain is included in non-operating income and the derivative liability of $35.0 million was reclassified into shareholders' equity on June 16, 2022. Underwriter discounts of approximately $2.5 million related to the Class B PFWs were expensed on the date of issuance since the fair value of the Class B PFWs exceeded the net proceeds received by the Company. Fair value of the Class B PFWs was determined using the BSM option-pricing model with the following assumptions as of June 16, 2022:

Market price of common stock	$ 3.20
Exercise price	$ 0.001
Risk-free interest rate	3.3 %
Dividend rate	0.0 %
Remaining expected term (years)	9.9
Historical volatility	95.0 %

NOTE 8 — SHAREHOLDERS' EQUITY

Changes in Authorized Capital Stock

On June 16, 2022, the Company's shareholders approved an increase of authorized shares from 40.0 million shares to 100.0 million shares of common stock. Accordingly, as of June 30, 2023 and 2022, the Company was authorized to issue 100.0 million shares of common stock and 0.4 million shares of preferred stock.

May 2022 Registered Direct Offering

On May 1, 2022, the Company entered into (i) an underwriting agreement with Jefferies LLC, as representative of the underwriters listed therein, relating to the issuance and sale of equity securities in an underwritten registered direct offering (the "2022 RDO"), and (ii) a placement agency agreement with Jefferies LLC, that provided for a private placement of equity securities (the "2022 Private Placement"). The 2022 RDO resulted in the issuance of (i) approximately 18.0 million shares of the Company's common stock, at a public offering price of $3.80 per share, (ii) Class A pre-funded warrants (the "Class A PFWs") to purchase up to approximately 2.0 million shares of common stock at a public offering price of $3.799 per Class A PFW and (iii) Class B PFWs to purchase up to 10.9 million shares of common stock at a public offering price of $3.799 per Class B PFW. The gross amount of the 2022 RDO was $117.6 million, before deducting an aggregate of $7.1 million incurred for underwriting discounts and approximately $0.4 million for professional fees and other offering expenses payable by the Company. The 2022 RDO closed on May 4, 2022 and the Company received net proceeds of approximately $110.5 million. In connection with the 2022 RDO, certain of the Company's officers and directors agreed not to sell or otherwise dispose of any common stock held by them through July 30, 2022.

2022 Private Placement

Pursuant to the 2022 Private Placement, the Company entered into a securities purchase agreement ("SPA") on May 4, 2022 with Handok, Inc. ("Handok"), an entity affiliated with a member of the Board of Directors, and certain of Handok's affiliates (collectively, the "Purchasers"). Contingent upon satisfaction of certain closing conditions set forth in the SPA, the Company agreed to sell to the Purchasers 3.2 million shares of common stock at a price of $3.80 per share. In July 2022 the Company entered into amended SPAs for the 2022 Private Placement resulting in gross proceeds of approximately $12.3 million in exchange for approximately 3.2 million shares of common stock. The Company incurred

approximately $0.8 million for underwriting commissions and other offering costs resulting in net proceeds of $11.6 million.

2022 Pre-Funded Warrants

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

Each Class A PFW is exercisable upon issuance. The Class B PFWs became exercisable for shares of common stock upon receipt of shareholder approval for an increase in the number of authorized shares of common stock as discussed below under the caption *Required Shareholder Approval*. As of June 30, 2023, none of the 2022 PFWs have been exercised.

Required Shareholder Approval

The closing of the 2022 RDO resulted in the issuance of approximately 18.0 million shares of common stock and Class A PFWs exercisable for approximately 2.0 million shares. After these issuances, the Company had utilized the entire 40.0 million of authorized shares of common stock that were available under its corporate charter, consisting of issued shares and shares of common stock reserved for issuance under stock option plans and outstanding warrants. Accordingly, the Company did not have a sufficient number of shares of common stock available to permit exercise of any of the Class B PFWs. Accordingly, the Class B PFWs were only exercisable for shares of common stock to the extent that shareholders subsequently approved an increase in the number of authorized shares (the "Shareholder Approval"), which the Company was required to use its best efforts to obtain at an annual meeting of shareholders to be held by June 30, 2022. As noted under the caption *Changes in Authorized Capital Stock* the Company obtained shareholder approval for an increase of authorized shares on June 16, 2022. As of June 30, 2023, the 10.9 million Class B PFWs issued were fully exercisable and no shares underlying the Class B PFWs had been exercised.

Upon closing of the 2022 RDO on May 4, 2022, the Company accounted for the gross proceeds of $41.6 million received from the issuance of the Class B PFWs as a derivative liability. As a result of subsequent reductions in the fair value of this derivative liability, the Company recognized a gain of $6.6 million through June 16, 2022 when Shareholder Approval was obtained. Upon receipt of Shareholder Approval for the increase in authorized shares to 100.0 million shares, the Company reclassified the related Class B PFW derivative liability of $35.0 million to shareholders' equity.

Registration Rights Agreement

In connection with the offer of the Class B PFWs, the Company entered into registration rights agreements with the purchasers. As required by the registration rights agreements, the Company filed a registration statement in June 2022 that was declared effective on July 1, 2022 to register the shares issuable upon exercise of the Class B PFWs. If the Company fails to comply with the registration rights agreement, it will be obligated to pay 2.0% of the purchase price of the Class B PFWs for an aggregate of approximately $0.8 million as liquidated damages. If liquidated damage payments are required in the future, they will be charged to expense in the period incurred.

2021 Underwritten Public Offering

On October 12, 2021, the Company entered into an underwriting agreement with Oppenheimer & Co., Inc., as representative of the underwriters listed therein (the "2021 Underwriters") for the planned issuance and sale of equity

securities in an underwritten public offering (the "2021 Underwritten Offering"). On October 15, 2021, closing occurred for the Underwritten Offering resulting in the issuance of (i) 6,030,847 shares of common stock at $6.50 per share for gross proceeds of $39.2 million, and (ii) 1,661,461 pre-funded warrants to purchase 1,661,461 shares of common stock at an issuance price of $6.49 per warrant (the "2021 PFWs") for gross proceeds of $10.8 million. The aggregate gross proceeds from the Underwritten Offering amounted to $50.0 million, excluding the Underwriters' Option discussed below, and before deductions for underwriting commissions of 6.0% of the gross proceeds and other offering costs of approximately $0.3 million. After deducting total offering costs of $3.3 million, the net proceeds of the Underwritten Offering amounted to approximately $46.7 million.

The Company granted the 2021 Underwriters a 30-day option to purchase up to an additional 1,153,845 shares of its common stock in the 2021 Underwritten Offering at a public offering price of $6.50 per share, less underwriting commissions (the "Underwriters' Option"). In November 2021, the Underwriters' Option was partially exercised for 116,266 shares resulting in gross proceeds of approximately $0.8 million.

2021 Pre-Funded Warrants

The 2021 PFWs have an exercise price of $0.01 per share, which is subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. Each 2021 PFW is exercisable at any time and from time to time after issuance with no stated expiration date. In the event of certain corporate transactions, the holders of the 2021 PFWs will be entitled to receive, upon exercise of the 2021 PFWs, the kind and amount of securities, cash or other property that the holders would have received had they exercised the 2021 PFWs immediately prior to such transaction. The 2021 PFWs do not entitle the holders thereof to any voting rights or any of the other rights or privileges to which holders of common stock are entitled.

The gross proceeds of $10.8 million received from issuance of the 2021 PFWs was recorded as a component of shareholders' equity within additional paid-in capital. In accordance with the terms of the warrant agreement, holders of the outstanding warrants are not entitled to exercise any portion of the 2021 PFWs if, upon exercise of such portion of the warrant, the holder's aggregate ownership of the Company's common stock or the combined voting power beneficially owned by such holder would exceed a designated percentage elected by the holder ranging from 4.99% to 19.99%, after giving effect to the exercise (the "Maximum Ownership Percentage"). Upon at least 61 days' prior notice to the Company, any warrant holder may elect to increase or decrease the Maximum Ownership Percentage to any other percentage not to exceed 19.99%. Through June 30, 2023, no shares underlying the 2021 PFWs have been exercised.

2021 Registered Direct Offering

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

Termination of EDA and Purchase Agreement

The Company entered an Equity Distribution Agreement ("EDA") with Oppenheimer & Co. Inc. ("Oppenheimer") in December 2020 and a purchase agreement ("Purchase Agreement") with Lincoln Park Capital Fund, LLC ("LPC") in August 2021. The Company sold 138,388 shares of its common stock pursuant to the EDA for net proceeds of approximately $1.5 million. From August 2021 through September 2021, LPC purchased 115,708 shares of common stock for gross proceeds of approximately $1.2 million. Concurrently, the Company issued 33,799 shares of common stock to LPC as an initial fee for its commitment to purchase shares under the Purchase Agreement. In May 2022, the Company provided notices to Oppenheimer and LPC whereby the EDA and the Purchase Agreement were terminated. As a result of these termination notices, no further equity securities are issuable under either agreement.

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NOTE 9 — SHARE-BASED COMPENSATION AND WARRANTS

Stock Option Plans

Presented below is a summary of the number of shares authorized, outstanding, and available for future grants under each of the Company's stock option plans as of June 30, 2023 (in thousands):

Description	Plan Termination Date	Number of Shares		
		Authorized	Outstanding	Available
2015 Plan	February 2020	17	17	—
2016 Plan	October 2021	140	140	—
2019 Plan	July 2029	200	200	—
2021 Plan	March 2031	10,700	8,388	2,312
Total		11,057	8,745	2,312

The Company currently has one active stock option plan, the 2021 Equity Incentive Plan (the "2021 Equity Plan"). On March 31, 2021, the Company's Board of Directors adopted the 2021 Equity Plan that will terminate on March 31, 2031. On May 26, 2021, the 2021 Equity plan was approved by the Company's shareholders with authority to issue up to 1.2 million shares of common stock. Pursuant to the 2021 Equity Plan, no awards may be granted under the three legacy stock option plans shown in the table above, but all outstanding awards previously granted under those plans shall remain outstanding and subject to the terms of the respective plans. On June 16, 2022, the Company's shareholders approved an amendment to the 2021 Equity Plan, increasing the number of shares of common stock to be issued under the plan up to 10.7 million shares of common stock. Stock options outstanding under these plans expire pursuant to their contractual provisions on various dates through 2033.

2022 Employee Stock Purchase Plan

On June 16, 2022, the Company's shareholders approved the adoption of the 2022 Employee Stock Purchase Plan (the "2022 ESPP"). The 2022 ESPP provides an opportunity for employees to purchase shares of the Company's common stock through accumulated payroll deductions.

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The 2022 ESPP has consecutive offering periods that begin approximately every 6 months commencing on the first trading day on or after July 1 and terminating on the last trading day of the offering period ending on December 31 and commencing on the first trading day on or after January 1 and terminating on the last trading day of the offering period ending on June 30. The 2022 ESPP reserves 0.5 million shares for purchases. There have been no offering periods under the 2022 ESPP through June 30, 2023.

Stock Options Outstanding

The following table sets forth a summary of the combined activity under all of the Company's stock option plans for the fiscal years ended June 30, 2023 and 2022 (shares in thousands):

	2023			2022		
	Shares	Price [1]	Term [2]	Shares	Price [1]	Term [2]
Outstanding, beginning of fiscal year	8,506	$ 5.24	9.7	1,285	$ 16.35	8.7
Grants to employees	740	2.00		7,373	3.51	
Expired	(116)	40.73		(78)	19.03	
Forfeited	(385)	3.75		(74)	9.72	
Outstanding, end of fiscal year	8,745	4.56	8.8	8,506	5.24	9.7
Vested, end of fiscal year	2,676	6.57	8.4	685	18.63	7.5

(1) Represents the weighted average exercise price.

(2) Represents the weighted average remaining contractual term until the stock options expire.

For the fiscal year ended June 30, 2023, the aggregate fair value of stock options granted for approximately 0.7 million shares of common stock amounted to $1.1 million or approximately $1.53 per share as of the grant dates. For the fiscal year ended June 30, 2022, the aggregate fair value of stock options granted for approximately 7.4 million shares of common stock amounted to $20.1 million or approximately $2.72 per share as of the grant dates. Fair value was computed using the BSM option-pricing model and will result in the recognition of compensation cost ratably over the expected vesting period of the stock options. The fair value of stock options was estimated on the dates of grant using the BSM option-pricing model, with the following weighted-average assumptions for the fiscal years ended June 30, 2023 and 2022:

	2023	2022
Market price of common stock on grant date	$ 3.73	$ 3.51
Expected volatility	91 %	94 %
Risk free interest rate	3.7 %	3.1 %
Expected term (years)	6.0	6.1
Dividend yield	0 %	0 %

Share-based compensation expense is included under the following captions in the consolidated statements of operations for the fiscal years ended June 30, 2023 and 2022 (in thousands):

	2023	2022
Research and development	$ 3,243	$ 1,405
General and administrative	4,025	2,280
Total	$ 7,268	$ 3,685

Unrecognized share-based compensation expense for stock options that provide solely for time-based vesting as of June 30, 2023 was approximately $16.9 million. This amount is expected to be recognized over a remaining weighted average period of 2.8 years. As of June 30, 2023, unrecognized compensation of $0.1 million related to the remaining Hybrid Options is being recognized ratably over a weighted average period of 1.1 years.

Pre-Funded Warrants

In connection with the 2021 RDO discussed in Note 8, the Company issued 2021 PFWs to purchase 1,661,461 shares of common stock at an issuance price of $6.49 per warrant for gross proceeds of $10.8 million. The 2021 PFWs may be exercised at any time by paying the exercise price of $0.01 per share, subject to the terms discussed in Note 8.

In connection with the 2022 RDO discussed in Note 8, the Company issued 1,973,684 Class A PFWs and 10,947,371 Class B PFWs to purchase an aggregate of 12,921,055 shares of common stock at an issuance price of $3.799 per warrant. As of June 30, 2023 all of the Class A PFWs and Class B PFWs may be exercised at any time by paying the exercise price of $0.001 per share, subject to the terms discussed in Note 8.

Other Warrants

In connection with an equity financing in October 2020, the Company issued warrants entitling the holders to purchase approximately 0.8 million shares of common stock. The warrants are exercisable at $19.50 per share for a period of seven years, may be exercised on a cash or cashless basis at the election of the holders, and holders are entitled to share in any dividends or distributions payable to holders of common stock on an as-converted basis (the "Participating Warrants"). Additionally, the Company has issued warrants to purchase shares of common stock in conjunction with other debt and equity financings and for services. As of June 30, 2023 and 2022, all of the warrants were vested. For the fiscal years ended June 30, 2023 and 2022, no warrants were granted or exercised. Excluding the pre-funded warrants discussed above, the following table summarizes activity for all other warrants for the fiscal years ended June 30, 2023 and 2022 (shares in thousands):

	2023			2022		
	Shares	Price [1]	Term [2]	Shares	Price [1]	Term [2]
Outstanding, beginning of fiscal year	1,150	$ 22.83	4.2	1,252	$ 28.91	4.8
Expirations	(262)	25.32		(102)	97.79	
Outstanding, end of fiscal year	888	22.10	3.5	1,150	22.83	4.2

(1) Represents the weighted average exercise price.

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

NOTE 10 — INCOME TAXES

Net Operating Loss Carryforwards

The Company files income tax returns in the U.S. federal jurisdiction and in several states including California, Colorado, and Oregon. The Company's federal and state tax returns for the 2020 fiscal year and forward are subject to examination by taxing authorities. Federal and state laws impose substantial restrictions on the utilization of federal net operation loss ("NOL") carryforwards in the event of an ownership change for income tax purposes, as defined in Section 382 of the Internal Revenue Code ("IRC"). Pursuant to IRC Section 382, annual use of the Company's NOL carryforwards is limited in the event that a cumulative change in ownership of more than 50% occurs within a three-year period. During the fiscal year ended June 30, 2022, the Company completed an IRC Section 382 analysis and concluded that the Company's NOL carryforwards are subject to limitations as a result of past ownership changes.

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As of June 30, 2023, the Company has U.S. federal net operating loss ("NOL") carryforwards of approximately $153.2 million, of which approximately $33.4 million of NOL carryforwards will never be available for use due to the limitations under IRC section 382 discussed above. The remainder of the Company's NOL carryforwards of $119.8 million consists of (i) $17.1 million that never expires and is currently available to offset taxable income, (ii) $7.9 million that is currently available to offset taxable income but if not utilized expires in 2031 through 2035, (iii) $13.4 million that become available through fiscal year 2038 and that expires by June 30, 2038 if not utilized, and (iv) $81.4 million that never expires. With respect to the $81.4 million of NOL carryforwards that never expire, this amount will become available in varying annual amounts for an aggregate approximately $15.6 million through fiscal year 2038 and $1.2 million annually thereafter. If the Company experiences future ownership changes that meet the aforementioned criteria under Section 382, further limitations will be imposed on the use of all NOL carryforwards existing through the date of such change. The Company also has Colorado and California NOL carryforwards that begin to expire in 2031 and are expected to be subject to similar limitations as those imposed under IRC Section 382.

Income Tax Expense

For the fiscal years ended June 30, 2023 and 2022, the reconciliation between the income tax benefit computed by applying the statutory U.S. federal income tax rate to the pre-tax loss before income taxes, and total income tax expense recognized in the consolidated financial statements is as follows (in thousands):

	2023	2022
Income tax benefit at statutory US federal rate	$ 10,875	$ 8,622
Income tax benefit attributable to US states	3,468	3,151
Impact of reduction in Colorado tax rate	(78)	—
Non-taxable derivative gains	—	1,379
Non-deductible expenses	(442)	(527)
Stock option expirations	(921)	(332)
Other	(399)	25
Change in valuation allowance	(12,503)	(12,318)
Total income tax expense	$ —	$ —

For the fiscal years ended June 30, 2023 and 2022, the Company did not recognize any current income tax expense or benefit due to a full valuation allowance on its net deferred income tax assets.

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Deferred Income Tax Assets and Liabilities

As of June 30, 2023 and 2022, the income tax effects of temporary differences that give rise to significant deferred income tax assets and liabilities are as follows (in thousands):

	2023	2022
Deferred income tax assets:		
Net operating loss carryforwards	$ 40,537	$ 38,361
Research and experimental costs	9,454	—
Intangible assets	5,595	5,215
Share-based compensation	2,884	2,725
Operating lease liabilities	694	—
Accrued expenses and other	603	293
Total deferred income tax assets	59,767	46,594
Valuation allowance for deferred income tax assets	(59,192)	(46,594)
Deferred income tax assets, net of valuation allowance	575	—
Deferred income tax liability right-of-use assets	(575)	—
Net deferred income tax assets	$ —	$ —

For the fiscal year ended June 30, 2023, the valuation allowance increased by $12.5 million, primarily as a result of the increase in net operating losses and capitalization of research and experimental costs that was required beginning in the fiscal year ended June 30, 2023. In assessing the realizability of deferred income tax assets, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized.

Unrecognized Tax Benefits

The Company did not have any unrecognized tax benefits as of June 30, 2023 and 2022. The Company's policy is to account for any interest expense and penalties for unrecognized tax benefits as part of the income tax provision. The Company does not anticipate that unrecognized tax benefits will significantly increase or decrease within the next twelve months.

NOTE 11 — COMMITMENTS AND CONTINGENCIES

Licensing Commitments

Please refer to Note 5 for further discussion of commitments to make milestone payments and to pay royalties under license agreements with XOMA and ActiveSite.

Employment Agreements

As of June 30, 2023, the Company was subject to employment agreements with two officers of the Company and one employee of the Company that provide for aggregate annual base salaries of $1.4 million.

The agreements with the Chief Executive Officer and Chief Medical Officer provides that if either of individuals is terminated outside of a change in control event and without cause, (i) all of their stock options that are subject to ongoing vesting conditions over subsequent periods ranging from 12 to 18 months will immediately vest, and (ii) such stock options will remain exercisable for periods ranging from 6 to 12 months following the occurrence of the termination event. In addition, if either or both of the executive officers are terminated solely due to a change of control event, all of their

respective unvested stock options will immediately vest and all outstanding stock options will remain exercisable for periods ranging from 6 to 12 months following the occurrence of the termination event.

The amendment to the Chief Medical Officer's employment agreement provides that upon the occurrence of a termination event other than a change of control, the Company is required to (i) make severance payments equal to 12 months of salary, a pro-rata bonus, and health insurance coverage for 12 months following the termination date, and (ii) all unvested stock options subject to vest over the subsequent 12 month period after the termination event will become immediately exercisable and all outstanding stock options will remain exercisable for 6 months following the termination event. In addition, upon the occurrence of a termination solely due to a change of control event, the Company is required to (i) make severance payments equal to 18 months of salary, a pro-rata bonus, and health insurance coverage for 18 months following the termination event.

401(k) Plan

The Company has a defined contribution employee benefit plan under section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all eligible employees who are entitled to participate six months after the commencement of employment. The Company matches contributions up to 4% of the participating employee's compensation with such matching contributions vested immediately. Total contributions by the Company to the 401(k) Plan amounted to approximately $0.3 million and $0.2 million for the fiscal years ended June 30, 2023 and 2022, respectively.

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, 2023, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the Company's results of operations. At each reporting period, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under ASC 450, *Contingencies*. Legal fees are expensed as incurred.

NOTE 12 — RELATED PARTY TRANSACTIONS

Related Party Licensing Agreement

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

Investors in Registered Direct Offerings

In connection with the 2021 Underwritten Offering discussed in Note 8, a group of affiliated investors purchased approximately (i)1,930,000 shares of common stock at $6.50 per share for a total of $12.5 million, and (ii) 2021 PFWs exercisable for the purchase of 123,000 shares at $6.49 per 2021 PFW for a total issuance price of $0.8 million.

In connection with the 2022 RDO discussed in Note 8, certain officers and directors of the Company purchased 111,840 shares of common stock at $3.80 per share for a total of $0.4 million. In addition, the group of affiliated investors discussed above purchased (i) 3,421,052 shares of common stock at $3.80 per share for a total of $12.2 million, and (ii) 3,421,053 Class B PFWs at $3.799 each for a total of $12.2 million.

Investors in 2022 Private Placement

Handok and certain of its affiliates were the sole investors in the 2022 Private Placement and the Registered Direct Offering discussed in Note 7.

NOTE 13 - SUPPLEMENTAL FINANCIAL INFORMATION

Cash and cash equivalents

Cash and cash equivalents consist of the following as of June 30, 2023 and 2022 (in thousands):

	2023	2022
Demand deposits at a single financial institution	$ 6,091	$ 150,410
Money market funds	5,464	—
Commercial paper	4,481	—
Total	$ 16,036	$ 150,410

The money market funds and commercial paper included in the table above were purchased with an original maturity of three months or less. These investments and the demand deposits are freely available for the Company's immediate and general business use.

Property and Equipment

Property and equipment consisted of the following as of June 30, 2023 and 2022 (in thousands):

	2023	2022
Office furniture and equipment	$ 210	$ 56
Less accumulated depreciation	(71)	(40)
Total	$ 139	$ 16

Depreciation expense related to property and equipment amounted to approximately $30,000 and $13,000 for the fiscal years ended June 30, 2023 and 2022, respectively.

NOTE 14 — NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss by the weighted average number of outstanding shares of common stock and pre-funded warrants that are accounted for as equity instruments. For the calculation of diluted net loss per share for the fiscal year ended June 30, 2022, since the impact of accounting for the pre-funded warrants as derivative liabilities was dilutive, the numerator was adjusted to eliminate gains on changes in fair value of such pre-funded warrants, and the denominator was adjusted to include the related pre-funded warrant shares.

Calculation of the weighted average number of shares outstanding for purposes of diluted net loss per share is also required to include the dilutive effect, if any, of stock options, warrants, and other common stock equivalents computed using the treasury stock method. For the fiscal years ended June 30, 2023 and 2022, all of such common stock equivalents were

antidilutive and exclude from the calculations. In addition, the impact of applying the two-class method related to the Participating Warrants, was antidilutive for the calculation of both basic and diluted net loss per share.

Presented below are the calculations of the numerators and the denominators for basic and diluted net loss per share for the fiscal years ended June 30, 2023 and 2022 (in thousands except per share amounts):

	2023	2022
Calculation of Numerators:		
Net loss for calculation of basic net loss per share	$ (51,787)	$ (41,060)
Dilutive derivative gains, net of losses, related to Class B PFWs:		
Gain from change in fair value of derivative liability	—	(6,565) (1)
Underwriting discount on issuance of derivative	—	2,495 (1)
Net loss for the calculation of diluted net loss per share	$ (51,787)	$ (45,130)
Calculation of Denominators:		
Weighted Average number of common shares outstanding	36,605	16,254
Weighted average shares related to pre-funded warrants:		
2021 PFWs	1,661 (6)	1,179 (2)
Class A PFWs	1,974 (6)	314 (3)
Class B PFWs	10,947 (6)	450 (4)
Weighted average shares for basic net loss per share	51,187	18,197
Weighted average adjustment for Class B PFWs	—	1,290 (5)
Weighted average shares for diluted net loss per share	51,187	19,487
Net loss per share of common stock:		
Basic	$ (1.01)	$ (2.26)
Diluted	$ (1.01)	$ (2.32)

(1) For the calculation of diluted net loss per share, the net impact of the discount expense and the derivative gain related to the Class B PFWs is dilutive and has been eliminated from the denominator for the period from the issuance date on May 4, 2022 through June 16, 2022, when the fair value of the Class B PFWs was reclassified to stockholders' equity.

(2) Represents the weighted average number of shares related to the 2021 PFWs discussed in Note 8 for the period from the issuance date on October 15, 2021 through June 30, 2022.

(3) Represents the weighted average number of shares related to the Class A PFWs discussed in Note 8 for the period from the issuance date on May 4, 2022 through June 30, 2022.

(4) Represents the weighted average number of shares related to the Class B PFWs discussed in Note 8 for the period when they became equity-classified on June 16, 2022 through June 30, 2022.

(5) Represents the weighted average number of shares related to the Class B PFWs discussed in Note 7 during the period when they were liability-classified from the issuance date on May 4, 2022 through June 15, 2022.

(6) Represents the number of PFWs that were outstanding for the entirety of the fiscal year ended June 30, 2023.

As of June 30, 2023 and 2022, the following potential common stock equivalents were excluded from the calculation of diluted net loss per share since the impact of inclusion was anti-dilutive (in thousands):

	2023	2022
Stock options	8,745	8,506
Other warrants	888	1,150
Total	9,633	9,656

NOTE 15 — FINANCIAL INSTRUMENTS AND SIGNIFICANT CONCENTRATIONS

Fair Value Measurements

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

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

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

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

The following table presents information about the Company's financial assets measured at fair value on a recurring basis and indicates the fair value hierarchy classification of such fair values as of June 30, 2023.

	Fair Value Measurement of Assets as of June 30, 2023			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents:				
Money market funds	$ 5,464	$ 5,464	$ —	$ —
Corporate commercial paper	4,481	4,481		
Marketable debt securities:				
Corporate commercial paper	41,597	—	41,597	—
U.S. Government agencies	26,394	—	26,394	—
U.S. Government treasuries	10,404	10,404	—	—
Corporate notes and bonds	19,240	—	19,240	—
Asset-backed securities	4,694	—	4,694	—
Total	$ 112,274	$ 20,349	$ 91,925	$ —

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Marketable debt securities classified as Level 2 within the valuation hierarchy generally consist of U.S. government agency securities, corporate bonds, and commercial paper. The Company determines the fair value of marketable debt securities based upon valuations obtained from third-party pricing sources. Except for the amounts shown in the table above, the Company did not have any other assets measured at fair value on a recurring basis as of June 30, 2023. As of June 30, 2022, the Company did not have any assets required to be measured at fair value on a recurring basis.

The derivative liabilities for the authorized share deficiencies discussed in Note 7 were classified under Level 3. These liabilities were required to be measured at fair value on a recurring basis from May 4, 2022 until June 16, 2022. Key valuation assumptions are summarized in Note 7.

The embedded derivative liabilities discussed in Note 6 were classified under Level 3 and were required to be measured at fair value on a recurring basis beginning on April 14, 2021. Fair value is determined using a discounted rate equal to the effective interest rate under the Loan Agreement and based on management's assessment of the probability that an Exit Event will occur prior to April 13, 2031.

The following table sets forth a summary of changes in the fair value of embedded derivative liabilities for which fair value was determined by Level 3 inputs for the fiscal years ended June 30, 2023 and 2022 (in thousands):

	2023	2022
Fair value, beginning of period	$ 407	$ 387
Loss from change in fair value, net	5	20
Fair value, end of period	$ 412	$ 407

Except for embedded derivative liabilities, the Company did not have any other liabilities measured at fair value on a recurring basis as of June 30, 2023 and 2022.

Due to the relatively short maturity of the respective instruments, the fair value of cash and cash equivalents, accounts payable, and accrued liabilities approximated their carrying values as of June 30, 2023 and 2022.

The Company's policy is to recognize asset or liability transfers among Level 1, Level 2 and Level 3 as of the actual date of the events or change in circumstances that caused the transfer. During the fiscal years ended June 30, 2023 and 2022, the Company did not have any transfers of its assets or liabilities between levels of the fair value hierarchy.

Significant Concentrations

Financial instruments that subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and investments in marketable debt securities. The Company maintains its cash in demand accounts at a high-quality financial institution. As of and for the fiscal years ended June 30, 2023 and 2022, cash deposits have exceeded the amount of insurance provided on such deposits by the Federal Deposit Insurance Corporation ("FDIC").

As of June 30, 2023, the Company has an aggregate of $54.0 million invested in marketable debt securities of issuers in the banking and financial services industries, and an aggregate of $26.5 million invested in marketable debt securities of a single agency of the U.S. government. While the Company's investment policy requires investments in highly rated securities, a wide variety of broad economic factors and issuer-specific factors could result in credit agency downgrades below the Company's minimum credit rating requirements that could result in losses regardless of whether the Company elects to sell the securities or hold them until maturity.

On March 10, 2023, Silicon Valley Bank ("SVB") was shut down, followed on March 11, 2023 by Signature Bank and on May 1, 2023 by First Republic Bank whereby the FDIC was appointed as receiver for each of those banks. Starting in January 2023, SVB Asset Management ("SAM"), a nonbank affiliate of SVB and a member of SVB Financial Group,

provided investment services relating to the Company's investment in marketable debt securities held in a segregated custodial account maintained by a third-party custodian, U.S. Bank. At the time of the closing of SVB, the Company had approximately $20.5 million in cash and certain cash equivalents in an Overnight Money Market Mutual Fund ("MMF"), for which SAM served as the investment advisor until April 13, 2023, when the MMF was liquidated and transferred to a similar investment under the control of a new investment advisor. The Company's investment portfolio did not and currently does not contain any securities of SVB, and the Company did not have any deposit accounts with SVB. The Company does not believe it was or will be impacted by the closure of SVB and will continue to monitor the banking industry situation as it evolves.

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 the individual that serves as both our chief executive officer and principal financial officer, 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 and 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, our chief executive officer concluded that whereby our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report.

Management's 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 all 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 as of June 30, 2023. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework (2013)*. Based on that assessment under those criteria, our management has determined that, as of June 30, 2023, our internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

Prior to the fiscal year ended June 30, 2023, we had identified a material weakness in the system of internal control that related to an inadequate segregation of duties. A material weakness is a deficiency, or combination of deficiencies, that creates a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected in a timely manner.

This material weakness previously identified by our management was that due to our limited number of employees, we had not adequately segregated certain duties to prevent employees from overriding the internal control system.

Over the past two fiscal years, we hired additional personnel which enabled us to better segregate many functions and we implemented more robust accounting software in order to facilitate stronger controls and further enable the segregation of duties. Additionally, we engaged an internal control specialist to improve the documentation of our control processes and to provide process improvements. As a result of these critical steps in our remediation efforts, we concluded that this material weakness in our internal control over financial reporting had been successfully remediated as of June 30, 2023.

Attestation Report of Independent Registered Public Accounting Firm

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to include an attestation report of our registered public accounting firm regarding internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth certain information as of June 30, 2023 with respect to our directors, executive officers and key employees. The term for each director expires at our next annual meeting or until his or her successor is appointed.

Name	Age	Position	Date Appointed
Nevan Charles Elam	55	Chief Executive Officer, Principal Financial Officer and Acting Chair of the Board of Directors	January 31, 2013
Gil Labrucherie	52	Director	November 20, 2019
Nerissa Kreher, M.D.	50	Director	March 2, 2021
Philippe Fauchet	65	Director	September 10, 2020
Wladimir Hogenhuis, M.D.	58	Director	March 2, 2021
Young-Jin Kim	66	Director	February 10, 2019
Brian Roberts, M.D.	48	Chief Medical Officer	June 1, 2022

Set forth below is biographical information with respect to each of the aforementioned individuals.

Nevan Charles Elam. Mr. Elam has served as our Chief Executive Officer since January 2013 and currently serves as our Principal Financial Officer. Mr. Elam is also serving as our Acting Chair of the Board since May 2022. Prior to Mr. Elam's service with Rezolute, he has served various leadership roles throughout his career including as Chief Executive Officer of a European medical device company, co-founder and Chief Financial Officer of a software company, as well as a Senior Vice President at Nektar Therapeutics. Earlier in his career, Mr. Elam was a corporate partner in the law firm of Wilson Sonsini Goodrich & Rosati. He serves as Director of Peak Bio, Inc. and Savara, Inc. Mr. Elam received his Juris Doctorate from Harvard Law School and a Bachelor of Arts from Howard University. We believe that Mr. Elam's experience advising pharmaceutical companies of their unique legal and regulatory obligations qualifies him to serve on the Board.

Gil Labrucherie. Mr. Labrucherie serves as a member of our Board. He brings more than 25 years of senior leadership experience in finance, legal and corporate development to the Board. Since August 2023, he is currently serving as the Chief Financial Officer of Acelyrin, Inc., a public late-stage clinical stage biotechnology company focused on auto-immune conditions, and also is the sole trustee and executive in charge of the Bloom Trust, a closely held family office with commercial real estate assets and operations. He served as Chief Financial Officer of Acelyrin, Inc., from July 2022

to November 2022. He served as Chief Financial Officer of Nektar Therapeutics, a publicly traded development stage biopharmaceutical company from 2016 to 2022, and also held the position of Chief Operating Officer from 2019 to 2022. Prior to serving as Chief Operating Officer and Chief Financial Officer of Nektar, he was Senior Vice President, General Counsel and Secretary of Nektar from 2007 to 2016. Earlier in his career, Mr. Labrucherie was an executive at different organizations where he was responsible for global corporate alliance and mergers and acquisitions. Mr. Labrucherie began his career as an associate in the corporate practice of the law firm of Wilson Sonsini Goodrich & Rosati. Mr. Labrucherie received his J.D. from University of California Berkeley School of Law, where he was a member of the California Law Review and Order of the Coif, and received his B.A., with highest honors from the University of California, Davis. Mr. Labrucherie is a CFA charter holder, a member of the State Bar of California, and a Certified Management Accountant. We believe Mr. Labrucherie's experience as the Chief Operating Officer and Chief Financial Officer of public biotechnology companies and his management background as an executive in different organizations qualify him to serve on the Board.

Nerissa Kreher, M.D., M.S., MBA. Dr. Kreher serves as a member of our Board. She has served as Chief Medical Officer of Entrada Therapeutics, Inc. since December 2020. From February 2019 to October 2020, Dr. Kreher served as Chief Medical Officer at Tiburio Therapeutics, Inc., where she was responsible for clinical development, clinical operations, regulatory and patient advocacy. From October 2016 to December 2018, Dr. Kreher served as Chief Medical Officer at Avrobio, Inc., where she oversaw clinical and regulatory development strategy for the Company's rare disease, ex vivo lentiviral gene therapy pipeline programs. From March 2015 to July 2016, Dr. Kreher served as Global Head (VP) of Clinical and Medical Affairs of Zafgen, Inc., where she was a strategic leader of a cross-functional team charged with creation of global development strategy for beloranib. Dr. Kreher is a board-certified pediatric endocrinologist and holds multiple degrees including her B.S. in biology from University of North Carolina at Chapel Hill, M.D. from East Carolina University, an M.S. in clinical research from Indiana University-Purdue University Indianapolis, and an MBA from Northeastern University Graduate School of Business Administration. We believe Dr. Kreher's experience in the pharmaceutical industry and her service as an executive and Chief Medical Officer of a range of private and publicly held companies qualify her to serve on the Board.

Philippe Fauchet. Mr. Fauchet serves as a member of our Board. Mr. Fauchet has spent more than 35 years in the pharmaceutical industry, most recently as the Chairman of GlaxoSmithKline K.K. from April 2017 to February 2019. Mr. Fauchet joined GlaxoSmithKline K.K. as President & Representative Director in 2010. Previously, he served as Senior Vice President, Corporate Business Development Head of Sanofi-Aventis Group and a member of the Management Committee. Mr. Fauchet is an external director on the board of three Japanese biotech companies and a consultant for various life sciences companies. Mr. Fauchet is a graduate of Hautes Etudes Commerciales in France and received a Bachelor of Law at Paris X University. He is an Honorary Officer of the Order of the British Empire (O.B.E.). We believe Mr. Fauchet's experience in the pharmaceutical industry as a director, consultant, and advisor qualifies him to serve on the Board.

Wladimir Hogenhuis, M.D., MBA. Dr. Hogenhuis serves as a member of our Board. He is currently the Chief Executive Officer and President of Chimera Bioengineering, where he also serves on the Board of Directors. He previously served as Chief Operating Officer of Ultragenyx Pharmaceutical Inc. (NASDAQ: RARE) with responsibilities for global commercial operations, business development, and manufacturing of medicines for patients with rare diseases. Before that, Dr. Hogenhuis served as Senior Vice President and Global Franchise Head, Specialty Pharmaceuticals of GlaxoSmithKline Plc. (LSE/NYSE: GSK), from December 2012 to September 2018. From 1994 to 2012, he served in leadership positions at Merck in the U.S., China, and Europe, where he was responsible for managing the P&L of specialty and cardiovascular care medicines. He also served as a National Institutes of Health Fellow in Medical Decision Making at New England Medical Centre in Boston, and as a Naval Lieutenant Surgeon in the Royal Dutch Navy. Dr. Hogenhuis currently serves on the board of GATT Technologies B.V., a private company in the Netherlands developing novel surgical hemostats and sealants. He previously served as a member of the Board of Directors of Vision 2020, a global initiative for the elimination of avoidable blindness, a joint program of the World Health Organization and the International Agency for the Prevention of Blindness. Dr. Hogenhuis received his M.D. Cum Laude from the University of Leiden in the Netherlands and received an M.B.A. from the Wharton School of Business at The University of Pennsylvania, Philadelphia. We believe Dr. Hogenhuis's experience in the pharmaceutical industry and his service on the board of directors of a range of private companies qualify him to serve on the Board.

Young-Jin Kim. Mr. Kim serves as a member of our Board and served as Chair of the Board until May 2022. Mr. Kim is Chairman & CEO of Handok Inc. ("Handok"), one of the leading pharmaceutical companies in the Republic of Korea. Mr. Kim also serves as Chairman of the Board of Directors of Genexine Inc. Mr. Kim joined Handok in 1984 and spent two years between 1984 and 1986 working at Hoechst AG in Frankfurt, Germany. Between 1991 and 2005, he served as CEO of Roussel Korea, Hoechst Marion Roussel Korea and Aventis Pharma Korea and also appointed as the Country Manager of Hoechst AG and Aventis in Korea between 1996 and 2005. In 1996, he was appointed as CEO of Handok. Mr. Kim has been serving as President of Handok Jeseok Foundation since 2014. He has also been serving as President of KDG (Korean-German Society) since 2010. Mr. Kim received an MBA at the Kelley School of Business at Indiana University in 1984 and received the award of Distinguished Alumni Fellows from Indiana University. Mr. Kim completed Advanced Management Program at the Harvard Business School in 1996. We believe Mr. Kim's experience working with pharmaceutical companies qualifies him to serve on the Board.

Brian Roberts, M.D. Dr. Roberts joined us in 2015 and has been serving as our Chief Medical Officer since June 1, 2022. Previously, Dr. Roberts served as Head of Clinical Development as consultant until 2017, followed by his employment as Vice President until October 23, 2020, when he was subsequently promoted to Senior Vice President of Clinical Development. Prior to joining us, Dr. Roberts directed clinical development at Fibrogen, Inc. from 2012 to 2017, where he led the successful launch and execution of the global Phase 3 program and out-licensing pharmaceutical partnership for Roxadustat, a novel oral therapy for anemia associated with kidney disease, concluding the largest Phase 3 program ever conducted in CKD anemia, and resulting in global NDA filings. During his tenure, Fibrogen achieved the largest biotech IPO in the previous 10 years. From 2007 until 2012, Dr. Roberts held clinical development positions of increasing responsibility at Metabolex, Inc., where he developed novel therapies for metabolic diseases such as diabetes, dyslipidemia, NASH, and gout. His program and clinical leadership from IND through clinical proof-of-concept helped secure a global licensing and co-development agreement with a major pharmaceutical partner for a novel diabetes therapy. He is an inventor or author on more than 25 patents and publications in the fields of Endocrinology and Metabolism. Dr. Roberts received his B.S. in biochemistry from the University of California, San Diego and his medical degree Magna Cum Laude from Georgetown University. He completed residency in Internal Medicine and fellowship in Endocrinology at Stanford University, where he also attends Endocrinology clinic and mentors trainees in his capacity as Adjunct Associate Professor in the Division of Endocrinology.

Family Relationships

There are no family relationships between any of our directors and executive officers.

Legal Proceedings

During the past ten years, none of our directors, executive officers, promoters, control persons, or nominees has been:

- the subject of any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- convicted in a criminal proceeding or is subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or any Federal or State authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities;
- found by a court of competent jurisdiction (in a civil action), the Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law;
- the subject of, or a party to, any Federal or State judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of (a) any Federal or State securities or commodities law or regulation; (b) any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order; or (c) any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

- the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act (15 U.S.C. 78c(a)(26))), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act (7 U.S.C. 1(a)(29))), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics that is applicable to all of our employees, officers and directors. The code is available on our website, *www.rezolutebio.com*, under the "Investors" tab, which was amended and restated on May 30, 2023. We intend to disclose future amendments to, or waivers from, certain provisions of our code of ethics, if any, either in (i) a Current Report on Form 8-K or (ii) on the above website within four business days following the date of such amendment or waiver.

Committees of the Board of Directors

The standing committees of our Board of Directors are the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee.

Audit Committee

The Audit Committee operates under an Audit Committee Charter that is available on our website, www.rezolutebio.com. The functions performed by our Audit Committee consist of selection of the firm of independent registered public accountants to be retained by us, periodic meetings with our independent registered public accountants to review our accounting policies and internal controls, review the scope and adequacy of the independent registered public accountants' examination of our annual financial statements, and pre-approval of services rendered by our independent registered public accountants and pre-approval of all related-party transactions.

Mr. Labrucherie serves as chair of the audit committee and along with Mr. Fauchet and Dr. Hogenhuis are "independent directors" as defined in Rule 5605(a)(2) of the Nasdaq Listing Rules. In addition, the Board determined that Mr. Labrucherie and Dr. Hogenhuis are qualified as "audit committee financial experts" as such term is used in the rules and regulations of the SEC. Our Audit Committee held four meetings during the fiscal year ended June 30, 2023.

For the fiscal year ended June 30, 2023, Mr. Labrucherie, Mr. Fauchet and Dr. Hogenhuis received additional compensation for their service as members of our Audit Committee as discussed under the caption *Non-Employee Director Compensation* below.

Compensation Committee

The Compensation Committee operates under a Compensation Committee Charter that is available on our website, www.rezolutebio.com. Dr. Hogenhuis serves as chair of the compensation committee. Mr. Labrucherie, Mr. Fauchet, and Dr. Kreher each serve as members of the Compensation Committee and are each considered an "independent director" as defined in Rule 5605(a)(2) of the Nasdaq Listing Rules. The Compensation Committee is responsible for establishing and administering our compensation arrangements for all executive officers.

The functions performed by our Compensation Committee provided for meetings no less frequently than annually (and more frequently as circumstances dictate) to discuss and determine executive officer and director compensation. The Compensation Committee may from time to time utilize the services of a compensation consultants and utilize compensation data from companies that the Compensation Committee deems to be competitive with us in connection with its annual review of executive compensation. The Compensation Committee has the power to form and delegate authority to subcommittees when appropriate, provided that such subcommittees are composed entirely of directors who would qualify for membership on the Compensation Committee pursuant to applicable Nasdaq Listing Rules. Our Compensation Committee held two meetings during the fiscal year ended June 30, 2023

For the fiscal year ended June 30, 2023, Dr. Hogenhuis, Mr. Labrucherie, Mr. Fauchet, and Dr. Kreher received additional compensation for their service as members of our Compensation Committee as discussed under the caption *Non-Employee Director Compensation* below.

Nominating and Governance Committee

The Nominating and Governance Committee operates under a Nominating and Governance Committee Charter that is available on our website at www.rezolutebio.com. Dr. Kreher serves as chair, while Mr. Labrucherie, Mr. Fauchet, Dr. Hogenhuis and Dr. Kreher each serve as members of the Nominating and Governance Committee and are each considered an "independent director" as defined in Rule 5605(a)(2) of the Nasdaq Listing Rules. The Nominating and Governance Committee is responsible for nominating and corporate governance committee is responsible for making recommendations to our Board regarding candidates for directorships and the size and composition of our Board. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies and reporting and making recommendations to our Board concerning governance matters.

Stockholders who wish to recommend nominees for consideration by the Nominating and Governance Committee must deliver their nominations in writing to our Corporate Secretary. Submissions must include sufficient biographical information concerning the recommended individual for the Nominating and Governance Committee to consider, including age, five-year employment history with employer names and a description of the employer's business, whether such individual can read and comprehend basic financial statements, and other board memberships (if any) held by the recommended individual. The submission must be accompanied by a written consent of the individual to stand for election if nominated by the Nominating and Governance Committee and to serve if elected by stockholders. The Nominating and Governance Committee may consider such stockholder recommendations when it evaluates and recommends nominees to the Board for submission to the stockholders at each annual meeting.

The Nominating and Governance Committee do not have a specific diversity policy, but consider diversity of race, ethnicity, gender, age, cultural background and professional experiences in evaluating candidates for Board membership. Diversity is important because a variety of points of view contribute to a more effective decision-making process. Our Nominating and Governance Committee held two meetings during the fiscal year ended June 30, 2022.

For the fiscal year ended June 30, 2023, Dr. Kreher, Mr. Labrucherie, Mr. Fauchet, and Dr. Hogenhuis received additional compensation for their service as members of our Nominating and Governance Committee as discussed under the caption *Non-Employee Director Compensation* below.

Scientific Advisory Board

We have established a Scientific Advisory Board ("SAB"). The members of the SAB are Adrian Vella, *M.D.*, Quan Dong Nguyen, *M.D., MSc,* Robert B. Bhisitkul, *M.D., PH.D.* Alvin Schmaier, *M.D.*, and Jerrold Olefsky, *M.D.*

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of our common stock, to file reports regarding ownership of, and transactions in, our securities with the SEC and to provide us with copies of those filings. Based solely on our review of the copies of such forms received by us, or written representations from certain reporting persons, we believe that during the fiscal year ended June 30, 2023, all filing requirements applicable to its executive officers, directors and ten percent beneficial owners were complied with except that (i) Handok failed to file a Form 4 for 3,157,895 shares of common stock purchased in July 2022 and (ii) Young-Jin Kim failed to file a Form 4 for 78,947 shares of common stock purchased in July 2022.

Item 11. Executive Compensation.

Summary Compensation Table

Our named executive officers consist of all individuals that served as our principal executive officer during the fiscal year ended June 30, 2023 and the next most highly compensated executive officer who was serving as an executive officer as of June 30, 2023. The following table sets forth information concerning the compensation of Mr. Elam and Dr. Roberts, (our "Named Executive Officers") during the fiscal years ended June 30, 2023 and 2022:

Name and Position	Fiscal Year	Salary	Bonus	Stock Option Awards	All Other Compensation	Total
Nevan Charles Elam	2023	$ 534,112 (1)	$ 416,068 (3)	$ — (5)	$ 23,466 (6)	$ 973,646
Chief Executive Officer	2022	$ 515,000 (1)	$ 378,750 (4)	$ 6,862,960 (5)	$ 24,590 (6)	$ 7,781,300
Brian Roberts, M.D.	2023	$ 457,809 (2)	$ 237,753 (3)	$ — (5)	$ 43,296 (7)	$ 738,858
Chief Medical Officer	2022	$ 401,500 (2)	$ 121,875 (4)	$ 1,847,720 (5)	$ 52,053 (8)	$ 2,423,148

(1) Pursuant to the amended and restated employment agreement discussed below, Mr. Elam's base salary increased to $505,000 on February 15, 2021. On May 25, 2022, Mr. Elam's base salary was increased to $525,000, with an effective date of January 1, 2022, and subsequently increased on January 3, 2023, to $543,375. Mr. Elam also serves as Acting Chair of our Board of Directors for which no incremental compensation is paid.

(2) Pursuant to the employment agreement discussed below, on February 15, 2021, Dr. Roberts' base salary increased to $390,000, and subsequently increased to $405,900 on January 1, 2022. On May 25, 2022, Dr. Roberts was appointed by our Board of Directors as our Chief Medical Officer, with a base salary of $450,000 effective June 1, 2022. Subsequently on January 3, 2023, Dr. Roberts base salary was increased to $465,750.

(3) On January 8, 2022, the Board of Directors approved bonus payments for calendar year 2022 services in the amounts shown in the table. In February 2023, these cash bonus payments were paid to each executive officer. As of June 30, 2023, the Company estimated approximately 31% of target bonus amounts had been met for the 2023 calendar performance year and included in this table. Cash payments for 2023 bonuses will be subject to Board of Director approval in early 2024.

(4) On May 25, 2022, the Board of Directors approved bonus payments for calendar year 2021 services in the amounts shown in the table. In June 2022, these cash bonus payments were paid to each executive officer.

(5) The aggregate grant date fair value for stock option awards is computed in accordance with ASC 718 set forth by the Financial Accounting Standards Board. A discussion of key assumptions made in the valuation of stock options is presented in Note 9 to our consolidated financial statements, included in Item 8 of this Annual Report. For purposes of this table, the entire fair value of awards with time-based vesting are reflected in the year of grant, whereas under ASC 718 the fair value of such awards is generally recognized over the vesting period in our financial statements.

(6) Amount consists of health, dental, disability and life insurance premiums under our employee benefit plans.

(7) Amount consists of health, dental, disability and life insurance premiums under our employee benefit plans of $26,796, health club fees of $3,300, and matching contributions under our 401(k) Plan of $13,200.

(8) Amount consists of health, dental, disability and life insurance premiums under our employee benefit plans of $36,553, health club fees of $3,300, and matching contributions under our 401(k) Plan of $12,200.

Narrative Disclosure to Summary Compensation Table

Presented below is summary of key terms of employment agreements with our Named Executive Officers:

Nevan Charles Elam

Effective February 15, 2021, we entered into an employment agreement with Nevan Charles Elam to serve as our Chief Executive Officer. The employment agreement requires Mr. Elam to undertake certain confidentiality, non-competition and non-solicitation obligations. The terms of this agreement provided that Mr. Elam was entitled to receive an annual base salary of $505,000 plus a calendar year target bonus up to 60% of his annual base salary based on achievement of performance criteria set forth by the Board of Directors. Effective January 1, 2022 and January 3, 2023, the Board of Directors approved an increase in Mr. Elam's base salary to $525,000 and $543,375, respectively. Mr. Elam is eligible to participate in all benefit programs available to our executives and employees, including medical, dental, life and disability insurance plans, and our employee stock option plans.

On January 8, 2023, we entered into an amended and restated employment agreement with Mr. Elam that provides in the event we terminate Mr. Elam's employment outside of a change in control event without "Cause" or if Mr. Elam resigns for "Good Reason", we are required to pay a severance benefit equal to (i) three times his then current annual base salary, (ii) 150% of his annual Target Bonus, (iii) payment of accrued vacation benefits, and (iv) continuation of certain other benefits such as medical and dental insurance. The aggregate severance benefit is payable over a period of twelve months, and any outstanding stock options that are subject to vesting shall have vesting accelerated with respect to the number of shares that would have vested during 18-month period following the termination of employment without cause or for Good Reason. All of the vested shares will have an exercise period of twelve months following the termination date under these circumstances.

Furthermore, if Mr. Elam is terminated without cause within 12 months of a Change of Control or if Mr. Elam terminates employment for Good Reason within 12 months following a Change of Control, in addition to the benefits noted above, (i) all Stock Options that are subject to vesting shall have the vesting accelerate and become fully vested, (ii) any shares of capital stock of the Company that are subject to a right of repurchase shall have such right of repurchase lapse and (iii) units then held by Mr. Elam pursuant to a restricted stock unit plan shall immediately vest and become exercisable. All of Mr. Elam's equity in the Company that has vested upon such termination shall have an exercise period of 12 months following Mr. Elam's termination of Employment without Cause or for Good Reason within 12 months following a Change of Control. The terms "Cause", "Change of Control" and "Good Reason" are defined in the employment agreement.

Brian Roberts, M.D.

On July 22, 2019, we entered into an employment agreement with Brian Roberts to serve as our Vice President of Clinical Development. Under the terms of this agreement Dr. Roberts was entitled to receive an annual base salary of $360,000 plus a calendar year target bonus of up to 25% of his annual base salary based on the achievement of performance criteria set forth by the Board of Directors. On October 23, 2020, Dr. Roberts was appointed our Senior Vice President, Clinical Development. Effective January 1, 2022, the Board of Directors approved an increase in Dr. Roberts' salary to $405,900. Effective June 1, 2022, Dr. Roberts was appointed Chief Medical Officer with an annual base salary of $450,000 and an increase in the target bonus to 40% of his annual base salary. Effective January 3, 2023, The Board of Directors approved an increase in Dr. Roberts annual salary to $465,750. The employment agreement requires Mr. Roberts to undertake certain confidentiality, non-competition and non-solicitation obligations.

On January 8, 2023, we entered into an amended and restated employment agreement with Dr. Roberts that provides in the event that we terminate Dr. Roberts' employment outside of a change of control event without "Cause" or if Dr. Roberts resigns for "Good Reason", we are required to pay all of his equity in the Company that is subject to vesting conditions will have accelerated vesting for 12 months and will also have an exercise period of 6 months following the occurrence of the termination event. In addition, upon the occurrence of a termination event other than a change of control and without cause, Mr. Roberts will be entitled to, (i) a severance payment equal to 12 months of salary, (ii) a pro-rata bonus payment equal to the pro-rata bonus amount earned as of the date of the termination event and (iii) continuation of certain other benefits such as medical and dental insurance for 12 months.

If Dr. Roberts is terminated related to a change of control event, all of his equity in the Company that is subject to vesting conditions will have accelerated vesting with an exercise period of 6 months following the occurrence of the termination

event. In addition, upon the occurrence of a termination event related to a change of control, Mr. Roberts will be entitled to, (i) a severance payment equal to 18 months of salary, (ii) a pro-rata bonus payment equal to the pro-rata bonus amount earned as of the date of the termination event and (iii) continuation of certain other benefits such as medical and dental insurance for 18 months. The terms "Cause", "Change of Control" and "Good Reason" are defined in the employment agreement.

Outstanding Equity Awards

As of June 30, 2023, there were no restricted stock awards and no stock options that provide for performance vesting conditions held by any of our Named Executive Officers. The following table provides a summary of equity awards outstanding, consisting solely of stock options, for each of our Named Executive Officers as of June 30, 2023:

Name	Grant Date	Number of Securities Underlying Unexercised Options		Option Exercise Price	Option Expiration Date
		Exercisable	Unexercisable		
Nevan Charles Elam					
	7/31/19	200,000	—	$ 14.50	7/31/29
	6/14/21	250,000	125,000 (1)	12.28	6/14/31
	6/23/22	650,000	1,950,000 (3)	3.40	6/23/32
Total for Mr. Elam		1,100,000	2,075,000		
Brian Roberts, M.D.					
	7/31/19	40,000	—	$ 14.50	7/31/29
	6/14/21	56,250	18,750 (2)	12.28	6/14/31
	6/23/22	175,000	525,000 (3)	3.40	6/23/32
Total for Dr. Roberts		271,250	543,750		

(1) These stock options vest in equal monthly installments over 36 months beginning on July 1, 2021, subject to the executive's continued service through each vesting date.

(2) These stock options vested for 25% of the shares underlying the options on the grant date and the remaining shares underlying the options become exercisable in equal monthly installments over the remaining 36 months following the grant date, subject to the executive's continued service through each vesting date.

(3) These stock options vest over a four-year period whereby 25% of the shares underlying the options became exercisable on the first anniversary of the grant date, and the options for the remaining shares become exercisable in equal monthly installments over the remaining 36 months beginning on July 1, 2023, subject to the executive's continued service through each vesting date.

Options Exercised

As of June 30, 2023, there were no shares acquired upon the exercise of stock options for any of our Named Executive Officers.

Director Compensation

Effective January 1, 2021, we began using a combination of cash and share-based incentive compensation to attract and retain qualified candidates to serve on our Board of Directors. Additionally, our directors are reimbursed for reasonable travel expenses incurred in attending meetings. Presented below is a listing of the individuals that served as directors and the related committee appointments during the fiscal year ended June 30, 2023:

		Committee Appointments		
Director Name		**Audit**	**Compensation**	**Nominating and Governance**
Committee Members as of June 30, 2023:				
Gil Labrucherie	(1)	**X**	**X**	**X**
Nerissa Kreher	(4)		**X**	**X**
Philippe Fauchet	(2)	**X**	**X**	**X**
Wladimir Hogenhuis	(3)	**X**	**X**	**X**
Young-Jin Kim	(5)			

(1) Mr. Labrucherie was appointed to serve as a member of our Board of Directors, Compensation Committee, Nominating and Governance Committee, and as chair of our Audit Committee on November 20, 2019.

(2) Mr. Fauchet was appointed to serve as a member of our Board of Directors, Audit Committee, Nominating and Governance Committee and as a chair of our Compensation Committee on September 10, 2020.

(3) Dr. Hogenhuis was appointed to serve as a member of our Board of Directors, Audit Committee, and Nominating and Governance Committee and on March 2, 2021.

(4) Dr. Kreher was appointed to serve as a member of our Board of Directors, Compensation Committee, and Nominating and Governance Committee on March 2, 2021.

(5) Mr. Young-Jin Kim was appointed to serve as our Chair of the Board of Directors on February 16, 2019. He resigned from this position as Chair in May 2022, but, remains a member of our Board of Directors.

Director Compensation Table

Nevan Charles Elam has served as our Chief Executive Officer and a member of our Board of Directors since January 2013. In addition, Mr. Elam has served as Acting Chair of the Board of Directors, since May 2022. Mr. Elam does not receive any additional compensation for serving as a director or as our Acting Chair and therefore has been excluded from the following table. Please refer to the "Executive Compensation" section above for a description of Mr. Elam's compensation.

The following table provides information related to the compensation of the remaining individuals that served as a members of our Board of Directors during the fiscal year ended June 30, 2023:

Name	**Fees Earned or Paid in Cash ($)**	**Option Awards ($)**	**Total ($)**
Gil Labrucherie	69,000 (1)	— (6)	69,000
Nerissa Kreher	62,000 (2)	— (6)	62,000
Philippe Fauchet	66,000 (3)	— (6)	66,000
Wladimir Hogenhuis	64,000 (4)	— (6)	64,000
Young-Jin Kim	33,750 (5)	— (6)	33,750

(1) Consists of $45,000 for serving as a member of the Board of Directors, $10,000 for serving as Chair of the Audit Committee, $7,000 for serving as a member of the Compensation Committee and $7,000 for serving as a member of the Nominating and Governance Committee.

(2) Consists of $45,000 for serving as a member of the Board of Directors, $10,000 for serving as Chair of the Nominating and Governance Committee and $7,000 for serving as a member of the Compensation Committee.

(3) Consists of $45,000 for serving as a member of the Board of Directors, $7,000 for serving as a member of the Compensation Committee, $7,000 for serving as a member of the Audit Committee and $7,000 for serving as a member of the Nominating and Governance Committee.

(4) Consists of $45,000 for serving as a member of the Board of Directors, $7,000 for serving as Chair of the Compensation Committee, $7,000 for serving as a member of the Audit Committee and $7,000 for serving as a member of the Nominating and Governance Committee.

(5) Consist of $33,750 for serving as a member of the Board of Directors.

(6) No stock options were granted to members of the Board of Directors during the fiscal year ended June 30, 2023.

The aggregate number of outstanding options held by our non-employee directors as of June 30, 2023 was as follows:

	Shares Underlying Options Outstanding	
	Vested	**Unvested**
Gil Labrucherie	37,999	55,001
Nerissa Kreher	33,332	56,668
Philippe Fauchet	35,110	54,890
Wladimir Hogenhuis	33,332	56,668
Young-Jin Kim	13,333	26,667

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information with respect to the beneficial ownership of shares of our common stock by (i) each director, (ii) each Named Executive Officer, (iii) all directors and executive officers as a group, and (iv) each person who we know beneficially owns more than 5% of our common stock, in each case as of September 8, 2023 (the "Determination Date"), unless otherwise indicated below. Beneficial ownership is determined in accordance with the rules and regulations of the SEC and generally includes voting or investment power with respect to such securities. Under these rules, beneficial ownership includes all shares as to which the individual or entity has sole or shared voting power and investment power and includes all shares that an individual or entity has the right to acquire within 60 days after the Determination Date through the exercise of pre-funded warrants, other warrants, stock options, or other rights.

Certain shareholders have voluntarily placed ownership blocker restrictions that prevent exercise of their pre-funded warrants and other warrants for a 60-day period. Accordingly, such pre-funded warrants and other warrants with ownership blocker restrictions are not considered to be beneficially owned by those shareholders because the underlying shares does not have voting and dispositive rights within 60 days after the Determination date.

Shares that are subject to beneficial ownership through the exercise of pre-funded warrants, other warrants and stock options are deemed to be outstanding and beneficially owned for the purpose of computing share and percentage ownership of that person or entity but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person or entity.

Except as indicated in the footnotes to this table, and as affected by applicable community property laws, all persons listed have sole voting and investment power for all shares shown beneficially owned by them. This information is not necessarily indicative of beneficial ownership for any other purpose.

The number of shares beneficially owned and the percentage of shares beneficially owned are based on 36,827,567 shares of common stock issued and outstanding as of the Determination Date. Unless otherwise indicated, the address of our directors and executive officers is c/o Rezolute, Inc., 275 Shoreline Drive, Suite 500, Redwood City, California 94065.

Name of Beneficial Owner	Position with Company	Beneficial Ownership	Percent of Class
Stockholders in excess of 5%			
Entities associated with Federated Hermes, Inc.	Stockholder	7,550,274 (1)	19.9 %
Handok, Inc.	Stockholder	5,942,617 (2)	16.1 %
First Manhattan Co. LLC	Stockholder	3,623,078 (3)	9.8 %
Stonepine Capital, L.P.	Stockholder	3,072,476 (4)	8.2 %
Directors and Executive Officers:			
Nevan Charles Elam	Chief Executive Officer, Acting Chair of the Board of Directors	1,371,566 (5)	3.6 %
Gil Labrucherie	Director	103,376 (6)	*
Nerissa Kreher	Director	45,832 (7)	*
Philippe Fauchet	Director	47,388 (8)	*
Wladimir Hogenhuis	Director	78,525 (9)	*
Young-Jin Kim	Director	6,040,452 (10)	16.4 %
Brian Roberts	Chief Medical Officer	364,947 (11)	*
Directors and executive officers as a group (7 people)		8,052,086 (12)	20.8 %

(1) The number of shares includes 6,610,274 shares of common stock held by entities associated with Federated Hermes, Inc., 123,000 shares currently issuable upon the exercise of pre-funded warrants at $0.01 per share and 817,000 shares currently issuable under the exercise of pre-funded warrants at $0.001 per share. The number of shares excludes 400,000 shares currently issuable upon the exercise of warrants at $19.50 per share due to a 14.99% ownership blocker and 2,604,053 shares currently issuable upon the exercise of Class B pre-funded warrants at $0.001 per share due to a 19.99% ownership blocker. These shares are owned by separate entities which are collectively referred to as the “Funds” which are managed by Federated Equity Management Company of Pennsylvania and subadvised by Federated Global Investment Management Corp., which are wholly owned subsidiaries of FII Holdings, Inc., which is a wholly owned subsidiary of Federated Hermes, Inc. (the “Parent”). All of the Parent’s outstanding voting stock is held in the Voting Shares Irrevocable Trust (the “Trust”) for which Thomas R. Donahue, Ann C. Donahue and J. Christopher Donahue act as trustees (collectively referred to as the “Trustees”). The Parent’s subsidiaries have the power to direct the vote and disposition of the securities held by the Funds. Each of the Parent, its subsidiaries, the Trust, and each of the Trustees expressly disclaim beneficial ownership of such securities. The address of the entities associated with Federated Hermes, Inc. is 4000 Ericsson Drive, Warrendale, PA 15086.

(2) Voting and investment authority over our shares of common stock owned by Handok, Inc. is held by the board of directors of Handok, Inc. The address of stockholder is 132, Teheran-Ro, Gangman Gu, Seoul, Republic of Korea.

(3) Based on Schedule 13F-HR filed with the SEC on August 14, 2023 and the Company’s knowledge of shares purchased in the Company’s May 2022 offering. This number may have changed subsequent to June 30, 2023. First Manhattan Co. has sole voting and investment power of the shares. The address of the filer is 399 Park Avenue, New York, New York 10022.

(4) The amount reported as beneficially owned in the table is based solely on a Schedule 13G/A filed with the SEC on February 14, 2022, reporting beneficial ownership as of December 31, 2021, a Schedule 13F-HR filed with the SEC on August 11, 2023, reporting holdings as of June 30, 2023, and this number may have changed

subsequent to June 30, 2023. Stonepine Capital Management, LLC, is the General Partner of the partnership and Jon M. Plexico and Timothy P. Lynch are the control persons of the General Partner. Each reporting person disclaims beneficial ownership of except to the extent of that person's pecuniary interest therein. The address of the filers is 919 NW Bond Street, Suite 20, Bend, Oregon 977003-2767.

(5) Consists of (i) 2,817 shares of our common stock and (ii) 1,368,749 shares of our common stock issuable upon exercise of stock options that are exercisable within 60 days of the Determination Date.

(6) Consists of (i) 53,752 shares of our common stock owned by a trust controlled by Mr. Labrucherie and (ii) 49,804 shares of our common stock issuable upon exercise of stock options that are exercisable within 60 days of the Determination Date.

(7) Consists of (i) 45,832 shares of our common stock issuable upon exercise of stock options that are exercisable within 60 days of the Determination Date.

(8) Consists of (i) 47,388 shares of our common stock issuable upon exercise of stock options that are exercisable within 60 days of the Determination Date.

(9) Consists of (i) 32,693 shares of our common stock and (ii) 45,832 shares of our common stock issuable upon exercise of stock options that are exercisable within 60 days of the Determination Date.

(10) Consists of (i) 78,947 shares of our common stock owned by Mr. Kim and (ii) 5,942,617 shares of our common stock that are owned by Handok, Inc. and (iii) 18,888 shares of our common stock issuable upon exercise of stock options that are exercisable within 60 days of the Determination Date. As Chairman and CEO of Handok, Inc., Mr. Kim has shared investment and voting authority over the shares owned by Handok, Inc.

(11) Consists of (i) 27,552 shares of our common stock and (ii) 337,395 shares of our common stock issuable upon exercise of stock options that are exercisable within 60 days of the Determination Date.

(12) Consists of (i) 6,138,198 shares of our common stock that are either owned or beneficially owned by our directors and officers as discussed above and (iii) an aggregate of 1,938,888 shares of our common stock issuable upon exercise of stock options that are exercisable within 60 days of the Determination Date.

* Less than 1%.

Equity Compensation Plan Information

The following table displays equity compensation plan information as of June 30, 2023:

	Plan Termination Date	Shares to be Issued Upon Exercise of Outstanding Options: Number of Shares	Weighted Average Exercise Price	Securities Available For Future Issuance
Equity compensation plans approved by security holders:				
2015 Non-Qualified Stock Option Plan	February 23, 2020	17	$ 19.86	—
2016 Non-Qualified Stock Option Plan	October 31, 2021	140	16.62	—
2021 Equity Incentive Plan	March 31, 2031	8,388	4.09	2,312
2022 Employee Stock Purchase Plan	Indefinite	—	—	500
Equity compensation plans not approved by security holders:				
2019 Non Qualified Stock Option Plan	July 31, 2029	200	14.50	—
Total		8,745	4.56	2,812

Item 13. Certain Relationships and Related Transactions and Director Independence.

Review, Approval or Ratification of Transactions with Related Persons

We rely on our Audit Committee to review related party transactions on an ongoing basis to prevent conflicts of interest. Our Audit Committee 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

As the Company is listed on the Nasdaq Capital Market, we have used the definition of "independence" of the Nasdaq Stock Market to determine whether our directors are independent. We have determined that as of June 30, 2023, Mr. Labrucherie, Mr. Fauchet, Dr. Hogenhuis and Dr. Kreher were independent directors as defined by Nasdaq Rule 5605(a)(2), 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 shareholder 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.

Presented below is a summary of transactions with related parties for the fiscal years ended June 30, 2023 and 2022:

Licensing Agreement

On September 15, 2020, we entered into an exclusive license agreement (the "Handok License") with Handok, Inc. ("Handok") for the territory of the Republic of Korea. Young-Jin Kim is the CEO and Chairman of Handok and has served as a member of our Board since February 2019. The Handok License relates to pharmaceutical products in final dosage form containing the pharmaceutical compounds developed or to be developed by us, including those related to RZ358 and RZ402. The Handok License is in effect for a period of 20 years after the first commercial sale of each product and requires (i) milestone payments of $0.5 million upon approval of a New Drug Application ("NDA") for each product in the territory, and (ii) we will sell products ordered by Handok at a transfer price equal to 70% of the net selling price of the products. To date, no milestone payments have been earned by us.

Investors in Registered Direct Offerings

In connection with the 2021 RDO, Handok purchased 769,231 shares of our common stock at a purchase price of $6.50 per share, whereby we received gross proceeds of $5.0 million.

In connection with the 2022 RDO, certain officers and directors of the Company purchased 111,840 shares of common stock at $3.80 per share, whereby we received gross proceeds of $0.4 million.

In connection with a Private Placement in July 2022, Handok and Young-Jin Kim purchased 3,157,895 and 78,947 shares, respectively, of common stock at $3.80 per share. The aggregate gross proceeds from these transactions amounted to $12.3 million.

Item 14. Principal Accounting Fees and Services.

Principal Accounting Fees and Services

The aggregate fees billed by Plante & Moran, PLLC for professional services rendered to us for the years ended June 30, 2023 and 2022 are set forth in the table below.

	2023		2022	
	Amount	Percent	Amount	Percent
Audit fees [1]	$ 190,000	84 %	$ 259,000	85 %
Tax fees[2]	36,550	16 %	47,225	15 %
Total	$ 226,550	100 %	$ 306,225	100 %

(1) Audit fees represent amounts billed for professional services rendered for the audit of our annual financial statements, the reviews of the financial statements included in our quarterly reports on Form 10-Q, and reviews of any other SEC filings.

(2) Tax fees consist of fees billed for professional services for tax compliance, tax planning and tax advice. These services include assistance regarding federal and state tax compliance.

Pre-Approval Policy

Our Audit Committee endeavors to approve in advance all services provided by our independent registered public accounting firm. All services provided by our independent registered public accounting firm for the fiscal years ended June 30, 2023 and 2022 were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(a)(1) Financial Statements

Reference is made to Item 8 of Part II for the Company's consolidated financial statements filed as part of this Report.

(a)(2) Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable, or the amounts are immaterial, not required, or the required information is presented in the financial statements and notes thereto included in Item 8 of Part II of this Report.

(a)(3) Exhibits

Certain of the agreements filed as exhibits to this Report contain representations and warranties by the parties to the agreements that have been made solely for the benefit of the parties to the agreement. These representations and warranties:

- may have been qualified by disclosures that were made to the other parties in connection with the negotiation of the agreements, which disclosures are not necessarily reflected in the agreements;
- may apply standards of materiality that differ from those of a reasonable investor; and
- were made only as of specified dates contained in the agreements and are subject to subsequent developments and changed circumstances.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date that these representations and warranties were made or at any other time. Investors should not rely on them as statements of fact.

The following exhibits of Rezolute, Inc. are filed or incorporated by reference as part of this Report. For exhibits that are incorporated by reference, we have indicated the document previously filed with the SEC in which the exhibit was included.

Exhibit No.	Description
1.1	Underwriting Agreement, dated as of May 1, 2022, by and between the Company and Jefferies LLC *(incorporated by reference to Exhibit 1.1 of the Company's Form 8-K filed on May 4, 2022)*
1.2	Underwriting Agreement, dated as of October 12, 2021, by and between the Company and Oppenheimer & Co., Inc. *(incorporated by reference to Exhibit 1.1 of the Company's Form 8-K filed on October 13, 2021)*
2.1	Agreement and Plan of Merger dated as of June 18, 2021, by and between Rezolute, Inc. and Rezolute Nevada Merger Corporation *(incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filed on June 21, 2021)*
3.1	Delaware Certificate of Merger, effective as of June 18, 2021 *(incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on June 21, 2021)*
3.2	Nevada Articles of Merger, effective as of June 18, 2021 *(incorporated by reference to Exhibit 3.3 of the Company's Form 8-K filed on June 21, 2021)*
3.3	Amended and Restated Articles of Incorporation of Rezolute Nevada Merger Corporation *(incorporated by reference to Exhibit 3.3 of the Company's Form 8-K filed on June 21, 2021)*
3.4	Certificate of Amendment, as filed with the Secretary of State of the State of Nevada on June 16, 2022 *(incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on June 17, 2022)*

3.5	Amended and Restated Bylaws of Rezolute Nevada Merger Corporation (*incorporated by reference to Exhibit 3.4 of the Company's Form 10-K filed on September 15, 2021*)
4.1	Description of Securities*
10.1	Amended and Restated Employment Agreement of Nevan Elam, dated January 8, 2023 *(incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q filed on May 11, 2023)*
10.2	Amended and Restated Employment Agreement of Brian Roberts, dated January 8, 2023 *(incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q filed on May 11, 2023)*
10.3	AntriaBio, Inc. 2015 Non Qualified Stock Option Plan *(incorporated by reference to Exhibit 10.5 of the Company's Form 8-K filed on February 24, 2015)*
10.4	AntriaBio, Inc. 2016 Non Qualified Stock Option Plan *(incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on November 4, 2016)*
10.5	AntriaBio, Inc. 2016 Non Qualified Stock Option Plan, as Amended *(incorporated by reference to Exhibit 10.25 of the Company's Form 10-K filed on September 21, 2017)*
10.6	Rezolute, Inc. First Amendment to the 2016 Non-Qualified Stock Option Plan *(incorporated by reference to Exhibit C to the Company's Schedule 14A definitive proxy statement filed on April 5, 2019)*
10.7	2019 Non Qualified Stock Option Plan *(incorporated by reference to Exhibit 10.3 of the Company's Form 8-K filed on August 6, 2019)*
10.8	Rezolute, Inc. Amended and Restated 2021 Equity Incentive Plan *(incorporated by reference to Exhibit 10.23 of the Company's Form 10-K filed on September 15, 2022)*
10.9	Rezolute, Inc. 2022 Employee Stock Purchase Plan *(Incorporated by reference to Exhibit 4.2 of the Registration Statement on Form S-8 filed on November 7, 2022)*
10.10	Development and License Agreement with ActiveSite Pharmaceuticals, Inc. *(incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on August 7, 2017)*
10.11	License Agreement with XOMA (US) LLC *(incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q filed on February 14, 2018)*
10.12	Amendment No. 2 to the Stock Purchase Agreement with XOMA (US) LLC *(incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q filed on February 14, 2019)*
10.13	Amendment No. 2 to the License Agreement with XOMA (US) LLC *(incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q filed on February 14, 2019)*
10.14	Amendment No. 3 to the License Agreement with XOMA (US) LLC *(incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q filed on May 14, 2020)*
10.15	License Agreement with Handok, Inc. entered into on September 15, 2020 *(incorporated by reference to Exhibit 10.21 of the Company's Form 10-K filed on October 13, 2020)*
10.16	Registration Rights Agreement, dated as of October 8, 2020, by and between Rezolute, Inc., and the Investors identified therein (*incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on October 13, 2020*)
10.17	Loan and Security Agreement, dated as of April 14, 2021 by and among Rezolute, Inc., SLR Investment Corp, as collateral agent and lender, and the other lenders named therein *(incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q filed on May 17, 2021)*
10.18	Exit Fee Agreement, dated as of April 14, 2021 by and among Rezolute, Inc., SLR Investment Corp, as collateral agent and lender, and the other lenders named therein *(incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q filed on May 17, 2021)*
10.19	Form of Subscription Agreement, dated October 12, 2021 *(incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on October 13, 2021)*
10.20	Registration Rights Agreement, dated as of May 4, 2022, by and between Rezolute, Inc., and the purchasers identified therein (*incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on May 4, 2022*)
10.21	Placement Agency Agreement, dated as of May 1, 2022, by and between the Company and Jefferies LLC (*incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on May 4, 2022*)

10.22	Form of Amended and Restated Securities Purchase Agreement, dated as of July 22, 2022 *(incorporated by reference to Exhibit 10.22 of the Company's Form 10-K filed on September 15, 2022)*
10.23	Form of Financing Warrant *(incorporated by reference to Exhibit 4.1 of the Company's Form 8-K filed on April 3, 2018)*
10.24	Form of Common Stock Purchase Warrant by and between the Company and the Investor identified therein *(incorporated by reference to Exhibit 4.1 the Company's Form 8-K filed on October 13, 2020)*
10.25	Form of Pre-Funded Warrant to Purchase Common Stock (*Incorporated by reference to Exhibit 4.1 of the Company's Form 8-K filed on October 13, 2021)*
10.26	Form of Class A Pre-Funded Warrant (*incorporated by reference to Exhibit 4.1 of the Company's Form 8-K filed on May 4, 2022*)
10.27	Form of Class B Pre-Funded Warrant (*incorporated by reference to Exhibit 4.2 of the Company's Form 8-K filed on May 4, 2022*)
14.1	Rezolute, Inc. Code of Ethics, as amended and restated as of May 30, 2023 *(incorporated by reference to Exhibit 14.1 of the Company's Form 8-K filed on June 2, 2023)*
21.1	Listing of Subsidiaries*
23.1	Consent of Plante & Moran, PLLC*
31.1	Certifications of Chief Executive Officer and Principal Financial Officer as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1	Certifications of Chief Executive Officer and Principal Financial Officer as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase*
104	Cover Page Interactive Data File, formatted in Inline XBRL (included as Exhibit 101)

* Filed herewith.

In accordance with SEC Release 33-8238, Exhibit 32.1 is being furnished and not filed.

Item 16. Form 10-K Summary.

Not applicable

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REZOLUTE, INC.

Date: September 14, 2023

By: /s/ Nevan Charles Elam
Nevan Charles Elam
Acting Chair of the Board of Directors and Chief Executive Officer
(Principal Executive and Financial Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Date: September 14, 2023

By: /s/ Nevan Charles Elam
Nevan Charles Elam
Acting Chair of the Board of Directors and Chief Executive Officer (Principal Executive and Financial Officer)

Date: September 14, 2023

By: /s/ Gil Labrucherie
Gil Labrucherie
Director

Date: September 14, 2023

By: /s/ Nerissa Kreher
Nerissa Kreher
Director

Date: September 14, 2023

By: /s/ Philippe Fauchet
Philippe Fauchet
Director

Date: September 14, 2023

By: /s/ Young-Jin Kim
Young-Jin Kim
Director

Date: September 14, 2023

By: /s/ Wladimir Hogenhuis
Wladimir Hogenhuis
Director

EXHIBIT 4.1

DESCRIPTION OF SECURITIES

General

The following description summarizes the most important terms of our capital stock. It is subject to and qualified in its entirety by reference to our Amended and Restated Articles of Incorporation, as amended ("Articles of Incorporation") and Amended and Restated Bylaws ("Bylaws"), which are included as exhibits to our annual report on Form 10-K, of which this Exhibit 4.1 is a part. We encourage you to read our Articles of Incorporation, our Bylaws and the applicable provisions of the Nevada Revised Statutes (the "NRS"), for additional information.

Common Stock

Our Articles of Incorporation provide authority for us to issue up to 100,000,000 shares of common stock, par value $0.001 per share (the "Common Stock"). Under the NRS, stockholders generally are not personally liable for our debts or obligations solely as a result of their status as stockholders. Our outstanding shares of Common Stock are fully paid and nonassessable.

Voting Rights. Holders of our Common Stock are entitled to one vote per share on all matters submitted to our stockholders for a vote. There are no cumulative voting rights in the election of directors. All elections of our Board of Directors at any meeting of our stockholders shall be determined by a plurality of the votes cast. Except as otherwise required by law, our Bylaws or the rules of any stock exchange upon which our company's securities are listed, all other matters determined by our stockholders at a meeting shall be determined by a majority of the votes cast affirmatively or negatively.

Dividend Rights. Our shares of Common Stock are entitled to receive such dividends as may be declared and paid by our Board of Directors out of funds legally available therefor and to share ratably in the net assets, if any, of our company upon liquidation.

Preemptive Rights. Our stockholders have no preemptive rights to purchase any shares of our capital stock.

Choice of Forum. Our Articles of Incorporation provides that the Eighth Judicial District Court of Clark County, Nevada shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the NRS Chapters 78 or 92A, our Articles of incorporation or our Bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. Notwithstanding this exclusive forum provision, the exclusive forum provision shall not preclude or contract the scope of exclusive federal or concurrent jurisdiction for actions brought under the Securities Exchange Act of 1934, as amended (the "Exchange Act") or the Securities Act of 1933, as amended (the "Securities Act") or the respective rules and regulations promulgated thereunder.

Preferred Stock

Our Articles of Incorporation provides authority for us to issue up to 400,000 shares of preferred stock, par value $0.001 per share. Our Board of Directors is authorized, without further stockholder action, to establish various series of preferred stock from time to time and to determine the rights, preferences and privileges of any unissued series including, among other matters, any dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms, the number of shares constituting any such series, and the description thereof and to issue any such shares.

The rights of the holders of our Common Stock will be subject to, and may be adversely affected by, the rights of holders of any preferred stock that may be issued in the future. Such rights may include voting and conversion rights which could adversely affect the holders of the Common Stock. Satisfaction of any dividend or liquidation preferences of outstanding preferred stock would reduce the amount of funds available, if any, for the payment of dividends or liquidation amounts on Common Stock.

Warrants

Class A Pre-Funded Warrants

In May 2022, we issued and sold Class A Pre-Funded Warrants (the "Class A Pre-Funded Warrants") to purchase an aggregate of 1,973,684 shares of our common stock at an offering price of $3.799 per Class A Pre-Funded Warrant in an underwritten public offering pursuant to a shelf registration on Form S-3.

Each Class A Pre-Funded Warrant entitles the holder to purchase one share of our common stock at an exercise price of $0.001 per share. The Class A Pre-Funded Warrants do not expire and may be exercised at any time after their original issuance.

Under the Class A Pre-Funded Warrants, we may not effect the exercise of any Class A Pre-Funded Warrant, and a holder will not be entitled to exercise any portion of any Class A Pre-Funded Warrant, which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder of the Class A Pre-Funded Warrant (together with its affiliates) to exceed 4.99% of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Class A Pre-Funded Warrants. However, any holder may increase or decrease such percentage to any other percentage upon at least 61 days' prior notice from the holder to us; provided, that a holder of a Class A Pre-Funded Warrants may not increase such percentage to a percentage in excess of 19.99%.The exercise price of the Class A Pre-Funded Warrants and the number of shares of our common stock issuable upon exercise of the Class A Pre-Funded Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. The Class A Pre-Funded Warrants also contain provisions that provide certain rights to holders in the event of a fundamental transaction, including a merger or consolidation with or into another entity, such as the right to receive the same amount and kind of consideration paid to the holders of our common stock in the fundamental transaction. The Class A Pre-Funded Warrants do not entitle the holders to any voting rights or any of the other rights or privileges to which holders of common stock are entitled.

As of September 8, 2023, we have 1,973,684 shares underlying the Class A Pre-Funded Warrants outstanding, of which there have been no exercises.

Class B Pre-Funded Warrants

In May 2022, we issued and sold Class B Pre-Funded Warrants (the "Class B Pre-Funded Warrants") to purchase an aggregate of 10,947,371 shares of our common stock at an offering price of $3.799 per Class B Pre-Funded Warrant in an underwritten public offering pursuant to a shelf registration on Form S-3.

Each Class B Pre-Funded Warrant entitles the holder to purchase one share of our common stock at an exercise price of $0.01 per share. The Class B Pre-Funded Warrants do not expire and may be exercised at any time after their original issuance.

Under the Class B Pre-Funded Warrants, we may not effect the exercise of any Class B Pre-Funded Warrant, and a holder will not be entitled to exercise any portion of any Class B Pre-Funded Warrant, which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99%, 9.99% or 19.99%, as applicable to the holder, of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder of the Class B Pre-Funded Warrant (together with its affiliates) to exceed 4.99%, 9.99% or 19.99%, as applicable to the holder, of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Class B Pre-Funded Warrants. However, any holder may increase or decrease such percentage to any other percentage upon at least 61 days' prior notice from the holder to us; provided, that a holder of

a Class B Pre-Funded Warrants may not increase such percentage to a percentage in excess of 19.99%.The exercise price of the Class B Pre-Funded Warrants and the number of shares of our common stock issuable upon exercise of the Class B Pre-Funded Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. The Class B Pre-Funded Warrants also contain provisions that provide certain rights to holders in the event of a fundamental transaction, including a merger or consolidation with or into another entity, such as the right to receive the same amount and kind of consideration paid to the holders of our common stock in the fundamental transaction. The Class B Pre-Funded Warrants do not entitle the holders to any voting rights or any of the other rights or privileges to which holders of common stock are entitled.

As of September 8, 2023, we have 10,947,371 shares underlying the Class B Pre-Funded Warrants outstanding, of which there have been no exercises.

October 2021 Pre-Funded Warrants

In October 2021, we issued and sold pre-funded warrants (the "2021 Pre-Funded Warrants") to purchase an aggregate of 1,661,461 shares of our common stock at an offering price of $6.49 per 2021 Pre-Funded Warrant in an underwritten public offering pursuant to a shelf registration on Form S-3.

Each 2021 Pre-Funded Warrant entitles the holder to purchase one share of our common stock at an exercise price of $0.01 per share. The 2021 Pre-Funded Warrants do not expire and may be exercised at any time after their original issuance.

Under the 2021 Pre-Funded Warrants, we may not effect the exercise of any 2021 Pre-Funded Warrant, and a holder will not be entitled to exercise any portion of any 2021 Pre-Funded Warrant, which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% or 19.99%, as applicable to the holder, of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder of the 2021 Pre-Funded Warrant (together with its affiliates) to exceed 4.99% or 19.99%, as applicable to the holder, of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the 2021 Pre-Funded Warrants. However, any holder may increase or decrease such percentage to any other percentage upon at least 61 days' prior notice from the holder to us; provided, that a holder of a 2021 Pre-Funded Warrants may not increase such percentage to a percentage in excess of 19.99%.The exercise price of the 2021 Pre-Funded Warrants and the number of shares of our common stock issuable upon exercise of the 2021 Pre-Funded Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. The 2021 Pre-Funded Warrants also contain provisions that provide certain rights to holders in the event of a fundamental transaction, including a merger or consolidation with or into another entity, such as the right to receive the same amount and kind of consideration paid to the holders of our common stock in the fundamental transaction. The 2021 Pre-Funded Warrants do not entitle the holders to any voting rights or any of the other rights or privileges to which holders of common stock are entitled.

As of September 8, 2023, we have 1,661,461 shares underlying the 2021 Pre-Funded Warrants outstanding, of which there have been no exercises.

Participating Warrants

In October 2020, we issued and sold 820,001 warrants (the "Participating Warrants"), and each 2020 Warrant entitles the holder to purchase 0.33 shares of our common stock at an exercise price of $19.50 per share of our common stock. Each 2020 Warrant is exercisable on or after October 9, 2020 and will expire on or prior to 5:00 p.m. (New York City time) on October 9, 2027. The 2020 Warrant were subsequently registered for resale by certain selling stockholders pursuant to a registration statement on Form S-3.

Under the Participating Warrants, we may not effect the exercise of any 2020 Warrant, and a holder will not be entitled to exercise any portion of any 2020 Warrant, which, upon giving effect to such exercise, would cause the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% or 19.99%, as applicable to the holder, of the number of shares of our common stock outstanding immediately after giving effect to the exercise. However, any holder may increase or decrease such percentage to any other percentage; provided, that a holder of 2020 Warrant may not increase such percentage to a percentage in excess of 9.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the 2020 Warrant held by the holder. Any increase in such percentage will not be effective until the 61st day after such notice is delivered to the company. The exercise price of the Participating Warrants and the number of shares of our common stock issuable upon exercise of the 2020 Warrant is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. The Participating Warrants also contain provisions that provide certain rights to holders in the event of a fundamental transaction, including a merger or consolidation with or into another entity, such as (i) the right to receive the same amount and kind of consideration paid to the holders of our common stock in the fundamental transaction and (ii) the right to require the company to repurchase the unexercised portion of certain warrants at the warrant's respective fair value using the Black Scholes option pricing formula. The Participating Warrants do not entitle the holders to any voting rights or any of the other rights or privileges to which holders of common stock are entitled.

As of September 8, 2023, we have 820,001 shares underlying the Participating Warrants outstanding, of which there have been no exercises.

Other Warrants

The Company has issued warrants in conjunction with debt and equity financings and for services from 2015 to 2019. Such warrants have various expiration dates and exercise prices.

Anti-Takeover Provisions

Provisions of the NRS, our Articles of Incorporation, and our Bylaws, as amended from time to time, could have the effect of delaying or preventing a third-party from acquiring us, even if the acquisition would benefit our stockholders. Such provisions of the NRS, our Articles of Incorporation, and our Bylaws are intended to enhance the likelihood of continuity and stability in the composition of our Board of Directors and in the policies formulated by the Board of Directors and to discourage certain types of transactions that may involve an actual or threatened change of control of our company. These provisions are designed to reduce our vulnerability to an unsolicited proposal for a takeover that does not contemplate the acquisition of all of our outstanding shares, or an unsolicited proposal for the restructuring or sale of all or part of our company.

Authorized but Unissued Shares

Our authorized but unissued shares of Common Stock are available for our Board of Directors to issue without stockholder approval, subject to the rules of any stock exchange upon which our securities are listed. We may use these additional shares for a variety of corporate purposes, including raising additional capital, corporate acquisitions and employee stock plans. The existence of our authorized but unissued shares of Common Stock could render it more difficult or discourage an attempt to obtain control of our company by means of a proxy context, tender offer, merger or other transaction since our Board of Directors can issue large amounts of capital stock as part of a defense to a take-over challenge. In addition, we have authorized in our Articles of Incorporation 400,000 shares of preferred stock. Our board acting alone and without approval of our stockholders, subject to the rules of any stock exchange upon which our securities are listed, can designate and issue one or more series of preferred stock containing super-voting provisions, enhanced economic rights, rights to elect directors, or other dilutive features, that could be utilized as part of a defense to a take-over challenge.

Bylaws

In addition, various provisions of our Bylaws may also have an anti-takeover effect. These provisions may delay, defer or prevent a tender offer or takeover attempt of our company that a stockholder might consider in his or her best interest, including attempts that might result in a premium over the market price for the shares held by our stockholders. Our Bylaws contain limitations as to who may call special meetings as well as require advance notice of stockholder matters to be brought at a meeting. Additionally, our Bylaws also provide that subject to the rights of the holders of any series of preferred stock then outstanding, any director, or the entire Board of Directors, may be removed only for cause and only by the affirmative vote of the holders of at least eighty percent (80%) of the voting power of all of the then outstanding shares of our company then entitled to vote at an election of directors, voting together as a single class. Our Bylaws also reserve the exclusive right of the Board of Directors to establish the number of directors and fill any vacancies and newly created directorships. These provisions will prevent a stockholder from increasing the size of our Board of Directors and gaining control of our Board of Directors by filling the resulting vacancies with its own nominees.

Our Bylaws also establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the Board of Directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board of Directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given us timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although our Bylaws do not give the Board of Directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, our Bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of our company.

Nevada Anti-Takeover Statutes

Business Combination Statute

We are subject to the "business combination" provisions of Sections 78.411 to 78.444 of the NRS. In general, such provisions prohibit a Nevada corporation with 200 or more stockholders from engaging in various "combination" transactions with any interested stockholder for a period of two years after the date of the transaction in which the person became an interested stockholder, unless the transaction is approved by the Board of Directors prior to the date the interested stockholder obtained such status or the combination is approved by the Board of Directors and thereafter is approved at a meeting of stockholders by the affirmative vote of stockholders representing at least 60% of the outstanding voting power held by disinterested stockholders, and extends beyond the expiration of the two-year period, unless (a) the transaction by which the person first became an interested stockholder was approved by the Board of Directors before the person became an interested stockholder; (b) the combination is later approved by a majority of the voting power held by disinterested stockholders; or (c) if the consideration to be paid by the interested stockholder is at least equal to the highest of: (i) the highest price per share paid by the interested stockholder within the two years immediately preceding the date of the announcement of the combination or in the transaction in which it became an interested stockholder, whichever is higher, or (ii) the market value per share of common stock on the date of announcement of the combination and the date the interested stockholder acquired the shares, whichever is higher.

A "combination" is generally defined to include mergers or consolidations or any sale, lease, exchange, mortgage, pledge, transfer, or other disposition, in one transaction or a series of transactions, with an "interested stockholder" or any affiliate or associate of an interested stockholder having: (a) an aggregate market value equal to more than 5% of the aggregate market value of the assets of the corporation, (b) an aggregate market value equal to more than 5% of the aggregate market value of all outstanding voting shares of the corporation, and (c) more than 10% of the earning power or net income of the corporation.

An "interested stockholder" is generally defined to mean a beneficial owner of at least 10% of the outstanding voting power or an affiliate or associate of the corporation that has been a 10% beneficial owner within the preceding 2 years. The statutes could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire our company even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Acquisition of Controlling Interest Statute

Nevada's Acquisition of Controlling Interest Statute (NRS Sections 78.378-78.3793) applies only to Nevada corporations with at least 200 stockholders, including at least 100 stockholders of record who are Nevada residents, which conduct business directly or indirectly in Nevada and whose articles of incorporation or bylaws in effect 10 days following the acquisition of a controlling interest by an acquiror do not prohibit its application. As of the date of this prospectus, we do not believe we have 100 stockholders of record who are residents of Nevada, although there can be no assurance that in the future the acquisition of controlling interest statutes will not apply to us.

Nevada's Acquisition of Controlling Interest Statute, prohibits an acquiror, under certain circumstances, from voting shares of a target corporation's stock after crossing certain threshold ownership percentages, unless the acquiror obtains the approval of the target corporation's stockholders. The statute specifies three thresholds that constitute a controlling interest: (a) at least one-fifth but less than one-third; (b) at least one-third but less than a majority; and (c) a majority or more, of the outstanding voting power. Once an acquiror crosses one of these thresholds, shares which it acquired in the transaction exceeding the threshold (or within ninety days preceding the date thereof) become "control shares" which could be deprived of the right to vote until a majority of the disinterested stockholders restore that right.

A special stockholders meeting may be called at the request of the acquiror to consider the voting rights of the acquiror's shares. If the acquiror requests a special meeting and gives an undertaking to pay the expenses of said meeting, then the meeting must take place no earlier than 30 days (unless the acquiror requests that the meeting be held sooner) and no more than 50 days (unless the acquiror agrees to a later date) after the delivery by the acquiror to the corporation of an information statement which sets forth the range of voting power that the acquiror has acquired or proposes to acquire and certain other information concerning the acquiror and the proposed control share acquisition.

If no such request for a stockholders meeting is made, consideration of the voting rights of the acquiror's shares must be taken at the next special or annual stockholders meeting. If the stockholders fail to restore voting rights to the acquiror, or if the acquiror fails to timely deliver an information statement to the corporation, then the corporation may, if so provided in its articles of incorporation or bylaws, call certain of the acquiror's shares for redemption at the average price paid for the control shares by the acquiror.

In the event the stockholders restore full voting rights to a holder of control shares that owns a majority of the voting stock, then all other stockholders who do not vote in favor of restoring voting rights to the control shares may demand payment for the "fair value" of their shares as determined by a court in dissenters rights proceeding pursuant to Chapter 92A of the NRS.

Limitation on Liability and Indemnification of Directors and Officers

Section 78.138 of the NRS provides that, unless the corporation's articles of incorporation provide otherwise, a director or officer will not be individually liable unless the presumption that it is acting in good faith and on an informed basis with a view to the interests of the corporation has been rebutted, and it is proven that (i) the director's or officer's acts or omissions constituted a breach of his or her fiduciary duties, and (ii) such breach involved intentional misconduct, fraud, or a knowing violation of the law.

Section 78.7502 of the NRS provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, except an action by or in the right of the corporation, by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with the action, suit or proceeding if he: (a) is not liable pursuant to NRS 78.138; or (b) acted in good faith and in a manner which he reasonably believed to be in or not opposed to the best

interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, does not, of itself, create a presumption that the person is liable pursuant to NRS 78.138 or did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the corporation, or that, with respect to any criminal action or proceeding, he had reasonable cause to believe that his conduct was unlawful.

Section 78.7502 of the NRS also provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses, including amounts paid in settlement and attorneys' fees actually and reasonably incurred by him in connection with the defense or settlement of the action or suit if he: (a) as not liable pursuant to NRS 78.138; or (b) acted in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the corporation. Indemnification may not be made for any claim, issue or matter as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

Section 78.751 of the NRS provides that to the extent that a director, officer, employee or agent of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to above, or in defense of any claim, issue or matter therein, the corporation shall indemnify him against expenses, including attorneys' fees, actually and reasonably incurred by him in connection with the defense.

Unless otherwise restricted by the articles of incorporation, bylaws, or an agreement made by the corporation, Section 78.751 of the NRS permits a Nevada company to indemnify its officers and directors against expenses incurred by them in defending a civil or criminal action, suit, or proceeding as they are incurred and in advance of final disposition thereof upon receipt of an undertaking by or on behalf of the director or officer to repay the amount if it is ultimately determined by a court of competent jurisdiction that the director or officer is not entitled to be indemnified by the corporation. The articles of incorporation, bylaws, or an agreement made by the corporation may require a corporation to advance such expenses upon receipt of such an undertaking. Section 78.751 of the NRS further permits a Nevada company to grant its directors and officers additional rights of indemnification under its articles of incorporation, bylaws, or other agreement; provided, however, that unless advanced or otherwise ordered by a court, indemnification may not be made to or on behalf of any director or officer finally adjudged by a court, after exhaustion of appeals, to be liable for intentional misconduct, fraud, or a knowing violation of law that was material to the cause of action.

Section 78.752 of the NRS provides that a Nevada company may purchase and maintain insurance or make other financial arrangements on behalf of any person who is or was a director, officer, employee, or agent of the company, or is or was serving at the request of the company as a director, officer, employee, or agent of another company, partnership, joint venture, trust, or other enterprise, for any liability asserted against him and liability and expenses incurred by him in his capacity as a director, officer, employee, or agent, or arising out of his status as such, whether or not the company has the authority to indemnify him against such liability and expenses.

Our Articles of Incorporation provides that an indemnitee shall also have the right to be paid by our company the expenses (including attorney's fees) incurred in defending any such proceeding in advance of its final disposition; provided, however, that, if NRS requires, an advancement of expenses incurred by an indemnitee in his capacity as a director or officer (and not in any other capacity in which service was or is rendered by such indemnitee, including, without limitation, service to an employee benefit plan) shall be made only upon delivery to our company of an undertaking, by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal that such indemnitee is not entitled to be indemnified for such expenses or otherwise.

In addition, we have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments and fines incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe these provisions in the Articles of Incorporation and the Bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or control persons, in the opinion of the United States Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Transfer Agent and Registrar

The transfer agent of our Common Stock is Issuer Direct Corporation. Their address is One Glenwood Avenue, Suite 1001, Raleigh, NC 27306.

Stock Exchange Listing

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "RZLT".

Exhibit 21.1

Subsidiaries of the Registrant

Name of Entity	Formation Date	Jurisdiction of Incorporation	Holder of Stock
Rezolute Bio UK, Ltd	July 11, 2019	United Kingdom	Rezolute, Inc.
Rezolute (Bio) Ireland Limited	July 19, 2019	Ireland	Rezolute, Inc.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (File Nos. 333-234766 and 333-233310); S-3 (File Nos. 333-250073, 333-251498, 333-265703, and 333-268046); and Form S-8 (File Nos. 333-258222 and 333-268221) of our report dated September 14, 2023 with respect to the consolidated financial statements of Rezolute, Inc. as of and for the years ended June 30, 2023 and 2022, that appears in this Annual Report on Form 10-K.

/s/ Plante & Moran, PLLC

September 14, 2023
Cleveland, Ohio

EXHIBIT 31.1

CERTIFICATIONS

I, Nevan Charles Elam, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: September 14, 2023

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

EXHIBIT 32.1

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

In connection with the annual report of Rezolute, Inc. (the "Company") on Form 10-K for the period ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nevan Charles Elam, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: September 14, 2023

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

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