# 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 December 31, 2022**

**OR**

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

**For the transition period from to**

**Commission File Number: 001-38586**

# RUBIUS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

| **Delaware** | **46-2688109** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **c/o Verdolino & Lowey, P.C.**<br>**124 Washington Street, Suite 101**<br>**Foxborough, Massachusetts** | **02035** |
| (Address of principal executive offices) | (Zip code) |

**(508) 543-1720**
(Registrant's telephone number, including area code)

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

| **Title of each class** | **Trading symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, par value $0.001 per share | RUBY | The Nasdaq Global Select 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 registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, 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. Yes ☐ No ☒

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 ☒

The aggregate market value of common stock held by non-affiliates of the registrant computed by reference to the price of the registrant's common stock as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was approximately (based on the last reported sale price on the NASDAQ Global Select Market as of such date) was $28.4 million.

As of January 31, 2023 the registrant had 90,397,732 shares of common stock, $0.001 par value per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Part III of this Annual Report on Form 10-K incorporates by reference certain information permitted to be so incorporated pursuant to Regulation 14A from the registrant's definitive Proxy Statement to the extent such Proxy Statement is filed no later than 120 days after the registrant's fiscal year end of December 31, 2022. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

**Rubius Therapeutics, Inc.**
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## CAUTIONARY STATEMENT

As previously announced, on February 20, 2023, following the conclusion of our review of strategic alternatives, our Board of Directors unanimously approved the dissolution and liquidation of Rubius Therapeutics, Inc., or the Dissolution, pursuant to a plan of complete liquidation and dissolution, or the Plan of Dissolution, which plan is subject to stockholder approval. We intend to call a special meeting of the stockholders to seek approval of the Plan of Dissolution. We plan to file a preliminary proxy statement relating to the special meeting with the SEC, and to subsequently file and provide stockholders with a definitive proxy statement, as soon as practical.

**Rubius Therapeutics, Inc., or the Company, cautions that trading in the Company's securities is highly speculative and poses substantial risks. Trading prices for the Company's securities may bear little or no relationship to the actual value realized, if any, by holders of the Company's securities. Accordingly, the Company urges extreme caution with respect to existing and future investments in its securities.**

## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are including this statement for purposes of complying with those safe harbor provisions. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, projected costs, prospects, plan and objectives of management are forward-looking statements. You can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "seeks," "approximately," "predicts," "intends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward-looking statements involve various risks and uncertainties that could cause actual outcomes or results to differ materially from those indicated in these statements. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- plans and expectations for the Dissolution;
- beliefs about our available options and financial condition;
- our ability to fund our planned operations for the next twelve months and our ability to continue as a going concern;
- expectations that our cash will be sufficient to fund our operating expenses into the future;
- estimates for our expenses and capital requirements; and
- our expectations regarding our ability to maintain the listing of our common stock on the Nasdaq Global Select Market.

All of our forward-looking statements are as of the date of this Annual Report on Form 10-K only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Annual Report on Form 10-K or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Therefore, you should not place undue reliance on forward-looking statements. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report on Form 10-K, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Annual Report on Form 10-K that modify or impact any of the forward-looking statements contained in this Annual Report on Form 10-K will be deemed to modify or supersede such statements in this Annual Report on Form 10-K.

**Summary of the Material Risks Associated with Our Business**

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- our Board of Directors recently approved, subject to stockholder approval, the dissolution and liquidation of the Company, pursuant to a Plan of Dissolution. We may not be able to complete the Dissolution in a timely manner or at all. Further, there can be no assurances as to the amount of distributions, if any, to our stockholders upon dissolution;
- if our stockholders do not approve the Dissolution, we would not be able to continue our business operations;
- our cash has been significantly depleted by the payoff of our credit facility with SLR Investment Corp., the fees paid in connection with our lease termination and the payment of our other creditor obligations; and
- if we fail to maintain the listing of our common stock with a United States national securities exchange, the liquidity of our common stock could be adversely affected.

The summary risk factors described above should be read together with the text of the full risk factors below and in the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. If any such risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

## PART I

*Except where the context otherwise requires or where otherwise indicated, the terms "Rubius," "Rubius Therapeutics," "we," "us," "our," "our company," "the Company," and "our business" refer to Rubius Therapeutics, Inc. and its consolidated subsidiary.*

*Solely for convenience, the trademarks, service marks and trade names referred to in this annual report are listed without the ®, (sm) and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names.*

### Item 1. Business

### Overview

We are a biopharmaceutical company that has developed a platform and pipeline focused on creating an entirely new class of cellular medicines called Red Cell Therapeutics, or RCTs, for the treatment of cancer and autoimmune diseases.

As previously announced, on February 20, 2023, following the conclusion of our review of strategic alternatives, our Board of Directors unanimously approved the dissolution and liquidation of Rubius, or the Dissolution, pursuant to a plan of complete liquidation and dissolution, or the Plan of Dissolution, which plan is subject to stockholder approval. As such, the following discussion and analysis of our business, financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K, and should also take into account our recent announcement regarding our planned Dissolution. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans, operations, intellectual property and other matters related to our business, includes forward-looking statements that involve risks and uncertainties, including risks associated with our planned Dissolution. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

On November 2, 2022, we announced that, in light of our financial condition and the early stage of our programs, our Board of Directors approved a plan to review strategic alternatives, including a sale or merger of the Company or one or more sales of our assets, and to significantly and immediately reduce our operations, which we refer to as our strategic plan. In connection with the strategic plan, we terminated 42 of our employees (representing 82% of our then-current employee base), leaving a core team of individuals to lead the strategic review process.

On September 13, 2022, our Board of Directors approved certain operational and organizational steps that we undertook in connection with a new strategic reorganization plan and related cost-saving measures. We discontinued our ongoing Phase 1 clinical trials of RTX-240 and RTX-224 for the treatment of advanced solid tumors and restructured the organization to support advancing drug candidates based on our next generation platform. Under this plan, we reduced our overall workforce by approximately 75%, primarily consisting of employees who were focused on clinical development of RTX-240 and RTX-224, with the remainder coming from our manufacturing and general and administrative functions.

Although we ceased enrolling patients in 2022, with more than 80 patients dosed across three clinical trials, we demonstrated that engineered red blood cells, or RBCs, can be manufactured at scale and observed initial evidence of tolerability clinical activity in certain cancer patients, including evidence of tumor shrinkage and prolonged stable disease in PD-(L)-1 refractory solid tumors. Based on these early findings, we firmly believe in the potential of RCTs for the treatment of cancer and autoimmune diseases.

#### *September 2022 Restructuring*

Following careful review of technical progress made during 2022 in an alternative format for making RCTs, we determined that this alternative process had the potential for substantive improvements over our first generation RED PLATFORM, and, therefore, continued investment in our two clinical candidates was no longer justified. As a result, in September 2022, we announced that we would be discontinuing our ongoing Phase 1 clinical trials of RTX-240 and RTX-224 for the treatment of advanced solid tumors and implemented a new strategic reorganization plan focused on advancing drug candidates based on this next generation RBC-based cell conjugation platform and related cost-saving measures.

The next generation platform leverages chemical conjugation to produce RCTs. Cell conjugation creates a covalent link between the cell surface and the molecule of interest. Compared to our first generation RED PLATFORM, this new approach is intended to:

- deliver a higher effective dose by enabling a longer circulation time and/or administering a higher cell dose;
- be more versatile, enabling the conjugation of different payloads, immunomodulatory agents, small molecules and proteins on the cell for enhanced potency; and
- reduce the cost of goods manufacturing by utilizing blood-banked RBCs versus biologically engineering and differentiating early progenitor cells into reticulocytes that express proteins.

These attributes have the potential to result in greater efficacy, a similar safety profile given the restricted biodistribution of RBCs to the spleen and vasculature, and a significant reduction in overall cost structure.

To enable continued investment in the new platform, the cost-saving measures implemented in September 2022 included:

- implementing an approximately 75% reduction in workforce, primarily focused on clinical development, manufacturing and general and administrative personnel;
- discontinuing our ongoing Phase 1 clinical trials of RTX-240 and RTX-224 for the treatment of advanced solid tumors; and
- exploring the sale of our manufacturing facility in Smithfield, Rhode Island.

With these cost-saving measures, our operations were significantly reduced and were focused on maintaining the new platform and related preclinical programs for purposes of exploring strategic alternatives.

***Overview of Discontinued Clinical Programs***

Phase 1/2 Clinical Trial of Monotherapy RTX-240

36 patients were dosed in the monotherapy arm of the Phase 1/2 clinical trial of RTX-240 in advanced solid tumors. To date, RTX-240 has been well tolerated with no treatment-related Grade 3/4 adverse events, or AEs.

Phase 1 Clinical Trial of RTX-240 + Pembrolizumab in Advanced Solid Tumors

Sixteen patients were dosed in the dose-escalation/expansion portion of the Phase 1 clinical trial evaluating RTX-240 in combination with pembrolizumab in advanced solid tumors. To date, the combination of RTX-240 with pembrolizumab has been well tolerated with no treatment or investigator-identified immune-related Grade 3/4 AEs.

Phase 1 Clinical Trial of RTX-224 in Select Advanced Solid Tumors

Seven patients were dosed across two dose cohorts in the Phase 1 clinical trial evaluating RTX-224 in select advanced solid tumors, including non-small cell lung cancer, cutaneous melanoma, head and neck squamous cell carcinoma, urothelial (bladder) carcinoma and triple-negative breast cancer. To date, there have been no treatment-related Grade 3/4 AEs.

***Termination of Credit Facility***

On October 13, 2022, we entered into a payoff letter with SLR Investment Corp. (f/k/a Solar Capital Ltd.), or SLR, our senior lender, under which we voluntarily prepaid SLR approximately $75.7 million, in full satisfaction of all obligations, including all outstanding principal, accrued interest, fees, costs, expenses and other amounts chargeable, under our Loan and Security Agreement, dated December 21, 2018, with SLR (as amended, the "Loan Agreement") and related security documents. The payoff letter also provided for the termination of all commitments and obligations under the Loan Agreement and related documents and release of all liens held by SLR on our assets.

***November 2022 Restructuring***

On November 2, 2022, we announced that, in light of our financial condition, including the repayment and termination of our $75.0 million credit facility with SLR, and the early stage of our programs, our Board of Directors approved a plan to review strategic alternatives, including a sale or merger of the Company or one or more sales of our assets, and to

significantly and immediately reduce our operations, which we refer to as our strategic plan. In connection with the strategic plan, we terminated 82% of our employee base as of November 2, 2022, leaving a core team of individuals to lead the strategic review process.

***Sale of Manufacturing Facility***

On December 6, 2022, we entered into a Purchase and Sale Agreement with DIV Acquisition V, LLC for the sale of our Smithfield, Rhode Island manufacturing facility and certain related fixtures and personal property, for an aggregate purchase price of $18,500,000, subject to adjustment. The transaction closed on December 21, 2022.

***Termination of Lease Agreement***

On December 12, 2022, or the Effective Date, we entered into an Agreement for Termination of Lease, or the Lease Termination Agreement, with ARE-MA Region No. 58, LLC, or ARE, relating to our corporate headquarters located at 399 Binney Street, Cambridge, Massachusetts 02139, or the Cambridge Facility. Under the Lease Termination Agreement, our Lease Agreement, dated as of January 18, 2018, with ARE (as amended, the "Lease") for the Cambridge Facility terminated on January 31, 2023.

Under the terms of the Lease Termination Agreement, we paid to ARE a lease termination payment of approximately $6,973,308, consisting of (i) ARE's right to draw the full amount of a letter of credit that it held under the Lease, in the amount of $1,573,308, (ii) an initial payment of $4,300,000, inclusive of rent previously paid by us to ARE for the month of December 2022 in the amount of $910,060, and (iii) a subsequent payment of $1,100,000. We also conveyed ownership to ARE of certain items of personal property, furniture, fixtures and equipment located within the Cambridge Facility. Pursuant to the Lease Termination Agreement, we have no further rent obligations to ARE pursuant to the Lease following the Effective Date.

***IND Withdrawals***

In connection with the strategic plan, we withdrew our Investigational New Drug Applications, or INDs, for RTX-134 and RTX-321 on December 9, 2022. We withdrew our INDs for RTX-224 and RTX-240 on December 13, 2022 and December 14, 2022, respectively.

***Approval of Plan of Dissolution***

On February 20, 2023, following the conclusion of our review of strategic alternatives, our Board of Directors unanimously approved the Dissolution, pursuant to the Plan of Dissolution, which plan is subject to stockholder approval. We intend to call a special meeting of the stockholders to seek approval of the Plan of Dissolution. We plan to file a preliminary proxy statement relating to the special meeting with the SEC, and to subsequently file and provide stockholders with a definitive proxy statement, as soon as practicable.

**The Company cautions that trading in the Company's securities is highly speculative and poses substantial risks. Trading prices for the Company's securities may bear little or no relationship to the actual value realized, if any, by holders of the Company's securities. Accordingly, the Company urges extreme caution with respect to existing and future investments in its securities.**

**Intellectual property**

We have a broad portfolio of patent applications, know how, trade secrets, and other intellectual property that covers our platform technologies as well as our product discoveries. We believe the breadth and depth of our intellectual property is a strategic asset that has the potential to provide a significant competitive advantage over other cell therapy companies.

We have striven to protect and enhance the proprietary technology, inventions and improvements in our intellectual property portfolio, including seeking, maintaining and defending patent rights, whether developed internally or licensed from collaborators or other third parties. Our policy has been to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and product discoveries. We have also historically relied on trade secrets and know-how relating to our proprietary technology and product discoveries and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of engineered red blood cell therapeutics.

We believe that we have a strong global intellectual property position and possess substantial know-how and trade secrets relating to our proprietary product discoveries, technology and platform, including related manufacturing processes and technology. As for our product discoveries, platform, and the processes we have developed, we have pursued, as appropriate, patent protection or trade secret protection relating to compositions, methods of use, treatment of indications, dosing, formulations and methods of manufacturing. Our former product candidates – RTX-240, RTX-321 and RTX-224 – are covered by three varieties of U.S. patent claims: (1) composition of matter; (2) method of treatment; and (3) method of making. As of January 31, 2023, our patent portfolio consists of 30 patent families (not including provisional applications and including licensed patent families), including 20 issued U.S. patents (including in-licensed U.S. patents), 30 patents issued outside the United States (including in-licensed patents outside of the United States), 22 owned or in-licensed pending U.S. utility patent applications, and more than 130 owned or in-licensed pending patent applications in jurisdictions outside of the United States (including Patent Cooperation Treaty, or PCT, applications) that, in many cases, are counterparts to the foregoing U.S. patents and patent applications. Examples of the products and technology areas covered by our intellectual property portfolio are described below.

**Disease-related intellectual property**

The disease-related patent rights in our intellectual property portfolio relate to pathological conditions and disorders and provide coverage for our former RCT product candidates to specifically address those conditions and the associated disease states. The disease-related patent applications include those described below. Each of the disease-related patent rights and applications described below are owned by us and are not licensed from any third party:

*RTX-240 and RTX-224 for certain oncology indications*

We developed RTX-240, our former RCT product candidate engineered to express 4-1BBL and IL-15TP (a fusion of the cytokine IL-15 and IL-15 receptor alpha), for the treatment of patients suffering from hematological or solid cancers that have lost response to conventional therapies, including anti-PD-1 therapies or other immune-oncology therapies, and to prevent the emergence of resistance to checkpoint inhibitors and other immune-oncology therapies. RTX-240 was designed to induce the proliferation and activation of two key target cells, the NK cell and CD8+ memory T cell.

We developed RTX-224, our former RCT product candidate engineered to co-express 4-1BBL and IL-12, for the treatment of patients suffering from solid tumors where a T cell mechanism of action is critical. The introduction of membrane-bound IL-12 is thought to have very broad T cell-based activation, including all subsets of CD8+ and CD4+ T cells, while sparing the induction of the CD4+ regulatory T cells.

- This aspect of our patent portfolio relates to RCTs that express 4-1BBL, RCTs that express IL-15 or IL-15TP, RCTs that express IL-12, RCTs that co-express 4-1BBL and IL-15TP, RCTs that co-express 4-1BBL and IL-12, methods of activating CD8+ T cells and NK cells, methods of treating cancer, methods of making RCTs that express 4-1BBL and IL-15TP, including RTX-240, and methods of making RCTs that express 4-1BBL and IL-12, including RTX-224.

- As of January 31, 2023, the patent rights relating to this technology includes five issued U.S. patents, two pending U.S. utility patent applications, and 18 pending foreign patent applications derived from National Stage entries, relating to RCT compositions of matter, methods of activating immune cells, methods of treatment, and methods of making RTX-240 and RTX-224. We expect the issued patents and patent applications in this portfolio, if issued, to expire between 2037 and 2039, without taking into account any patent term adjustments or extensions we may obtain.

*RTX-321, an artificial antigen presenting cell for the treatment of HPV-positive tumors*

We developed our former product candidate RTX-321, an artificial antigen presenting cell RCT, to express an HPV 16 peptide antigen bound to MHC class I, 4-1BBL and IL-12 on the cell surface to mimic human T cell-APC interactions. RTX-321 was formerly in development for the treatment of HPV 16-positive tumors.

- This aspect of our patent portfolio relates to RCTs that express 4-1BBL, RCTs that express IL-12, RCTs that co-express 4-1BBL and IL-12, RCTs that express an HPV 16 peptide antigen bound to MHC class I, 4-1BBL, and IL-12, methods of treating cancer, and methods of making RCTs that express an HPV 16 peptide antigen bound to MHC class I, 4-1BBL and/or IL-12, including RTX-321.

- As of January 31, 2023, the patent rights relating to this technology includes four issued U.S. patents, three pending U.S. patent applications, and 32 pending foreign patent applications derived from National Stage entries,

relating to RCT compositions of matter, methods of treatment and methods of making RTX-321. We expect the issued patents and patent applications in this portfolio, if issued, to expire between 2037 and 2039, without taking into account any patent term adjustments or extensions we may obtain.

*Additional oncology intellectual property*

We own disease-related patent applications directed to RCTs for use in oncology, including immuno-oncology. These patent applications relate to RCT compositions that comprise a variety of agents, including anti-tumor antibodies, tumor starvation enzymes, pro-apoptotic proteins, costimulatory molecules, immune checkpoint inhibitors, tumor antigens, MHC molecules and numerous combinations thereof. These patent applications also cover the use of RCTs to treat cancer, including lung cancer, melanoma, renal cancer, bladder cancer, gastric cancer, squamous cell carcinoma, Hodgkin lymphoma, hepatocellular carcinoma, Merkel cell carcinoma, colorectal cancer, and acute myeloid leukemia, as well as various relapsed or refractory cancers.

We expect the patent applications in this portfolio, if issued, to expire between 2034 and 2040, without taking into account any patent term adjustments or extensions we may obtain.

*Autoimmune disease intellectual property*

We own disease-related patent applications directed to RCTs for use in treating autoimmune diseases. These patent applications relate to RCT compositions having autoimmune antigens, anti-cytokine antibodies, agents for cleaving autoimmune antibodies and numerous combinations thereof. The RCTs covered by these patent applications operate through various mechanisms, including through induction of tolerance to self-antigens, clearance of autoimmune antibodies from the bloodstream, clearance of cytokines from the bloodstream and inactivation of autoimmune antibodies. The patent applications also cover the use of these RCTs to treat a number of diseases, such as Type 1 diabetes, membranous nephropathy, autoimmune hepatitis, myasthenia gravis, celiac disease and neuromyelitis optica.

We expect the patent applications in this portfolio, if issued, to expire between 2034 and 2040, without taking into account any patent term adjustments or extensions we may obtain.

*Cardio-metabolic disorders intellectual property*

We own disease-related patent applications directed to RCT compositions and their use in treating cardiac disorders and metabolic disorders, including diabetes, obesity heart failure, atherosclerosis and hemophilia. We expect the patent applications in this portfolio, if issued, to expire in 2037, without taking into account any patent term adjustments or extensions we may obtain.

*Infectious disease intellectual property*

We own disease-related patent applications directed to RCT compositions and their use in treating infectious diseases, such as a viral infection (e.g., cytomegalovirus or HIV) or a bacterial infection (e.g., bacteremia). We expect the patent applications in this portfolio, if issued, to expire between 2034 and 2040 without taking into account any patent term adjustments or extensions we may obtain.

**Platform-related intellectual property**

In addition to the disease-related intellectual property, our intellectual property portfolio also includes know-how and patent applications directed to our first and second generation RED PLATFORM and other technologies developed internally and exclusively in-licensed from the Whitehead Institute for Biomedical Research, or WIBR, that relate to the engineering and culturing of RCTs. Exemplary platform technologies that are the subject of such patent applications include:

- methods related to the in vitro production of enucleated red blood cells;
- gene editing and transcriptional modulation systems for engineering RCTs;
- targeted lipid nanoparticle compositions and RNA delivery techniques;
- amplifiable nucleic acid constructs for optimizing protein production;

- methods for chemically conjugating biotherapeutic proteins to cell surfaces; and
- methods for increasing percent enucleation during RCT production.

Individual patent terms extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued from applications filed in the United States are effective for 20 years from the earliest effective filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The duration of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

**Trademark protection**

As of January 31, 2023, our trademark portfolio contains approximately 59 registrations and pending applications. For the RUBIUS THERAPEUTICS mark, we have issued registrations in the U.S., Argentina, Canada, Brazil, the United Kingdom, and Hong Kong, and an International Registration designating Australia, China, the E.U., India, Indonesia, Israel, Japan, Mexico, New Zealand, Norway, Russia, Singapore, South Korea, and Switzerland. In addition, we have two U.S. trademark registrations for the RUBIUS mark. For the RCT mark, we have a U.S. registration, as well as an International Registration designating China, the E.U., India, and Japan. Under this International Registration, the mark is registered in all listed countries. In addition, we have issued registrations for the RCT mark in the United Kingdom and Canada. We also have issued U.S. registrations for the RED CELL THERAPEUTICS mark, as well as an International Registration designating Japan. Under this International Registration, the mark is registered in Japan. In addition, we have a pending application in Singapore for the RED CELL THERAPEUTICS mark. We have issued registrations for the RED PLATFORM mark in the U.S. and the United Kingdom, as well as an International Registration designating China, the E.U., India, Japan and Russia. Under this International Registration, the mark is registered in all listed countries. In addition, we have a registration for this mark in Canada. We have issued registrations for the REALIZING THE POWER OF RED mark in the U.S. and the United Kingdom, as well as an International Registration designating Canada, China, the E.U., India, Japan, and Russia. Finally, we have a U.S. registration for the RTX mark.

**Trade secrets**

We have historically relied, in some circumstances, on trade secrets to protect our technology and aspects of our platform. However, trade secrets are difficult to protect. We have sought to protect our technology and product discoveries, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators and advisors. We have also sought to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or may be independently discovered by third parties. To the extent that our employees, contractors, consultants, collaborators and advisors have used intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our proprietary technology, inventions, improvements and products, please see the section on “Risk factors—Risks related to intellectual property.”

**Licenses**

In January 2016, we entered into an exclusive license with WIBR that grants us an exclusive, worldwide, sublicensable license under patent rights comprising two patent families to research, develop, make and commercialize products and processes covered by such patent rights for all uses, or the WIBR License. The WIBR License was amended in December 2017 to grant us an exclusive license to the commercialization rights under a third patent family jointly owned by WIBR and Tufts University, or Tufts. The WIBR License was amended in July 2018 to grant us an exclusive license to the commercialization rights under a fourth patent family owned by WIBR. As of January 31, 2023, the patent portfolio licensed from WIBR includes five issued U.S. patents, and 19 pending U.S. and foreign patent applications and issued foreign patents. We expect these WIBR-licensed patent applications, if issued, to expire between 2034 and 2038, without taking into account any patent term adjustments or extensions that may be obtained.

The patent rights licensed to us under the WIBR License are directed, in part, to the in vitro production of RBCs and the use of the enzyme sortase to conjugate a protein of interest to the cell surface. We have certain diligence obligations under the WIBR License, which include using commercially reasonable efforts to develop and commercialize any products under the patents and achieving certain milestones as further described in the WIBR License. Additionally, under certain circumstances, we may in the future be obligated to negotiate in good faith field-limited, non-exclusive sublicenses to allow third parties to exploit the patent rights licensed to us under the WIBR License.

WIBR retains the right with respect to all four patent families licensed to us to (i) practice the patent rights licensed under the agreement for research, teaching and educational purposes, including sponsored research and collaboration, and (ii) grant non-exclusive licenses to academic and not-for-profit research institutes to practice under the patent rights for research, teaching and educational purposes (excluding sponsored research), while Tufts retains such rights only with respect to the patent family that it co-owns. Pursuant to a Defense Advanced Research Projects Agency agreement between WIBR and a global biopharmaceutical company, the biopharmaceutical company funded research resulting in one of the licensed patent families and WIBR granted the biopharmaceutical company the right to retain a worldwide, irrevocable, non-exclusive, royalty-free right to use this patent family for research and development purposes. In addition, under the WIBR agreement, the U.S. federal government retains a royalty-free, non-exclusive, non-transferable license to practice any government-funded invention claimed in the patent rights, as set forth in 35 U.S.C. §§ 201-211 and Executive Order 12591.

As partial consideration for the license, we issued 366,667 shares of our common stock to WIBR. In addition, we paid WIBR an upfront payment and are required to pay annual license maintenance fees, creditable against royalties and milestone payments. Under the terms of the license, we are obligated to pay to WIBR low single-digit royalties based on any annual net sales by us, our affiliates and our sublicensees of licensed products and licensed services that are covered by a valid claim of the licensed patent rights at the time and in the country of sale. On a country-by-country basis, upon expiration of the last valid claim of the licensed patent rights covering such licensed product or licensed service in such country, our license becomes royalty-free, perpetual and irrevocable with respect to such country. The terms of the WIBR License require us to make aggregate milestone payments of up to $1.6 million upon the achievement of specified preclinical, clinical and regulatory milestones. In addition, we are required to pay to WIBR a percentage of the non-royalty payments that we receive from sublicensees of the patent rights licensed to us by WIBR. This percentage varies from low single digits to low double digits and will be based upon the clinical stage of the product at the time of the sublicense.

Under the WIBR License, WIBR controls the prosecution and maintenance of the patent rights licensed to us and we have the right to review and comment on such prosecution and maintenance. We have the first right to enforce the patent rights licensed to us against third party infringers. We may terminate the WIBR License for convenience upon three months prior written notice to WIBR. WIBR may terminate the WIBR License upon written notice to us if we, along with our affiliates and sublicensees, cease to carry on business related to the WIBR License for more than six months. WIBR may terminate the WIBR License for our material breach that remains uncured for sixty days after receiving notice thereof, if we fail to pay amounts due under the agreement within thirty days after receiving notice of such failure, or if we challenge the validity or enforceability of any of the licensed patent rights.

**Government regulation**

Although our operations are currently focused on winding down our operations in connection with our anticipated Dissolution, we remain subject to numerous federal, state and local laws and regulations, including securities, tax, anti-bribery and privacy laws and regulations.

**Human Capital Resources**

As of January 31, 2023, we had six full-time U.S.-based employees engaged to facilitate exploration and consummation of a strategic transaction. None of our employees are represented by labor unions or covered by collective bargaining agreements. As discussed more fully elsewhere in this Annual Report on Form 10-K, our Board of Directors recently approved the Dissolution of the Company pursuant to the Plan of Dissolution. In connection therewith, our employee base has been further reduced. Going forward, any continuing employees will be focused on facilitating the wind-down of the Company.

**Facilities**

Until January 31, 2023, our corporate headquarters were located in approximately 85,000 square feet of office and laboratory space at 399 Binney Street, Cambridge, Massachusetts. As described further under the section captioned

"Business—Termination of Lease Agreement" above, on December 12, 2022, we entered into a Lease Termination Agreement with our landlord ARE, pursuant to which our lease for this facility terminated on January 31, 2023.

As of February 1, 2023, in light of our exit from our previous headquarters and in connection with our planned Dissolution, we have engaged Verdolino & Lowey, P.C. to provide administrative services to Rubius, including serving as our virtual principal executive office, and they are located at 124 Washington St., Suite 101, Foxborough, Massachusetts 02035.

We formerly owned a 135,000 square foot clinical manufacturing facility located in Smithfield, Rhode Island. On December 6, 2022, we entered into a Purchase and Sale Agreement with DIV Acquisition V, LLC for the sale of this facility and certain related fixtures and personal property for an aggregate purchase price of $18,500,000, subject to adjustment. The transaction closed on December 21, 2022.

**Legal Proceedings**

We are not currently a party to any material legal proceedings.

**Corporate Information**

Rubius was incorporated in April 2013 as VL26, Inc. under the laws of the State of Delaware. In January 2015, the Company changed its name to Rubius Therapeutics, Inc. Our principal executive office is located at c/o Verdolino & Lowey, P.C., 124 Washington Street, Suite 101, Foxborough, Massachusetts, 02035 and our telephone number is (508) 543-1720.

**Financial Information and Segments**

The financial information required under this Item 1 is incorporated herein by reference to the section of this Annual Report titled "Part II—Item 8—Consolidated Financial Statements and Supplementary Data." The company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The company has developed a platform and pipeline focused on creating RCTs for the treatment of patients with severe diseases. All of the Company's tangible assets are held in the United States. See Note 2 to our consolidated audited financial statements included in this Annual Report on Form 10-K. For financial information regarding our business, see "Part II—Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K and our consolidated audited financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

**Available Information**

Our Internet address is www.rubiustx.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available through the "Investors and Media" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not to be deemed to be incorporated by reference in, and is not part of, this Annual Report on Form 10-K or any of our other securities filings, unless specifically incorporated herein by reference, and should not be relied upon in making a decision as to whether or not to purchase our common stock. Our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at http://www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

**Item 1A. Risk Factors**

*Our business is subject to numerous risks. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's discussion and analysis of financial condition and results of operations," and in our other filings with the Securities and Exchange Commission. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations*.

**Risks related to our recently announced Dissolution**

***We cannot predict the timing of distributions, if any, to our stockholders.***

Our current intention is that, if approved by our stockholders, a Certificate of Dissolution would be filed promptly after such approval however, the decision of whether or not to proceed with the Dissolution will be made by our Board of Directors, or the Board, in its sole discretion. No further stockholder approval would be required to effect the Dissolution. However, if the Board determines that the Dissolution is not in our best interest or the best interest of our stockholders, the Board may, in its sole discretion, abandon the Dissolution or may amend or modify the Plan of Dissolution to the extent permitted by Delaware law without the necessity of further stockholder approval. After the Certificate of Dissolution has been filed, revocation of the Dissolution would require stockholder approval under Delaware law.

Under Delaware law, before a dissolved corporation may make any distribution to its stockholders, it must pay or make reasonable provision to pay all of its claims and obligations, including all contingent, conditional or unmatured contractual claims known to the corporation. Furthermore, we may be subject to potential liabilities relating to indemnification obligations, if any, to third parties or to our current and former officers and directors. It might take significant time to resolve these matters, and as a result we are unable to predict the timing of distributions, if any are made, to our stockholders.

***If our stockholders do not approve the Dissolution proposal, we would not be able to continue our business operations.***

On November 2, 2022, we announced that, in light of our financial condition and the early stage of our programs, our Board had approved a plan to review strategic alternatives, including a sale or merger of the Company or one or more sales of our assets, and to significantly and immediately reduce our operations (which we refer to herein as the "strategic plan"). In connection with the strategic plan, we terminated all but a core team of individuals to lead the strategic review process, and most individuals that remain are doing so on a part-time and consulting basis. While the strategic plan resulted in the sale of our Smithfield, Rhode Island manufacturing facility and certain related fixtures and personal property, for an aggregate purchase price of $18.5 million, we have been unable to identify a merger partner or purchaser of our Company or most of our other assets. If our stockholders do not approve the Dissolution proposal, the Board will continue to explore what, if any, alternatives are available for the future of the Company in light of its discontinued business activities; however, those alternatives are likely limited to seeking voluntary dissolution at a later time with potentially diminished assets, seeking bankruptcy protection (should our net assets decline to levels that would require such action) or investing our cash in another operating business. It is unlikely that these alternatives would result in greater stockholder value than the proposed Plan of Dissolution and the Dissolution.

***The Board may determine not to proceed with the Dissolution.***

Even if the Dissolution proposal is approved by our stockholders, the Board may determine in its sole discretion not to proceed with the Dissolution. If our Board elects to pursue any alternative to the Plan of Dissolution, our stockholders may not receive any of the funds that might otherwise be available for distribution to our stockholders. After the Certificate of Dissolution has been filed, revocation of the Dissolution would require stockholder approval under Delaware law.

**Risks related to our financial condition and capital requirements**

***We do not currently have sufficient working capital to fund our planned operations for the next twelve months and may not be able to continue as a going concern, and our cash has been significantly depleted by our payoff of the SLR loan and other obligations. Further, we have recently announced that the Board unanimously approved the Dissolution of the Company pursuant to a Plan of Dissolution.***

As of February 27, 2023, the issuance date of the consolidated financial statements, there is substantial doubt about our ability to continue as a going concern, as we currently do not have adequate financial resources to fund our forecasted operating costs for at least twelve months from the filing of this Annual Report on Form 10-K. As of December 31, 2022, we have incurred a cumulative deficit of $856.7 million. For the years ended December 31, 2022, 2021, and 2020, we reported net losses of $179.7 million, $196.5 million, and $167.7 million, respectively. In addition, during the years ended December 31, 2022, 2021, and 2020, we used $137.2 million, $63.8 million and $27.2 million in operating and investing activities, respectively, resulting in a cash and cash equivalents balance of $14.9 million, $225.8 million, and $176.3 million as of December 31, 2022, 2021, and 2020, respectively. As a result, our existing cash resources are not sufficient to meet our anticipated needs over the next twelve months from the date hereof, even after taking into account our significantly reduced operations, and we would need to raise additional capital to continue our operations, which capital is unlikely to be available on favorable terms or at all.

Our operating history and near-term forecast of incurring net losses and negative operating cash flows raise substantial doubt about our ability to continue as a going concern. Our cash position has required us to significantly reduce our operations and liquidate certain assets to remain afloat.

As previously announced, on February 20, 2023, following the conclusion of our review of strategic alternatives, our Board unanimously approved the dissolution and liquidation of Rubius, pursuant to a Plan of Dissolution, which plan is subject to stockholder approval. We intend to call a special meeting of the stockholders to seek approval of the Plan of Dissolution. We plan to file a preliminary proxy statement relating to the special meeting with the SEC, and to subsequently file and provide stockholders with a definitive proxy statement, as soon as practicable.

**The Company cautions that trading in the Company's securities is highly speculative and poses substantial risks. Trading prices for the Company's securities may bear little or no relationship to the actual value realized, if any, by holders of the Company's securities. Accordingly, the Company urges extreme caution with respect to existing and future investments in its securities.**

***We have significantly reduced our employee base and operations.***

In September 2022, we announced a corporate restructuring that resulted in a 75% reduction in workforce and refocused our efforts on preclinical research and platform development. In November 2022, we announced the strategic plan, significantly further reducing our operations and personnel and shifting our focus to a review of strategic alternatives. Following these restructurings and further headcount downsizing in January 2023, as of January 31, 2023, we had only six full-time employees, each focused on reviewing and, if appropriate, pursuing strategic alternatives.

As discussed more fully elsewhere in this Annual Report, our Board of Directors recently approved the Dissolution of the Company pursuant to the Plan of Dissolution. In connection therewith, our employee base has been further reduced. Going forward, any remaining employees will be engaged to facilitate the wind-down of the Company.

***We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future***.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2013. For the years ended December 31, 2022, 2021, and 2020, we reported net losses of $179.7 million, $196.5 million, and $167.7 million, respectively. As of December 31, 2022, we had an accumulated deficit of $856.7 million. Further, our cash resources have been significantly depleted, including $75.7 million used to extinguish our long-term debt and satisfy our obligations under the loan and security agreement with SLR Investment Corp. As noted elsewhere in this report, there is substantial doubt as to our ability to fund our planned operations for the next twelve months and to continue to operate as a going concern. As previously announced, on February 20, 2023, following the conclusion of our review of strategic alternatives, our Board of Directors unanimously approved the Dissolution pursuant to the Plan of Dissolution, which plan is subject to stockholder approval.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital and may result in holders of our common stock and other securities suffering a total loss of their investment.

***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.***

Our results of operations and general business strategy could be adversely affected by general conditions in the global economy and in the global financial markets. In the past several years, global credit and financial markets have experienced volatility, instability and disruptions, including as a result of the ongoing COVID-19 pandemic. From time to time, this volatility, instability and disruption has caused, and may cause in the future, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. For example, since early 2020, the coronavirus, or COVID-19, pandemic has caused disruption in the financial markets both globally and in the United States. While certain negative effects of the ongoing COVID-19 pandemic have lessened as vaccines are distributed and administered and prevention and treatment methods improve, there have been and may continue to be resurgences of cases, including as a result of the emergence of variants that may be more contagious or more resistant to the vaccine and treatment options available, placing renewed and prolonged strain on both health care facilities and our workforce. Given the inter-connectivity of the global economy, pandemic disease and health events have the potential to continue to negatively impact economic activities in many countries, including the United States. The ongoing spread of the coronavirus, including variants thereof and resurgences in geographies experiencing some relief, could have a negative material impact on our business, prospects, financial condition and results of operations of the Company.

In addition, our results of operations and financial condition may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions.
As of December 31, 2022, we had cash and cash equivalents of $14.9 million. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since December 31, 2022, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

***Changes in tax law could adversely affect our business and financial condition.***

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our business. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

***The amount of and our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations and uncertainty***.

As of December 31, 2022, we had federal and state net operating loss, or NOL, carryforwards of $584.8 million and $583.6 million, respectively, which may be available to offset future taxable income. The federal NOLs include $37.2 million which expire at various dates through 2037 and $547.6 million which carryforward indefinitely. The state NOLs expire at various dates through 2041. As of December 31, 2022, we also had federal and state research and development tax credit carryforwards of $29.5 million and $19.9 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2034 and 2026, respectively.

Federal NOLs generated in taxable years after December 31, 2017 generally may not be carried back to prior taxable years, and while such federal NOLs generated in taxable years beginning after December 31, 2017 will not be subject to expiration, the deduction for such NOL in any taxable year will be limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. However, the Coronavirus Aid, Relief and Economic Security Act repeals the 80% limitation on the utilization of such federal NOLs generated in taxable years beginning after December 31, 2017 and beginning before January 1, 2021 and allows for federal NOLs generated in taxable years beginning after December 31, 2017 and before January 1, 2021, to be carried back to each of the five taxable years preceding the taxable year in which the loss arises. It is uncertain whether this change in law temporarily allowing for the carryback of federal NOLs will produce any material benefit for our business.

In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs or tax credits, or NOLs or credits (including federal research and development tax credits), to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, including in connection with our earlier private placements, IPO, our previous underwritten offering and other transactions. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code and limit our ability to utilize our NOLs and our credits. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above under this section captioned "Risk factors—Risks related to our financial condition and capital requirements," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOLs or credits that are subject to limitation by Sections 382 and 383 of the Code.

**Risks related to our intellectual property**

***If we are unable to obtain and maintain patent protection for any intellectual property we have developed, third parties could develop and commercialize products or technology similar or identical to our inventions, and our ability to successfully monetize any product candidates or technologies we have developed may be adversely affected.***

The value of our intellectual property portfolio depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product discoveries, RED PLATFORM and other technologies we have developed. We have sought to protect our proprietary position by in-licensing intellectual property and filing patent applications in the United States and abroad relating to our product discoveries, RED PLATFORM and other technologies. Given that the development of our technology and product discoveries is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product discoveries is also at an early stage.

With respect to our patent portfolio, as of January 31, 2023, most of the patent rights that we own or in-license are currently pending patent applications, except that we own 15 issued U.S. patents and we have five in-licensed U.S. patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from third parties.

We have filed patent applications directed to the composition of matter of our product discoveries and various processes of our RED PLATFORM; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our technology and product discoveries and each of these provisional patent applications is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. Although we have secured issued United States composition of matter patents related to our former product candidates RTX-240, RTX-321 and RTX-224, we cannot be certain that the claims in our pending patent applications covering the composition of matter of all of our product discoveries will be considered patentable by the United States Patent and Trademark Office, or the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions of matter relating to our product discoveries, RED PLATFORM and other technologies, and instead may need to rely on patent applications with claims covering a method of use and/or method of manufacture. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a third party from making and marketing a product that is identical to our invention for an indication that is outside the scope of the patented method. Moreover, even if third parties do not actively promote their products for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our product discoveries and RED PLATFORM could have a material adverse effect on the value of our intellectual property portfolio and on our financial condition, results of operations, and prospects.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. There is no assurance that all potentially relevant prior art relating to our patents and patents applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents successfully issue, and even if such patents cover our inventions, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product discoveries, or prevent others from designing around our claims. Additionally, the patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. Any of these outcomes could have an adverse impact on the value of our intellectual property portfolio.

***Our rights relating to our product discoveries and RED PLATFORM are subject, in part, to the terms and conditions of licenses granted to us by others.***

We have relied upon licenses to certain patent rights and proprietary technology from third parties that have been important or necessary to the development of our product discoveries and RED PLATFORM. For example, under our license agreement with the Whitehead Institute for Biomedical Research, or WIBR, as amended (the "WIBR License"), WIBR grants us an exclusive, worldwide, sublicensable license under four patent families to research, develop, make, and commercialize products and processes covered by such patent rights for all uses. The portfolio of patent rights licensed to us under the WIBR License is directed, in part, to the *in vitro* production of red blood cells, including the use of the enzyme sortase to conjugate a protein of interest to the cell surface. Patent rights that we in-license may be subject to a reservation of rights by one or more third parties. For example, our in-licensed patent rights from WIBR under the WIBR License were funded in part by the U.S. government. As a result, the U.S. government may have certain rights to such intellectual property. Furthermore, pursuant to a Defense Advanced Research Projects Agency Agreement between WIBR and a global biopharmaceutical company, the biopharmaceutical company funded research resulting in one of the patent families licensed to us under the WIBR License and retained a worldwide, irrevocable, non-exclusive, royalty-free right to use the inventions and technologies covered by this patent family for research and development purposes.

WIBR also retains the right with respect to all four patent families licensed to us to (i) to practice the patent rights licensed under the agreement for research, teaching and educational purposes, including sponsored research and collaboration, and (ii) to grant non-exclusive licenses to academic and not-for-profit research institutes to practice under the patent rights for research, teaching and educational purposes (excluding sponsored research), while Tufts University, or Tufts, which co-owns certain of our in-licensed patent rights with WIBR, retains such rights only with respect to the patent family that it co-owns.

Further, our licensors may co-own the patent rights we in-license with other third parties with whom we do not have a direct relationship. Our exclusive rights to certain of these patent rights are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such patent rights, who are not parties to our license agreements. For example, under the WIBR License, we license certain patents rights co-owned by WIBR and Tufts. Our rights to Tufts' interest in such patent rights depends on an inter-institutional agreement between WIBR and Tufts, pursuant to which WIBR controls the licensing of such patent rights. If our licensors do not have exclusive control of the grant of licenses under any such third-party co-owners' interest in such patent rights or we are otherwise unable to secure such exclusive rights, such co-owners may be able to license their rights to other third parties, who could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on the value of our intellectual property portfolio, and on our financial conditions, results of operations, and prospects.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution and maintenance, and we may not have the right to control the enforcement, and defense of patents and patent applications covering the technology that we license from third parties. For example, under the WIBR License, WIBR controls prosecution of the patent rights licensed to us, and we control enforcement of the patent rights. We cannot be certain that our in-licensed patent applications (and any patents issuing therefrom) that are controlled by our licensors will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with our best interests. If our

licensors fail to prosecute, maintain, enforce, and defend such patents rights, or lose rights to those patent applications (or any patents issuing therefrom), the rights we have licensed may be reduced or eliminated, the right to exploit any of our product discoveries and RED PLATFORM technologies that are the subject of such licensed rights could be adversely affected, and it may not be possible to prevent third parties from making, using and selling competing inventions. Moreover, we cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution. Finally, subject to the terms of any such license agreements, the licensor may be able to terminate the license without our consent, as further described below.

***If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose important license rights.***

The WIBR License imposes various development, diligence, commercialization, and other obligations on us in order to maintain the licenses. WIBR may terminate the WIBR License upon written notice to us if we, along with our affiliates and sublicensees, cease to carry on business related to the WIBR License for more than six months. WIBR may also terminate the WIBR License for our material breach that remains uncured for sixty days after receiving notice thereof, if we fail to pay amounts due under the agreement within thirty days after receiving notice of such failure, or if we challenge the validity or enforceability of any of the licensed patent rights. In spite of our efforts, WIBR or a future licensor might conclude that we have materially breached our obligations under such license agreements and seek to terminate the license agreements, thereby removing or limiting the ability to exploit the intellectual property covered by these license agreements. If these in-licenses are terminated, or if the underlying patent rights licensed thereunder fail to provide the intended exclusivity, third parties would have the freedom to seek regulatory approval of, and to market, products and technologies identical to our product discoveries and/or RED PLATFORM technologies. Any of the foregoing could have a material adverse effect on the value of our intellectual property portfolio and on our financial conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which a licensee's technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights that are the subject of the licensing agreement;
- the licensee's diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property;
- whether and the extent to which inventors are able to contest the assignment of their rights to the licensors; and
- the priority of invention of patented technology.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to exploit such

intellectual property, which could have a material adverse effect on our financial conditions, results of operations, and prospects.

***If we are unable to protect the confidentiality of our trade secrets, the value of our intellectual property portfolio would be adversely affected.***

In addition to seeking patents for our product discoveries, RED PLATFORM and other technologies, we have also relied on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information. Trade secrets and know-how can be difficult to protect. We expect our trade secrets and know-how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We have sought to protect our know-how, trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements, and including in our vendor and service agreements terms protecting our confidential information, know-how and trade secrets, with parties who have access to such information. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We have also sought to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Despite our efforts, any of the aforementioned parties may breach the agreements and disclose our proprietary information, including our trade secrets, or there may be a lapses or failures in our physical and electronic security systems which lead to our proprietary information being disclosed, and we may not be able to obtain adequate remedies in the event of any such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that has been licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a third party, we would have no right to prevent them from using that technology or information. If any of our trade secrets were to be disclosed to or independently developed by a third party, the value of our intellectual property portfolio would be materially and adversely affected.

***Third-party claims of intellectual property infringement, misappropriation or other violation against us or our licensors may adversely affect our intellectual property portfolio.***

The field of cellular therapeutics is competitive and dynamic. Due to the focused research and development that is taking place by several companies in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed, and other third-party, intellectual property and proprietary rights in the future.

The value of our intellectual property portfolio depends in part on our and our licensors' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. This reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to red blood cell technologies and therapeutic proteins, and in the fields in which we have developed our pipeline products. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product discoveries, RED PLATFORM technologies and other technologies may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product discoveries, RED PLATFORM technologies and other technologies that we have developed will not infringe patents owned by third parties. We may not be aware of patents that have already been issued and that a third party might assert are infringed by our product discoveries, RED PLATFORM or other

technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product discoveries, RED PLATFORM or other technologies.

It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product discoveries, RED PLATFORM or other technologies, could be found to be infringed by our product discoveries, RED PLATFORM or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product discoveries, RED PLATFORM or other technologies may infringe. We cannot provide any assurances that third-party patents do not exist which might be enforced against our technology, including our RED PLATFORM technologies, manufacturing methods, product discoveries.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our product discoveries, RED PLATFORM or other technologies infringes upon these patents. We are aware of an issued patent outside the United States that is directed to erythrocytes that comprise exogeneous polypeptides. While we believe that we have reasonable defenses against a claim of infringement should such a claim be brought, including that certain claims in this patent are invalid, there can be no assurance that we will prevail in any such action by the holder of the patent. In the event that any third party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our product discoveries, RED PLATFORM or other technologies. In this case, the holders of such patents may be able to block the ability to exploit the applicable intellectual property unless a license under the applicable patents is obtained, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement.
Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive and time-consuming.

We or our licensors may also be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our intellectual property portfolio. Even if we are successful in defending against such claims, litigation could result in substantial costs.

The occurrence of any of the foregoing could have a material adverse effect on the value of our intellectual property portfolio and on our financial condition, results of operations and prospects.

***We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming, and unsuccessful.***

Third parties may infringe our patents or the patents of our licensing partners and, if litigated in an infringement proceeding, a court may decide that a patent owned or in-licensed by us is invalid or unenforceable or that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1), or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for operations. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately.

***Intellectual property rights do not necessarily address all potential threats.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations. For example:

- others may be able to make products that are similar to our product discoveries or utilize similar technology but that are not covered by the claims of the patents that we license or own;
- we or our licensors might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own;
- we or our licensors, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications will not lead to issued patents;
- coverage claimed in a patent application can be significantly reduced before the patent is issued resulting in an issued patent that fails to provide any meaningful protection, or a patent's scope can be reinterpreted after issuance;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by third parties, which could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our product discoveries, RED PLATFORM technologies, or other technologies;
- changes in U.S. and international patent law could impair our ability to protect our intellectual property;
- laws of foreign countries may not protect our rights to the same extent as the laws of the United States;
- we may have failed to identify patentable aspects of our research and development output in time to obtain patent protection;
- although we have entered into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection;
- third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competing inventions;
- the patents of others may harm our business (for example, third parties may have blocking patents that could be used to prevent the exploitation of our proprietary inventions); and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on the value of our intellectual property portfolio and on our financial condition, results of operations and prospects.

**Risks related to our common stock**

***The price of our stock has been and may continue to be volatile, and our stockholders could lose all or part of their investment***.

The trading price of our common stock has been highly volatile and could continue to be subject to large fluctuations in response to the risk factors discussed in this section and elsewhere in this Annual Report on Form 10-K, and other risk factors beyond our control, including:

- the recent announcement that our Board of Directors unanimously approved the dissolution and liquidation of the Company, subject to stockholder approval;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or cellular therapies in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- adoption of new accounting standards;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation; and
- general political and economic conditions.

In recent years, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Since our common stock began trading on The Nasdaq Global Select Market on July 18, 2018, our stock price has traded at prices as low as $0.14 per share and as high as $38.71 per share through January 31, 2023.

Additionally, technical factors in the public trading market for our stock may produce price movements that may or may not comport with macro, industry or company-specific fundamentals, including, without limitation, the sentiment of retail investors (including as may be expressed on financial trading and other social media sites), speculation in the press, in the investment community, or on the internet, including on online forums and social media, about us, our industry or our securities, the amount and status of short interest in our securities (including a “short squeeze”), access to margin debt, trading in options and other derivatives on our common stock and other technical trading factors. We may incur rapid and substantial decreases in our stock price in the foreseeable future that are unrelated to our operating performance or prospects. There can be no guarantee that our stock price will remain at current prices or that future sales of our common stock will not be at prices lower than the sales price in previous offerings. If the market price of our common stock does not exceed their purchase price, our stockholders may not realize any return on their investment in us and may lose some or all of their investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs, which would harm our business, operating results or financial condition.

***If we fail to maintain the listing of our common stock with a United States national securities exchange, the liquidity of our common stock could be adversely affected.***

As previously disclosed, on July 27, 2022, we received written notice from the Listing Qualifications Department, or the Staff, of The Nasdaq Stock Market LLC, or Nasdaq, indicating that, based upon the closing bid price for our common stock for the previous 30 consecutive business days, we no longer satisfied the minimum bid price requirement for continued listing on The Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1) (which we refer to as the "Minimum Bid Price Requirement"). In accordance with the Nasdaq Listing Rules, we were afforded a 180-calendar day grace period, through January 23, 2023, to regain compliance with the Minimum Bid Price Requirement.

On February 6, 2023, we were notified by the Staff that, based upon our non-compliance with the Minimum Bid Price Requirement as of January 23, 2023, and the Staff's determination that we are a "public shell" as that term is defined in Nasdaq Listing Rule 5101, we would be delisted at the opening of business on February 15, 2023 unless we were to timely request a hearing before a Nasdaq Hearings Panel, or the Panel, to address the deficiencies and present a plan to regain compliance.

On February 13, 2023, we timely requested a hearing before the Panel, which request will stay any further delisting action by the Staff pending the ultimate outcome of the hearing and the expiration of any extension that may be granted by the Panel, unless we determine to withdraw our hearing request in connection with the Dissolution. Unless we determine to withdraw our hearing request, our common stock will remain listed and eligible for trading on Nasdaq pending the ultimate conclusion of the hearing process. However, there can be no assurance that we will successfully appeal the delisting determination, or that, if successful, we will be able to maintain compliance with any of the other Nasdaq continued listing requirements. Further, in connection with our planned Dissolution, we may determine not to move forward with the hearing.

If our common stock is ultimately delisted by Nasdaq, our common stock may be eligible to trade on the OTC Bulletin Board or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, our common stock. In addition, there can be no assurance that our common stock would be eligible for trading on any such alternative exchange or markets.

***We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock***.

We currently anticipate that we will retain future earnings for the operation of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of their stock.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval***.

Our executive officers, directors and their affiliates beneficially hold, in the aggregate, over 43% of our outstanding voting stock. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest as one of our stockholders.

***We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives***.

As a public company, even with our reduced operations, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive

compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access.

As of December 31, 2021, we ceased to be eligible for the emerging growth company provisions of the Jumpstart Our Business Startups Act, or the JOBS Act, as of such date and are no longer able to avail ourselves of exemptions from various reporting requirements applicable to non-emerging growth companies. Accordingly, we will no longer have the option to delay the adoption of new or revised accounting standards until such time as those standards apply to private companies. As a result, we may incur additional expenses or challenges relating to our loss of emerging growth company status. Further, stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies substantially increase our legal and financial compliance costs and make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will increase our net loss and may require us to reduce costs in other areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline***.

The trading market for our common stock is influenced by research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

***We have broad discretion in the use of our existing cash, cash equivalents and investments and may not use them effectively***.

Our management has broad discretion in the application of our cash, cash equivalents and investments, including as we wind down our operations in connection with our planned Dissolution. Because of the number and variability of factors that will determine our use of our cash, cash equivalents and investments, their ultimate use may vary substantially from their currently intended use. Our management might not apply our cash, cash equivalents and investments in ways that ultimately increase the value of our stockholders' investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest our cash in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not use our resources in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

**Risks related to corporate governance**

***Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management***.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for our stockholders and other stockholders to elect directors of their choosing or cause us to take other corporate actions they desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

***Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.***

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claim for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim against us governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts is the sole and exclusive forum (1) for resolving any complaint asserting a cause of action arising under the Securities Act or the rules and regulations promulgated thereunder, and (2) of all suits in equity and actions at law brought to enforce any liability or duty created by the Securities Act or the rules and regulations thereunder, or the Federal Forum Provision, as our principal executive offices are located in Cambridge, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, the forum selection clauses in our amended and restated by-laws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and

employees even though an action, if successful, might benefit our stockholders. While the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. The Federal Forum Provision may also impose additional litigation costs on us and/or our stockholders who assert that the provision is invalid or unenforceable, and if the Federal Forum Provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Court of Chancery of the State of Delaware or the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Until January 31, 2023, our corporate headquarters were located in approximately 85,000 square feet of office and laboratory space at 399 Binney Street, Cambridge, Massachusetts. As described further under the section captioned "Business—Termination of Lease Agreement" above, on December 12, 2022, we entered into a Lease Termination Agreement with our landlord, ARE, pursuant to which our lease for this facility terminated on January 31, 2023.

We formerly owned a 135,000 square foot manufacturing facility located in Smithfield, Rhode Island. On December 6, 2022, we entered into a Purchase and Sale Agreement with DIV Acquisition V, LLC, for the sale of this facility and certain related fixtures and personal property, for an aggregate purchase price of $18,500,000, subject to adjustment.
The transaction closed on December 21, 2022.

**Item 3. Legal Proceedings**

We are not currently a party to any material legal proceedings.

**Item 4. Mine Safety Disclosures**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

**Certain Information Regarding the Trading of Our Common Stock**

Our common stock trades under the symbol "RUBY" on the Nasdaq Global Select Market and has been publicly traded since July 18, 2018. Prior to this time, there was no public market for our common stock.

**Holders of Our Common Stock**

As of January 31, 2023, there were approximately 13 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

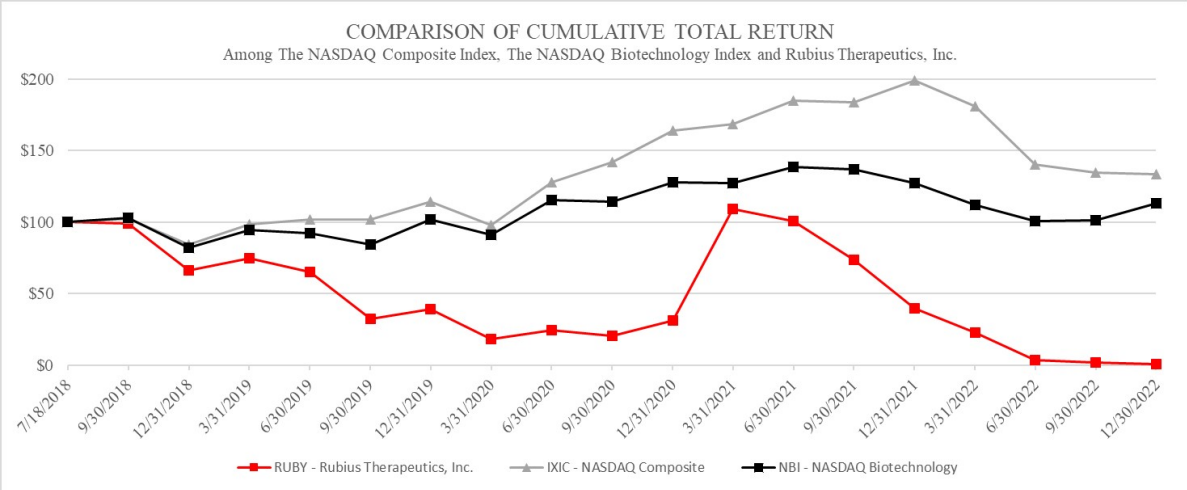
**Dividends**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

**Stock Performance Graph**

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the SEC, for purposes of Section 18 of the Exchange Act, nor shall such information be incorporated by reference into any future filing under the Exchange Act or Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the performance of our common stock to the Nasdaq Composite Index and to the Nasdaq Biotechnology Index from July 18, 2018 (the first date that shares of our common stock were publicly traded) through December 31, 2022. The comparison assumes $100 was invested in our common stock and in each of the foregoing indices after the market closed on July 18, 2018, and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of future stock price performance.




**Securities Authorized for Issuance Under Equity Compensation Plans**

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

**Unregistered Sales of Equity Securities and Use of Proceeds**

***Recent Sales of Unregistered Equity Securities***

None.

**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

**Item 6. Reserved**

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Objective

The purpose of the following discussion and analysis is to provide material information relevant to an assessment of our financial condition and results of operations from management's perspective, including to describe and explain key trends, events and other factors that impacted our reported results and that are reasonably likely to impact our future performance.

As previously announced, on February 20, 2023, following the conclusion of our review of strategic alternatives, our Board of Directors unanimously approved the dissolution and liquidation of Rubius, or the Dissolution, pursuant to a plan of complete liquidation and dissolution, or the Plan of Dissolution, which plan is subject to stockholder approval. As such, the following discussion and analysis of our business, financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K, and should also take into account our recent announcement regarding our planned Dissolution. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans, operations, intellectual property and other matters related to our business, includes forward-looking statements that involve risks and uncertainties, including risks associated with our planned Dissolution. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

### Overview

We are a biopharmaceutical company that has developed a platform and pipeline focused on creating an entirely new class of cellular medicines called Red Cell Therapeutics, or RCTs, for the treatment of cancer and autoimmune diseases.

On November 2, 2022, we announced that, in light of our financial condition and the early stage of our programs, our Board of Directors approved a plan to review strategic alternatives, including a sale or merger of the Company or one or more sales of our assets, and to significantly and immediately reduce our operations, which we refer to as the "strategic plan." In connection with the strategic plan, we terminated 42 of our employees (representing 82% of our then-current employee base), leaving a core team of individuals to lead the strategic review process. On February 20, 2023, following the conclusion of our review of strategic alternatives, our Board unanimously approved the dissolution and liquidation of the Company pursuant to a Plan of Dissolution, which plan is subject to stockholder approval.

**The Company cautions that trading in the Company's securities is highly speculative and poses substantial risks. Trading prices for the Company's securities may bear little or no relationship to the actual value realized, if any, by holders of the Company's securities. Accordingly, the Company urges extreme caution with respect to existing and future investments in its securities.**

***Nasdaq Delisting Notification***

As previously disclosed, on July 27, 2022, we received a deficiency letter from the Listing Qualifications Department, or the Staff, of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the $1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1) (which we refer to as the "Minimum Bid Price Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), or the Compliance Period Rule, we were provided a period of 180 calendar days, or until January 23, 2023 (which we refer to as the "Compliance Date"), to regain compliance with the Minimum Bid Price Requirement.

On February 6, 2023, we were notified by the Staff that, based upon our non-compliance with the Minimum Bid Price Requirement as of January 23, 2023, and the Staff's determination that we are a "public shell" as that term is defined in Nasdaq Listing Rule 5101, we would be delisted at the opening of business on February 15, 2023 unless we were to timely request a hearing before a Nasdaq Hearings Panel, or the Panel, to address the deficiencies and present a plan to regain compliance.

On February 13, 2023, we timely requested a hearing before the Panel, which request will stay any further delisting action by the Staff at pending the ultimate outcome of the hearing and the expiration of any extension that may be granted by the Panel, unless we determine to withdraw our hearing request in connection with the Dissolution. Unless we determine to withdraw our hearing request, our common stock will remain listed and eligible for trading on Nasdaq pending the ultimate conclusion of the hearing process.

However, there can be no assurance that we will successfully appeal the delisting determination, or that, if successful, we will be able to maintain compliance with any of the other Nasdaq continued listing requirements. Further, in connection with our planned Dissolution, we may determine not to move forward with the hearing.

**Components of Our Results of Operations**

***Revenue***

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products given our significant reduction in operations and focus on review of strategic alternatives.

***Operating Expenses***

*Research and Development Expenses*

Research and development expenses consist of costs incurred for our research activities conducted during the periods presented, including our drug discovery efforts, and the development and manufacturing of our since-discontinued product candidates during such time, which include:

- employee-related expenses, including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of such product candidates and the wind-down of our research and clinical programs, including under agreements with third parties, such as consultants, contractors and contract research organizations, or CROs;
- the cost of developing and scaling our manufacturing process and the manufacturing of product candidates for use in our preclinical studies and clinical trials, including those produced in our manufacturing facility as well as components produced under agreements with third parties, such as consultants, contractors and contract manufacturing organizations, or CMOs;
- laboratory supplies and research materials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance; and
- payments made under third-party licensing agreements.

We expense research and development costs as incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct research, manufacturing and development expenses are tracked on a program-by-program basis. These consist mostly of fees, reimbursed materials, testing and other costs paid to consultants, contractors, CMOs and CROs, as well as the cost of materials incurred for internal manufacturing. In addition, we allocate the cost of operating our manufacturing facility to research and development program costs, consisting of associated personnel costs, other than stock-based compensation expense, and manufacturing facility costs, including depreciation. We do not allocate costs associated with our platform development, early-stage research and shared research and development, including associated personnel costs, laboratory supplies, non-manufacturing facilities expenses and other indirect costs, to research and development programs, because these costs are deployed across multiple programs and our technology platform and, as such, are not separately classified.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, due to the increased size and duration of later-stage clinical trials.

*General and Administrative Expenses*

General and administrative expenses include salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs, as well as professional fees for legal, patent, consulting, investor and public relations, accounting and audit services.

*Restructuring and Impairment Charges*

During the year ended December 31, 2022, we undertook certain operational and organizational steps in connection with a strategic reorganization plan and related cost-saving measures that we initiated in the third quarter of 2022. These measures included discontinuing the ongoing clinical trials of RTX-240 and RTX-224 for the treatment of advanced solid tumors and reducing our overall workforce. We also initiated a plan to review strategic alternatives in the fourth quarter of 2022 in which we significantly and immediately reduced our operations, which included terminating all of our remaining employees except for a core team of individuals retained to lead the strategic review process.

***Other Income (Expense)***

*Interest Income*

Interest income consists of interest earned on our invested cash balances.

*Interest Expense*

Interest expense consists of interest owed on outstanding borrowings under our Loan Agreement (as defined below), as well as amortization of debt discount.

*Other Income, Net*

Other income, net consists of miscellaneous income and expense unrelated to our core operations.

***Income Taxes***

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each year or for our research and development tax credits generated, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss, or NOL, carryforwards and tax credits will not be realized. As of December 31, 2022, we had U.S. federal and state net operating loss carryforwards of $584.8 million and $583.6 million, respectively, which may be available to offset future taxable income. The federal NOLs include $37.2 million, which expire at various dates through 2037, and $547.6 million, which carryforward indefinitely. The state NOLs expire at various dates through 2041. As of December 31, 2022, we also had U.S. federal and state research and development tax credit carryforwards of $29.5 million and $19.9 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2034 and 2026, respectively. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

**Results of Operations**

***Comparison of the Years Ended December 31, 2022 and 2021***

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | Change |
| | (in thousands) | | |
| Revenue | $ — | $ — | $ — |
| Operating expenses: | | | |
| Research and development | 96,414 | 141,587 | (45,173) |
| General and administrative | 30,835 | 53,029 | (22,194) |
| Restructuring and impairment charges | 51,197 | — | 51,197 |
| Total operating expenses | 178,446 | 194,616 | (16,170) |
| Loss from operations | (178,446) | (194,616) | 16,170 |
| Other income (expense): | | | |
| Interest income | 819 | 91 | 728 |
| Interest expense | (3,863) | (6,434) | 2,571 |
| Other income, net | 1,824 | 4,412 | (2,588) |
| Total other income (expense), net | (1,220) | (1,931) | 711 |
| Net loss | $ (179,666) | $ (196,547) | $ 16,881 |

*Research and Development Expenses*

| | Twelve Months Ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | Change |
| | (in thousands) | | |
| Research and development program expenses: | | | |
| Rare disease | $ — | $ 284 | $ (284) |
| Cancer | 50,138 | 74,080 | (23,942) |
| Platform development, early-stage research and unallocated expenses: | | | |
| Personnel-related | 19,445 | 27,827 | (8,382) |
| Stock-based compensation expense | 6,863 | 12,338 | (5,475) |
| Contract research and development | 3,839 | 7,115 | (3,276) |
| Laboratory supplies and research materials | 4,742 | 5,186 | (444) |
| Facility-related and other | 11,387 | 14,757 | (3,370) |
| Total research and development expenses | $ 96,414 | $ 141,587 | $ (45,173) |

Research and development expenses were $96.4 million for the year ended December 31, 2022, compared to $141.6 million for the year ended December 31, 2021. The decrease in research and development program expenses of $45.2 million related to the deprioritization of RTX-321 in May 2022 and RTX-240 AML and monotherapy studies in September 2022. This decrease was partially offset by an increase in clinical costs related to RTX-224 that were incurred prior to the discontinuation of the ongoing clinical trials of RTX-240 and RTX-224 for the treatment of advanced solid tumors. We do not expect to incur these costs in future periods as our research and development has stopped and all remaining costs have been accrued as of December 31, 2022. Platform development, early-stage research and unallocated expenses decreased by $20.9 million principally due to decreases of $8.4 million in personnel-related expenses resulting from our headcount reductions and $5.5 million in stock-based compensation expense resulting from expense reversals on forfeited equity awards in the third and fourth quarters of 2022. In addition, contract research and development decreased $3.3 million and laboratory supplies and research materials decreased $0.4 million as drug discovery activities and platform development

were discontinued in the current year. The reduction in facility-related and other expenses of $3.4 million was primarily due to the termination of our lease for office and laboratory facilities in Cambridge, Massachusetts.

*General and Administrative Expenses*

| | Twelve Months Ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | Change |
| | (in thousands) | | |
| Personnel-related | $ 8,220 | $ 13,895 | $ (5,675) |
| Stock-based compensation expense | 8,920 | 23,272 | (14,352) |
| Professional and consultant fees | 8,491 | 9,278 | (787) |
| Facility-related and other | 5,204 | 6,584 | (1,380) |
| Total general and administrative expenses | $ 30,835 | $ 53,029 | $ (22,194) |

General and administrative expenses for the year ended December 31, 2022 were $30.8 million, compared to $53.0 million for the year ended December 31, 2021. The decrease in general and administrative expenses of $22.2 million was primarily due to a decrease in stock-based compensation expense of $14.4 million, which was driven by expense reversals on forfeited equity awards in the third and fourth quarters of 2022, as well as a reduction in the market price of our common stock, resulting in a lower valuation of stock options granted in 2022. Additionally, personnel-related expenses decreased by $5.7 million driven by headcount reductions in general and administrative functions during 2022, facility-related and other expenses decreased $1.4 million primarily due to the termination of our lease for office and laboratory facilities in Cambridge, Massachusetts, and professional and consultant fees decreased $0.8 million due to the reduction in operations in the fourth quarter of 2022.

*Restructuring and Impairment Charges*

| | Twelve Months Ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | Change |
| | (in thousands) | | |
| Employee termination benefits | $ 12,929 | $ — | $ 12,929 |
| Impairment of property, plant and equipment | 25,841 | — | 25,841 |
| Contract termination costs | 12,427 | — | 12,427 |
| Total restructuring and impairment charges | $ 51,197 | $ — | $ 51,197 |

During the year ended December 31, 2022, we recorded charges of $12.9 million, $25.8 million and $12.4 million related to employee termination benefits, impairment of property, plant and equipment and contract termination costs, respectively, due to the reorganization plan we initiated in the third quarter of 2022 and the plan to review strategic alternatives initiated in the fourth quarter of 2022. We paid or otherwise settled $22.6 million of employee termination benefits and contract termination costs during the year ended December 31, 2022 and expect to pay or otherwise settle approximately $26.0 million in total to implement the two plans.

*Interest Income*

Interest income was $0.8 million for the year ended December 31, 2022, compared to $0.1 million for the year ended December 31, 2021. Interest income increased due to higher prevailing interest rates.

*Interest Expense*

Interest expense was $3.9 million for the year ended December 31, 2022, compared to $6.4 million for the year ended December 31, 2021. The decrease in interest expense was principally due to a gain of $1.1 million on the extinguishment of our Loan Agreement (as defined below).

*Other Income, Net*

Other income, net was $1.8 million for the year ended December 31, 2022, compared to $4.4 million for the year ended December 31, 2021. The decrease in other income, net was due to greater monetization of certain tax credits during the prior period.

**Liquidity and Capital Resources**

Since our inception, we have incurred significant operating losses. We have not commercialized any product candidates and we do not expect to generate revenue from sales of any products given our significant reduction in operations and focus on review of strategic alternatives. To date, we have funded our operations with proceeds from the sale of preferred stock, with borrowings under our recently terminated Loan Agreement, with proceeds from our IPO and with proceeds from our March 2021 Offering, described and defined further below. In July 2018, we completed our IPO, pursuant to which we issued and sold 12,055,450 shares of common stock, inclusive of 1,572,450 shares pursuant to the full exercise of the underwriters' option to purchase additional shares. We received proceeds of $254.3 million, after deducting underwriting discounts and commissions and other offering costs. In December 2018, we entered into a Loan and Security Agreement with SLR Investment Corp. (f/k/a Solar Capital Ltd.) (the "Loan Agreement"), which was amended in June 2021, and which provided for aggregate borrowings of up to $75.0 million. In March 2021, we completed the March 2021 Offering, pursuant to which we issued and sold 6,896,552 shares of common stock. We received proceeds of $187.2 million, after deducting underwriting discounts and commissions and other offering costs. In October 2022, pursuant to a payoff letter, we voluntarily prepaid approximately $75.7 million, in full satisfaction of all obligations, including all outstanding principal, accrued interest, fees, costs, expenses and other amounts chargeable, under the Loan Agreement, considerably depleting our cash resources.

As of December 31, 2022, we had cash and cash equivalents of $14.9 million and as of January 31, 2023, we had cash and cash equivalents of $11.7 million, which includes the proceeds from the sale of our Rhode Island facility for an aggregate purchase price of $18.5 million. As noted elsewhere in this report, there is substantial doubt as to our ability to fund our planned operations for the next twelve months and to continue to operate as a going concern. Further, we have recently announced that our Board unanimously approved the dissolution and liquidation of the Company pursuant to a Plan of Dissolution, which plan is subject to stockholder approval.

***Cash Flows***

The following table summarizes our sources and uses of cash for each of the periods presented:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| | (in thousands) | | |
| Cash used in operating activities | $ (150,142) | $ (145,122) | $ (127,648) |
| Cash provided by investing activities | 12,944 | 81,351 | 100,432 |
| Cash provided by (used in) financing activities | (75,470) | 198,453 | 26,484 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | $ (212,668) | $ 134,682 | $ (732) |

*Operating Activities*

During the year ended December 31, 2022, operating activities used $150.1 million of cash, primarily resulting from our net loss of $179.7 million, offset by net non-cash charges of $47.0 million, predominantly consisting of impairment charges and stock-based compensation expense. Net cash used in our operating assets and liabilities for the year ended December 31, 2022 consisted of a net decrease in accounts payable, accrued expenses and other current liabilities, other long-term liabilities and operating lease liabilities of $27.3 million, offset by a $9.7 million increase in prepaid expenses and other current assets, operating lease, and right-of-use assets.

During the year ended December 31, 2021, operating activities used $145.1 million of cash, primarily resulting from our net loss of $196.5 million, partially offset by net non-cash charges of $44.7 million, predominantly consisting of stock-based compensation expense. Net cash used in our operating assets and liabilities for the twelve months ended December 31, 2021 consisted of a $0.1 million decrease in accounts payable, accrued expenses and other current liabilities, other long-term liabilities and operating lease liabilities, offset by a decrease in prepaid expenses and other current assets, other assets and operating lease, right-of-use asset of $6.6 million.

During the year ended December 31, 2020, operating activities used $127.6 million of cash, primarily resulting from our net loss of $167.7 million, partially offset by net non-cash charges of $40.0 million, predominantly consisting of stock-

based compensation expense. Net cash used in our operating assets and liabilities for the twelve months ended December 31, 2020 consisted of a $6.5 million decrease in accounts payable, accrued expenses and other current liabilities, other long-term liabilities and operating lease liabilities, offset by a decrease in prepaid expenses and other current assets, other assets and operating lease, right-of-use asset of $6.6 million.

Changes in accounts payable, accrued expenses and other current liabilities and prepaid expenses and other current assets in all periods presented were generally due to growth in our business, the advancement of our research programs and the timing of vendor invoicing and payments.

*Investing Activities*

During the year ended December 31, 2022, net cash provided by investing activities was $12.9 million, consisting of sales and maturities of investments of $83.9 million and sales of property, plant and equipment of $17.9 million, offset by purchases of investments of $83.6 million and purchases of property, plant and equipment of $5.3 million. Our property, plant and equipment sales primarily relate to the sale of our manufacturing facility in Smithfield, Rhode Island.

During the year ended December 31, 2021, net cash provided by investing activities was $81.4 million, consisting of sales and maturities of investments of $85.0 million, offset by purchases of property, plant and equipment of $3.6 million. Our cash purchases of property, plant and equipment primarily relate to the purchase of computer and laboratory equipment installed in our manufacturing facility in Smithfield, Rhode Island and our laboratory space in Cambridge, Massachusetts.

During the year ended December 31, 2020, net cash provided by investing activities was $100.4 million, consisting of sales and maturities of investments of $228.6 million, offset by net purchases of investments of $122.7 million and purchases of property, plant and equipment of $5.5 million. Our cash purchases of property, plant and equipment consisted of $2.9 million for purchases related to our manufacturing facility in Smithfield, Rhode Island, largely driven by payments for manufacturing equipment purchases and construction costs incurred in 2019, and $2.6 million for the purchase of computer and laboratory equipment installed in our manufacturing facility and our laboratory space in Cambridge, Massachusetts.

*Financing Activities*

During the year ended December 31, 2022, net cash used in financing activities of $75.5 million consisted of the repayment of our long-term debt under the Loan Agreement.

During the year ended December 31, 2021, net cash provided by financing activities of $198.5 million consisted primarily of proceeds of $187.2 million, after deducting underwriting discounts and commissions and other offering costs, from the March 2021 Offering, as well as proceeds received from issuance of common stock upon exercise of stock options and under the employee stock purchase plan of $11.0 million. Net cash used in financing activities includes $0.4 million of offering cost payments in connection with the March 2021 Offering and $0.2 million of debt issuance cost payments related to our Loan Agreement in June 2021.

During the year ended December 31, 2020, net cash provided by financing activities of $26.5 million consisted of $25.0 million proceeds received from borrowings under our Loan Agreement and $1.5 million proceeds received from issuance of common stock upon exercise of stock options.

***Contractual Obligations and Commitments***

The following table summarizes our contractual obligations as of December 31, 2022 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | Total | Less Than 1 Year | 1 to 3 Years | 4 to 5 Years | More Than 5 Years |
| | (in thousands) | | | | |
| Operating lease commitments (1) | $ 1,100 | $ 1,100 | $ — | $ — | $ — |
| Total | $ 1,100 | $ 1,100 | $ — | $ — | $ — |

(1) Amounts in table reflect payments due for our leases of office and laboratory space in Cambridge, Massachusetts under an operating lease agreement terminated in December 2022 with an effective date in January 2023.

As of December 31, 2022, we were party to contracts in the normal course of business with third parties for various services. These contracts generally do not contain minimum purchase commitments and are cancelable by us upon prior written notice; many such contracts have been cancelled since December 31, 2022. Payments due upon cancellation typically consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the table above.

We have also entered into a license agreement with the Whitehead Institute for Biomedical Research, or WIBR, as amended, under which we have been granted an exclusive, sublicensable, nontransferable license under certain patent families related to the development of our RCTs, or the WIBR License. Under the terms of the WIBR License, we are obligated to pay to WIBR low single-digit royalties based on any annual net sales by us, our affiliates and our sublicensees of licensed products and licensed services that are covered by a valid claim of the licensed patent rights at the time and in the country of sale. The terms of the agreement require us to make aggregate milestone payments of up to $1.6 million upon the achievement of specified preclinical, clinical and regulatory milestones. In addition, the license requires us to pay to WIBR a percentage of the non-royalty payments that we receive from sublicensees of the patent rights licensed by WIBR. This percentage varies from low single-digit to low double-digit percentages and is based upon the clinical stage of the product that is the subject of the sublicense. The WIBR License provides that royalties shall be paid by us on a licensed product-by-licensed product and country-by-country basis, beginning on the first commercial sale of such licensed product in such country until expiration of the last valid patent claim covering such licensed product in such country.

We have the right to terminate the WIBR License in its entirety, on a patent-by-patent or country-by-country basis, at will upon three months' notice to WIBR. WIBR may terminate the agreement upon breach of contract or in the event of bankruptcy, liquidation, insolvency or cessation of business related to the license. For additional information, see "Business—Licenses."

***Loan and Security Agreements***

In December 2018, or the Closing Date, we entered into a Loan and Security Agreement with SLR Investment Corp., or SLR (formerly Solar Capital Ltd.), as collateral agent for the lenders party thereto for an aggregate principal amount of $75.0 million. The aggregate principal amount was funded in three tranches of term loans of $25.0 million each, on the Closing Date, in June 2019, and in June 2020. On October 13, 2022, we entered into a payoff letter with SLR, under which we voluntarily prepaid SLR approximately $75.7 million, in full satisfaction of all obligations, including all outstanding principal, accrued interest, fees, costs, expenses and other amounts chargeable, under the Loan Agreement. The payoff letter also provided for the termination of all commitments and obligations under the Loan Agreement and release of all liens held by SLR on our assets.

***Common Stock Sales Agreement***

On August 1, 2019, we entered into a Distribution Agreement, or the Distribution Agreement, with multiple sales agents, pursuant to which the Company was entitled to offer and sell to or through the agents, from time to time, shares of the Company's common stock, par value $0.001 per share, having an aggregate gross sales price of up to $100.0 million. No shares of the Company's common stock were sold under the Distribution Agreement, which expired in accordance with its terms on August 21, 2022, and the applicable registration statement is no longer effective.

***Off-Balance Sheet Arrangements***

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and related disclosures. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

***Accrued Research and Development Expenses***

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical and assay development activities;
- CMOs in connection with raw material acquisition; and
- CROs in connection with clinical trials.

We base the expense recorded related to contract research and manufacturing on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply materials and conduct services. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

***Stock-based Compensation***

We measure stock-based awards with service-based and performance-based vesting conditions granted to employees, directors and non-employees based on their fair value on the date of the grant using the Black-Scholes option-pricing model for options or the difference between the purchase price per share of the award, if any, and the fair value of our common stock for restricted common stock awards. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. We use the straight-line method to record the expense of awards with service-based vesting conditions. We use the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing when achievement of the performance condition becomes probable.

The Black-Scholes option-pricing model uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our common stock options, the risk-free interest rate for a period that approximates the expected term of our common stock options, and our expected dividend yield.

We measure the fair value of stock-based awards with market-based vesting conditions on the date of grant using a Monte Carlo simulation model. When service-based vesting conditions also exist, we recognize stock-based compensation expense using the graded-vesting method over the longer of the derived service period from the market condition or the required service period. In accordance with accounting guidance for awards with market conditions, the stock-based compensation expense will be recognized over the appropriate period regardless of whether the award achieves the market condition and will only be adjusted to the extent the service condition is not met. When an award contains a market-based vesting condition and a performance-based vesting condition where both must be achieved to earn the award, we recognize stock-based compensation expense over the longer of the derived service period from the market condition or the period estimated for the performance-based vesting condition to be achieved. We begin recording stock-based compensation expense for this type of award when the achievement of the performance-based vesting condition becomes probable regardless of whether the market condition has been achieved.

**Recently Issued Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows are disclosed in Note 2 to our consolidated financial statements.

**Item 7A. Quantitative and Qualitative Disclosure about Market Risk**

As of December 31, 2022, we had cash and cash equivalents of $14.9 million, which consisted of cash, money market accounts and U.S. government money market funds. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates.

Inflation generally affects us by increasing our cost of labor and materials. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the year ended December 31, 2022.

**Item 8. Consolidated Financial Statements and Supplementary Data**

**RUBIUS THERAPEUTICS, INC.**

**Index to Consolidated Financial Statements**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of Rubius Therapeutics, Inc.

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of Rubius Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2022, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America.

*Substantial Doubt about the Company's Ability to Continue as a Going Concern*

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 of these consolidated financial statements 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

***Critical Audit Matter***s

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Restructuring and Impairment Charges*

As described in Notes 1 and 13 to the consolidated financial statements, the Company's Board of Directors approved a strategic reorganization plan on September 13, 2022 to discontinue the RTX-240 and RTX-224 clinical trials and reduce the Company's overall workforce (the "Reorganization Plan"). On November 2, 2022, the Board of Directors approved a plan to review strategic alternatives, including a sale or merger of the Company or one or more sales of the Company's assets and to significantly and immediately reduce its operations and workforce except for a core team of individuals to

lead the strategic review process (the "Strategic Plan"). The Reorganization Plan and the Strategic Plan required management to evaluate matters related to involuntary termination benefits provided pursuant to a one-time benefit arrangement, contract termination costs, and the impairment of long-lived assets in accordance with generally accepted accounting principles. The recognition of the Company's liability for one-time termination benefits is based on contractual agreements and whether employees are required to render service until they are terminated in order to receive the termination benefits and, if so, whether the employee will be retained to render service beyond a minimum retention period. The Company's contract termination costs represent costs to terminate a contract before the end of its term or costs that will continue to be incurred under a contract for its remaining term without economic benefit to the Company and is recognized at fair value when the contract is terminated or the Company ceases using the right conveyed by the contract. The impairment of long-lived assets is based on the fair value of the Company's long-lived asset group as determined by actual sale transactions. Management recorded restructuring and impairment charges of $51.2 million for the year ended December 31, 2022.

The principal considerations for our determination that performing procedures relating to the Company's restructuring and impairment charges is a critical audit matter are a high degree of auditor effort in performing procedures and evaluating audit evidence related to management's recognition of restructuring and impairment charges related to (i) liabilities for one-time termination benefits and contract termination costs; and (ii) long-lived asset impairment.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, (i) testing contractual agreements related to the liabilities for one-time termination benefits and contract termination costs, (ii) evaluating management's accounting conclusions, (iii) evaluating, on a sample basis, the recognition of the restructuring and impairment charges for one-time termination benefits, contract termination costs and long-lived asset impairment, and (iv) evaluating actual sale transactions occurring before or after the measurement date related to the Company's long-lived asset group.

/s/PricewaterhouseCoopers LLP
Boston, Massachusetts
February 27, 2023

We have served as the Company's auditor since 2016.

**RUBIUS THERAPEUTICS, INC.**
**CONSOLIDATED BALANCE SHEETS**
**(In thousands, except share and per share amounts)**

| | December 31, | |
|---|---|---|
| | 2022 | 2021 |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 14,865 | $ 225,848 |
| Assets held for sale | 4,070 | — |
| Prepaid expenses and other current assets | 1,260 | 3,975 |
| Total current assets | 20,195 | 229,823 |
| Operating lease, right-of-use-asset | 2,679 | 35,095 |
| Property, plant and equipment, net | 146 | 51,530 |
| Restricted cash | 50 | 1,573 |
| Total assets | $ 23,070 | $ 318,021 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,232 | $ 11,572 |
| Accrued expenses and other current liabilities | 5,607 | 14,072 |
| Operating lease liabilities | 1,100 | 9,015 |
| Total current liabilities | 7,939 | 34,659 |
| Long-term debt, net of discount | — | 76,154 |
| Other long-term liabilities | — | 135 |
| Operating lease liabilities, net of current portion | — | 28,291 |
| Total liabilities | 7,939 | 139,239 |
| Commitments and contingencies (see Note 10) | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2022 and December 31, 2021; no shares issued or outstanding at December 31, 2022 and December 31, 2021 | — | — |
| Common stock, $0.001 par value; 300,000,000 and 150,000,000 shares authorized at December 31, 2022 and December 31, 2021, respectively; 90,387,732 and 90,063,770 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively | 90 | 90 |
| Additional paid-in capital | 871,725 | 855,710 |
| Accumulated deficit | (856,684) | (677,018) |
| Total stockholders' equity | 15,131 | 178,782 |
| Total liabilities and stockholders' equity | $ 23,070 | $ 318,021 |

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

**RUBIUS THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(In thousands, except share and per share amounts)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Revenue | $ — | $ — | $ — |
| Operating expenses: | | | |
| Research and development | 96,414 | 141,587 | 116,107 |
| General and administrative | 30,835 | 53,029 | 50,341 |
| Restructuring and impairment charges | 51,197 | — | — |
| Total operating expenses | 178,446 | 194,616 | 166,448 |
| Loss from operations | (178,446) | (194,616) | (166,448) |
| Other income (expense): | | | |
| Interest income | 819 | 91 | 1,760 |
| Interest expense | (3,863) | (6,434) | (4,185) |
| Other income, net | 1,824 | 4,412 | 1,142 |
| Total other income (expense), net | (1,220) | (1,931) | (1,283) |
| Net loss | (179,666) | (196,547) | (167,731) |
| Net loss per share, basic and diluted | $ (1.99) | $ (2.23) | $ (2.08) |
| Weighted average common shares outstanding, basic and diluted | 90,305,463 | 87,950,440 | 80,624,608 |
| | | | |
| Comprehensive loss: | | | |
| Net loss | $ (179,666) | $ (196,547) | $ (167,731) |
| Other comprehensive income (loss): | | | |
| Unrealized losses on investments, net of tax of $0 | — | (4) | (71) |
| Comprehensive loss | $ (179,666) | $ (196,551) | $ (167,802) |

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

**RUBIUS THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**
**(In thousands, except share amounts)**

| | Common stock | | Additional paid-in capital | Accumulated other comprehensive income (loss) | Accumulated deficit | Total stockholders' equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balances at December 31, 2019** | 80,016,245 | $ 80 | $ 586,798 | $ 75 | $ (312,740) | $ 274,213 |
| Issuance of common stock upon exercise of stock options | 1,037,406 | 1 | 1,483 | — | — | 1,484 |
| Stock-based compensation expense | — | — | 33,665 | — | — | 33,665 |
| Unrealized losses on investments | — | — | — | (71) | — | (71) |
| Net loss | — | — | — | — | (167,731) | (167,731) |
| **Balances at December 31, 2020** | 81,053,651 | $ 81 | $ 621,946 | $ 4 | $ (480,471) | $ 141,560 |
| Issuance of common stock from public offering, net of commissions, underwriting discounts and offering costs of $800 | 6,896,552 | 7 | 187,193 | — | — | 187,200 |
| Issuance of common stock upon exercise of stock options | 1,933,523 | 2 | 10,683 | — | — | 10,685 |
| Issuance of common stock under employee stock purchase plan | 26,444 | — | 278 | — | — | 278 |
| Vesting of restricted stock units | 153,600 | — | — | — | — | — |
| Stock-based compensation expense | — | — | 35,610 | — | — | 35,610 |
| Unrealized losses on investments | — | — | — | (4) | — | (4) |
| Net loss | — | — | — | — | (196,547) | (196,547) |
| **Balances at December 31, 2021** | 90,063,770 | $ 90 | $ 855,710 | $ — | $ (677,018) | $ 178,782 |
| Issuance of common stock upon exercise of stock options | 42,228 | — | 98 | — | — | 98 |
| Issuance of common stock under employee stock purchase plan | 143,906 | — | 134 | — | — | 134 |
| Vesting of restricted stock units | 137,828 | — | — | — | — | — |
| Stock-based compensation expense | — | — | 15,783 | — | — | 15,783 |
| Net loss | — | — | — | — | (179,666) | (179,666) |
| **Balances at December 31, 2022** | 90,387,732 | $ 90 | $ 871,725 | $ — | $ (856,684) | $ 15,131 |

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

**RUBIUS THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(in thousands)**

| | Year ended December 31, | | |
|---|---|---|---|
| | **2022** | **2021** | **2020** |
| **Cash flows from operating activities:** | | | |
| Net loss | $ (179,666) | $ (196,547) | $ (167,731) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Stock-based compensation expense | 15,783 | 35,610 | 33,665 |
| Depreciation and amortization expense | 6,254 | 7,723 | 5,691 |
| Amortization (accretion) of premium (discount) on investments | (305) | 118 | 266 |
| Non-cash interest expense | 604 | 1,280 | 349 |
| Impairment charges | 25,841 | — | — |
| Gain on debt extinguishment | (1,128) | — | — |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses and other current assets | 2,738 | 1,249 | 992 |
| Operating lease, right-of-use-asset | 7,002 | 5,352 | 5,539 |
| Other assets | — | 5 | 46 |
| Accounts payable | (9,811) | 5,858 | (1,369) |
| Accrued expenses and other current liabilities | (6,615) | (816) | (96) |
| Other long-term liabilities | (135) | (553) | 283 |
| Operating lease liabilities | (10,704) | (4,401) | (5,283) |
| Net cash used in operating activities | (150,142) | (145,122) | (127,648) |
| **Cash flows from investing activities:** | | | |
| Purchases of property, plant and equipment | (5,304) | (3,649) | (5,497) |
| Proceeds from sale of property, plant and equipment | 17,943 | — | — |
| Purchases of investments | (83,626) | — | (122,671) |
| Sales and maturities of investments | 83,931 | 85,000 | 228,600 |
| Net cash provided by investing activities | 12,944 | 81,351 | 100,432 |
| **Cash flows from financing activities:** | | | |
| Proceeds from underwritten public offering of common stock, net of commissions and underwriting discounts | — | 188,000 | — |
| Payments of offering costs | — | (360) | — |
| Payments of debt issuance costs | — | (150) | — |
| Proceeds from borrowings under loan and security agreement | — | — | 25,000 |
| Payment of long-term debt | (75,702) | — | — |
| Proceeds from issuance of common stock upon exercise of stock options and under employee stock purchase plan | 232 | 10,963 | 1,484 |
| Net cash provided by (used in) financing activities | (75,470) | 198,453 | 26,484 |
| **Net increase (decrease) in cash, cash equivalents and restricted cash** | (212,668) | 134,682 | (732) |
| Cash, cash equivalents and restricted cash at beginning of period | 227,583 | 92,901 | 93,633 |
| Cash, cash equivalents and restricted cash at end of period | $ 14,915 | $ 227,583 | $ 92,901 |
| | | | |
| **Supplemental cash flow information:** | | | |
| Cash paid for interest | $ 4,387 | $ 5,092 | $ 3,822 |
| Cash paid for leases | $ 11,565 | $ 7,364 | $ 8,486 |
| | | | |
| **Supplemental disclosure of non-cash investing and financing information:** | | | |
| Purchases of property, plant and equipment included in accounts payable or accrued expenses | $ — | $ 1,989 | $ 317 |
| Offering costs included in accounts payable and accrued expenses | $ — | $ 35 | $ — |
| Lease assets obtained in exchange for new operating lease liabilities | $ — | $ — | $ 496 |
| Lease asset derecognized upon lease cancellation | $ 78 | $ — | $ 982 |
| Remeasurement of operating lease liabilities and right-of-use assets due to lease modification | $ 25,502 | $ — | $ — |

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

**RUBIUS THERAPEUTICS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Nature of the Business and Basis of Presentation**

Rubius Therapeutics, Inc. ("Rubius" or the "Company") is a biopharmaceutical company that has developed a platform and pipeline focused on creating an entirely new class of cellular medicines, called Red Cell Therapeutics, for the treatment of cancer and autoimmune diseases. Rubius was incorporated in April 2013 as VL26, Inc. under the laws of the State of Delaware. In January 2015, the Company changed its name to Rubius Therapeutics, Inc.

On July 27, 2022, the Company received a deficiency letter from the Listing Qualifications Department, or the Staff, of The Nasdaq Stock Market LLC, or Nasdaq, notifying the Company that, for the last 30 consecutive business days, the bid price for its common stock had closed below the $1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Global Select Market. In February 2023, the Company was notified by the Staff that it would be delisted at the opening of business on February 15, 2023 unless the Company were to timely request a hearing before a Nasdaq Hearings Panel, or the Panel, to address the deficiencies and present a plan to regain compliance. On February 13, 2023, the Company timely requested a hearing before the Panel, which request will stay any further delisting action by the Staff pending the ultimate outcome of the hearing and the expiration of any extension that may be granted by the Panel, unless the Company determine to withdraw its hearing request. The Company's common stock will remain listed and eligible for trading on Nasdaq at least pending the ultimate conclusion of the hearing process.

On September 13, 2022, the Company's Board of Directors approved certain operational and organizational steps that the Company undertook in connection with a new strategic reorganization plan and related cost-saving measures (collectively, the "Reorganization Plan"). The Company discontinued its ongoing Phase 1 clinical trials of RTX-240 and RTX-224 for the treatment of advanced solid tumors and restructured the organization to support advancing drug candidates based on its next generation platform. Under the Reorganization Plan, the Company reduced its overall workforce by approximately 75%, primarily consisting of employees who were focused on clinical development of RTX-240 and RTX-224, with the remainder coming from its manufacturing and general and administrative functions.

On November 2, 2022, in light of the Company's financial condition, including the repayment and termination of its $75.0 million credit facility with SLR Investment Corp., and the early stage of its programs, its Board of Directors approved a plan to review strategic alternatives, including a sale or merger of the Company or one or more sales of its assets, and to significantly and immediately reduce its operations (the "Strategic Plan"). In connection with the Strategic Plan, the Company terminated 42 of its employees (representing 82% of its then-current employee base), leaving a core team of individuals to lead the strategic review process.

On February 20, 2023, following the conclusion of the Company's review of strategic alternatives, the Company's Board of Directors unanimously approved the dissolution and liquidation of the Company pursuant to a plan of complete liquidation and dissolution, which plan is subject to stockholder approval.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the ability to establish clinical- and commercial-scale manufacturing processes and the ability to secure additional capital to fund operations. In addition, the Company is subject to uncertainty regarding the performance and safety of its product candidates in humans. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. It is uncertain when, if ever, the Company will realize significant revenue from product sales.

Under Accounting Standards Update ("ASU") 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40) ("ASC 205-40"), the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the date that the financial statements are issued. As required by ASC 205-40, this evaluation shall initially not take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued.

As of December 31, 2022, the Company had an accumulated deficit of $856.7 million, and cash and cash equivalents of $14.9 million. For the year ended December 31, 2022, the Company incurred a net loss of $179.7 million and used $150.1 million of cash in operations. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. Management has assessed the Company's ability to continue as a going concern in accordance with the requirements of ASC 205-40 and determined that the Company's accumulated deficit, history of losses and future expected

losses met the ASC 205-40 standard for raising substantial doubt about the Company's ability to continue as a going concern. The Company does not have adequate financial resources to fund its forecasted operating costs for at least twelve months from the filing of its Annual Report on Form 10-K.

Through the implementation of its Strategic Plan, the Company's primary goal was to successfully complete a review of strategic alternatives and consummate a transaction or series of transactions to realize value for the Company's platform and programs. On February 20, 2023, following the conclusion of the Company's review of strategic alternatives, the Company's Board of Directors unanimously approved the dissolution and liquidation of the Company. As a result, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern.

The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

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

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

**2. Summary of Significant Accounting Policies**

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of stock-based awards. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.

***Concentrations of Credit Risk and of Significant Suppliers***

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company's cash and cash equivalents as of December 31, 2022 consisted of cash, money market accounts and U.S. government money market funds. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

***Deferred Offering Costs***

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss.

***Deferred Financing Costs***

The Company capitalizes certain legal and other third-party fees that are directly associated with obtaining access to capital under credit facilities. Deferred financing costs incurred in connection with obtaining access to capital are recorded in other assets and are amortized over the term of the credit facility. Deferred financing costs related to a recognized debt liability are recorded as a reduction of the carrying amount of the debt liability and amortized to interest expense using the effective interest method over the repayment term.

***Cash Equivalents***

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

***Restricted Cash***

As of December 31, 2021, the Company maintained letters of credit totaling $1.7 million for the benefit of the landlords of its leased properties. The Company was required to maintain separate cash balances of these amounts to secure the letters of credit. Related to these separate cash balances, the Company included $0.1 million in prepaid expenses and other current assets and $1.6 million in restricted cash (non-current) in its consolidated balance sheet as of December 31, 2021.

Cash, cash equivalents and restricted cash presented in the accompanying consolidated statement of cash flows was $14.9 million, $227.6 million and $92.9 million for the years ended December 31, 2022, 2021 and 2020, respectively, of which $0.1 million, $1.7 million and $1.7 million was restricted cash for each year, respectively.

***Property, Plant and Equipment***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

| | Estimated useful life |
|---|---|
| Computer equipment | 3 years |
| Laboratory equipment | 5 years |
| Furniture and fixtures | 7 years |
| Manufacturing equipment | 10 years |
| Manufacturing facility | 30 years |
| Leasehold improvements | Shorter of life of lease or 10 years |

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Interest costs incurred during the construction of major capital projects are capitalized until the underlying asset is ready for its intended use, at which point the interest costs are amortized as depreciation expense over the life of the underlying asset. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for major renewals and improvements which extend the life or usefulness of the asset are capitalized. Items of an ordinary repair or maintenance nature are charged directly to operating expense as incurred.

***Impairment of Long-Lived Assets***

Long-lived assets consist of property, plant and equipment and operating lease, right-of-use asset. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use and eventual disposition of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows.

***Fair Value Measurements***

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial

assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

***Investments***

The Company's investments are classified as available-for-sale and are carried at fair value. Realized gains and losses and declines in value are based on the specific identification method and are included as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. The Company classifies its investments with maturities beyond one year as short-term, based on their highly liquid nature and because such investments are available for current operations.

The Company evaluates its investments with unrealized losses for impairment. When assessing investments for unrealized declines in value, the Company considers whether the decline in value is related to a credit loss or non-credit loss. For credit losses, the Company reduces the investment to fair value through an allowance for credit losses recorded to the balance sheet and corresponding charge to the statement of operations. The allowance for credit losses and corresponding impairment charge is adjusted each period for changes in fair value. For non-credit losses, the Company reduces the investment to fair value through a charge to the statement of comprehensive loss, reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. No such credit losses were recorded during the periods presented.

***Assets Held for Sale***

The Company classifies its long-lived assets to be sold as held for sale in the period (i) the Company has approved and committed to a plan to sell the asset, (ii) the asset is available for immediate sale in its present condition, (iii) an active program to locate a buyer and other actions required to sell the asset have been initiated, (iv) the sale of the asset is probable, (v) the asset is being actively marketed for sale at a price that is reasonable in relation to its current fair value and (vi) it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn. The Company initially measures a long-lived asset that is classified as held for sale at the lower of its carrying value or fair value, less any costs to sell. Any loss resulting from this measurement is recognized in the period in which the held for sale criteria are met. Conversely, gains are not recognized on the sale of a long-lived asset until the date of sale. Upon designation as an asset held for sale, the Company stops recording depreciation and amortization expense on long-lived assets. The Company assesses the fair value of a long-lived asset, less any costs to sell, at each reporting period and until the asset is no longer classified as held for sale.

***Leases***

At the inception of an arrangement as lessee or lessor, the Company determines whether the arrangement is or contains a lease. Operating lease cost is recognized over the lease term on a straight-line basis. Variable lease cost and short-term leases (lease terms less than 12 months) are recognized as incurred. For both lessee and lessor arrangements, variable lease payments are the amounts owed by the Company to a lessor that are not fixed, such as reimbursement for common area maintenance and utilities costs, and are expensed when incurred. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that it will exercise that option.

For lessee arrangements, operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain

adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. Operating leases are recognized on the balance sheet as right-of-use assets, operating lease liabilities current and operating lease liabilities non-current.

The Company has elected the following lease policies at the inception of a lease: (1) for lessee and lessor arrangements within all asset classes, combine lease and non-lease components as a single component, with the lease expense recognized over the expected term on a straight-line basis and (2) for lessee arrangements, apply short-term lease exemption for all leases that qualify, where a right-of-use asset or lease liability will not be recognized for leases with terms of one year or less.

***Segment Information***

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. All of the Company's tangible assets are held in the United States.

***Research and Development Costs***

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, manufacturing expenses and external costs of vendors engaged to conduct preclinical development activities and clinical trials, as well as the cost of licensing technology.

Upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

***Research and Manufacturing Contract Costs and Accruals***

The Company has entered into various research and development and manufacturing contracts with research institutions and other companies both inside and outside of the U.S. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations as of period end with those third parties to record accruals for estimated ongoing research and development costs. Any accrual estimates are based on a number of factors, including the Company's knowledge of the progress towards completion of the research and development activities, invoicing to date under the contracts, communication from the research institution or other companies of any actual costs incurred during the period that have not yet been invoiced, and the costs included in the contracts. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

***Patent Costs***

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

***Stock-Based Compensation***

The Company measures stock options with service-based vesting or performance-based vesting granted to employees, non-employees and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model. The Company measures restricted common stock awards using the difference between the purchase price per share of the award, if any, and the fair value of the Company's common stock. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. The Company measures restricted stock units with service-based vesting as the market value of the Company's stock on the date of grant. The Company uses the straight-line method to record the expense of awards with only service-based vesting conditions. The Company uses the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing once achievement of the performance condition becomes probable. The Company accounts for forfeitures as they occur and records compensation cost assuming all option holders will complete the requisite service period. If an award is forfeited, the Company reverses compensation expense previously recognized in the period the award is forfeited.

For stock-based awards with market-based vesting conditions, the Company measures the fair value on the date of grant using a Monte Carlo simulation model. When service-based vesting conditions also exist, the Company recognizes stock-based compensation expense using the graded-vesting method over the longer of the derived service period from the market condition or the required service period. In accordance with accounting guidance for awards with market conditions, the stock-based compensation expense will be recognized over the appropriate period regardless of whether the award achieves the market condition and will only be adjusted to the extent the service condition is not met. When an award contains a market-based vesting condition and a performance-based vesting condition where both must be achieved to earn the award, the Company recognizes stock-based compensation expense over the longer of the derived service period from the market condition or the period estimated for the performance-based vesting condition to be achieved. The Company begins recording stock-based compensation expense for this type of award once the achievement of the performance-based vesting condition becomes probable regardless of whether the market condition has been achieved.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

***Comprehensive Loss***

Comprehensive loss includes net loss, as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2021 and 2020, the Company's only element of other comprehensive loss was unrealized gains (losses) on investments. For the year ended December 31, 2022 there was no difference between the Company's net loss and comprehensive loss.

***Net Income (Loss) per Share***

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding common stock equivalents. Accordingly, in periods in which the Company reported a net loss, dilutive common shares were not assumed to have been issued as their effect was anti-dilutive, and as a result, diluted net loss per common share was the same as basic net loss per common share.

***Income Taxes***

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate, as well as the related net interest and penalties.

***Recently Adopted Accounting Pronouncements***

*ASU No. 2016-13, Financial Instruments—Credit Losses*

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses* on Financial Instruments. The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren't measured at fair value through net income. For available-for-sale debt securities, entities are required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities are no longer permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. For public entities, the guidance was effective for annual reporting periods beginning after December 15, 2019 and for interim periods within those fiscal years. Early adoption was permitted. The Company early adopted this standard as of January 1, 2020 on a prospective basis. The adoption did not have a material impact on the Company's consolidated financial statements.

*ASU No. 2019-12, Simplifying the Accounting for Income Taxes*

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes (ASC 740).* The ASU enhances and simplifies various aspects of the income tax accounting guidance in ASC 740, including requirements related to hybrid tax regimes, the tax basis step-up in goodwill obtained in a transaction that is not a business combination, separate financial statements of entities not subject to tax, the intra-period tax allocation exception to the incremental approach, ownership changes in investments, changes from a subsidiary to an equity method investment, interim-period accounting for enacted changes in tax law, and the year-to-date loss limitation in interim-period tax accounting. This guidance is effective for the Company for annual and interim periods beginning after December 31, 2020; however, early adoption is permitted. The Company adopted this standard as of January 1, 2021 on a prospective basis. The adoption did not have an impact on the Company's consolidated financial statements.

**3. Investments and Fair Value of Financial Assets and Liabilities**

The Company had no investments as of December 31, 2022 or December 31, 2021.

The following tables present the Company's fair value hierarchy for its assets and liabilities, which are measured at fair value on a recurring basis (in thousands):

| | December 31, 2022 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash equivalents: | | | | |
| U.S. government money market funds | $ 1,010 | $ — | $ — | $ 1,010 |
| | $ 1,010 | $ — | $ — | $ 1,010 |

| | December 31, 2021 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash equivalents: | | | | |
| U.S. government money market funds | $ 217,009 | $ — | $ — | $ 217,009 |
| | $ 217,009 | $ — | $ — | $ 217,009 |

U.S. government money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. There were no changes to the valuation methods during the year ended December 31, 2022. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between Level 1, Level 2 or Level 3 during the year ended December 31, 2022 and 2021, respectively.

**4. Property, Plant and Equipment, Net and Assets Held for Sale**

Property, plant and equipment, net and assets held for sale consisted of the following, after the effects of impairment charges and held-for-sale reclassifications (in thousands):

| | December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Land | $ — | $ 1,300 |
| Manufacturing facility | — | 33,203 |
| Manufacturing equipment | — | 8,831 |
| Laboratory equipment | — | 17,501 |
| Computer equipment | — | 2,645 |
| Furniture and fixtures | — | 1,281 |
| Leasehold improvements | 570 | 444 |
| Construction-in-progress | — | 4,181 |
| | 570 | 69,386 |
| Less: Accumulated depreciation and amortization | (424) | (17,856) |
| | $ 146 | $ 51,530 |
| | | |
| Assets held for sale | $ 4,070 | $ — |

During the year ended December 31, 2022, the Company recorded impairment charges of $25.8 million due to its Reorganization Plan (Note 13). Depreciation and amortization expense was $6.3 million, $7.7 million and $5.7 million for the years ended December 31, 2022, 2021 and 2020, respectively.

**5. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Accrued employee termination benefits | $ 1,401 | $ — |
| Accrued contract termination costs | 1,387 | — |
| Accrued general and administrative expenses | 521 | 889 |
| Accrued employee compensation and benefits | — | 7,451 |
| Accrued external research and development expenses | — | 2,713 |
| Accrued manufacturing facility expenses | — | 2,349 |
| Deposit received for assets held for sale | 2,125 | — |
| Other | 173 | 670 |
| | $ 5,607 | $ 14,072 |

**6. Debt**

Long-term debt consisted of the following (in thousands):

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Principal amount of long-term debt | $ — | $ 75,000 |
| Less: Current portion of long-term debt | — | — |
| Long-term debt, net of current portion | — | 75,000 |
| Accrued final interest payment | — | 1,654 |
| Debt discount | — | (500) |
| Long-term debt, net of discount and current portion | $ — | $ 76,154 |

***Loan Agreement***

On December 21, 2018 (the “Closing Date”), the Company entered into a loan and security agreement(the "Original Loan Agreement," and, as amended, the “Loan Agreement”) with Solar Capital Ltd., now SLR Investment Corp. ("SLR"), as collateral agent for the lenders party thereto for an aggregate principal amount of $75.0 million. The aggregate principal amount will be funded in three tranches of term loans of $25.0 million each. On the Closing Date, the Company made an initial borrowing of $25.0 million. In June 2019, the Company made a second borrowing of $25.0 million and in June 2020, the Company made a third and final borrowing of $25.0 million.

On June 22, 2021 (the “Amendment Closing Date”), the Company entered into an amendment (the “Amendment”) to the Original Loan Agreement. Pursuant to the Amendment, the Company and its lenders agreed to extend the interest-only period applicable to borrowings under the Loan Agreement from December 21, 2021 until July 1, 2024 and the final maturity date from December 21, 2023 until June 1, 2026. An additional tranche in the amount of $35.0 million is available at the request of the Company prior to the final maturity date, to be provided at the sole discretion of the lenders. The Amendment increases the LIBOR interest rate floor from 0.00% to 2.10%. Interest on the outstanding loan balance will accrue at a rate of 5.50%, plus the greater of 2.10% or the one-month U.S. LIBOR rate. Certain back-end fees are due to the lender at the time of final repayment based on the total funded term loans. The Company accrues the back-end fees that will be due at final repayment to outstanding debt by charges to interest expense over the term of the loans using the effective interest method. The term loans are subject to a prepayment fee of 1.00% if prepayment occurs within the first year subsequent to the Amendment Closing Date, 0.50% in the second year and 0.25% in the third year through final maturity date.

As the terms of the Amendment were not substantially different than the terms of the Original Loan Agreement, the Amendment was accounted for as a debt modification. In conjunction with the Amendment, the Company incurred issuance costs of $0.2 million payable to the lenders, which were recorded as an additional debt discount and will be amortized to interest expense over the remaining term, together with unamortized original issuance costs as of the Amendment Closing Date, using the effective interest method.

On October 13, 2022, the Company entered into a payoff letter with SLR, under which the Company voluntarily prepaid SLR approximately $75.7 million, in full satisfaction of all obligations, including all outstanding principal, accrued interest, fees, costs, expenses and other amounts chargeable, under the Loan Agreement. The payoff letter also provided for the termination of all commitments and obligations under the Loan Agreement and release of all liens held by SLR on the Company’s assets. The Loan Agreement was extinguished and accounted for as a troubled debt restructuring as the Company was experiencing financial difficulty and SLR granted the Company a concession by forgiving certain contractually owed amounts. The Company recognized a gain on the extinguishment of the Loan Agreement of $1.1 million, which is recorded in interest expense on the consolidated statements of operations and comprehensive loss. As of December 31, 2022, the Company does not have any debt outstanding.

**7. Equity**

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company’s stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

On July 20, 2018, the Company filed a restated certificate of incorporation in the State of Delaware, which, among other things, restated the number of shares of all classes of stock that the Company has authority to issue to 160,000,000 shares, consisting of (i) 150,000,000 shares of common stock, $0.001 par value per share, and (ii) 10,000,000 shares of preferred stock, $0.001 par value per share. The preferred stock will have such rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be determined by the Company's board of directors upon issuance. The shares of preferred stock are currently undesignated.

On August 1, 2019, the Company entered into a Distribution Agreement (the "Distribution Agreement") with J.P. Morgan Securities LLC, Jefferies LLC and SVB Leerink LLC (the "Sales Agents"), pursuant to which the Company was able to issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to $100.0 million through the Sales Agents. As of December 31, 2022, no shares of common stock have been issued and sold pursuant to the Distribution Agreement, which expired in accordance with its terms on August 21, 2022, and the applicable registration statement is no longer effective.

On March 18, 2021, the Company completed the March 2021 Offering, pursuant to which it issued and sold 6,896,552 shares of common stock. The aggregate net proceeds received by the Company from the March 2021 Offering were $187.2 million, after deducting underwriting discounts and commissions and other offering costs.

On July 7, 2022, the Company filed an amendment to its Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware which increased the number of shares of common stock that the Company has authority to issue from 150,000,000 to 300,000,000 shares. The number of shares of preferred stock authorized for issuance was not impacted by this amendment.

**8. Stock-Based Compensation**

***2018 Equity Incentive Plan***

On July 6, 2018, the Company's board of directors adopted, and its stockholders approved, the 2018 Plan, which became effective on July 16, 2018. The 2018 Plan provides for the grant of incentive stock options, non-qualified options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares initially reserved for issuance under the 2018 Plan is 5,708,931, which shall be cumulatively increased on January 1, 2019 and each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's board of directors or compensation committee of the board of directors. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Plan. As of December 31, 2022, 9,666,433 shares remained available for issuance under the 2018 Plan. The number of authorized shares reserved for issuance under the 2018 Plan was increased by 3,615,509 shares effective as of January 1, 2023.

***2018 Employee Stock Purchase Plan***

On July 6, 2018, the Company's board of directors adopted and its stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"), which became effective on July 16, 2018. On December 15, 2022, the Company's board of directors voted to terminate the ESPP effective immediately.

The Company issued 143,906 and 26,444 shares of common stock under the ESPP during the years ended December 31, 2022 and December 31, 2021, respectively. The Company recorded $0.1 million and $0.1 million of stock-based compensation expense as a result of the ESPP for the year ended December 31, 2022 and December 31, 2021, respectively. There were no shares of common stock issued and no stock-based compensation expense recorded under the ESPP for the year ended December 31, 2020. Due to the plan termination, no further shares will be issued under to the ESPP.

***Stock Option Valuation***

*Service-Based and Performance-Based Stock Options*

The fair value of stock option grants with service-based and performance-based vesting conditions is estimated using the Black-Scholes option-pricing model. The Company estimates expected volatility based on the historical volatility of publicly traded peer companies. For options with service-based vesting conditions, the expected term of the Company's

stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model to determine the fair value of stock-based awards granted to employees, directors, and non-employees:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Risk-free interest rate | 2.37 % | 0.81 % | 1.10 % |
| Expected volatility | 78.4 % | 77.4 % | 69.4 % |
| Expected dividend yield | — | — | — |
| Expected term (in years) | 5.87 | 6.08 | 6.05 |

The following table summarizes the Company's service-based and performance-based option activity since December 31, 2022:

| | Number of shares | Weighted average exercise price | Weighted average contractual term | Aggregate intrinsic value |
|---|---|---|---|---|
| | | | (in years) | (in thousands) |
| Outstanding as of December 31, 2021 | 17,138,772 | $ 12.04 | 7.22 | $ 23,511 |
| Granted | 4,104,403 | 4.37 | | |
| Exercised | (42,228) | 2.32 | | |
| Forfeited | (7,105,039) | 10.31 | | |
| Outstanding as of December 31, 2022 | 14,095,908 | $ 10.71 | 3.55 | $ 6 |
| Vested and expected to vest as of December 31, 2022 | 14,095,908 | $ 10.71 | 3.55 | $ 6 |
| Options exercisable as of December 31, 2022 | 12,061,182 | $ 11.29 | 2.82 | $ 6 |

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2022, 2021 and 2020 was $0.1 million, $34.6 million and $5.7 million, respectively.

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2022, 2021 and 2020 was $2.98 per share, $10.55 per share and $4.51 per share, respectively.

*Market-Based Stock Options*

The fair value of stock option grants with market-based vesting conditions is estimated using a Monte Carlo simulation model.

In October 2018, the Company granted to an executive officer an option to purchase 164,400 shares of common stock ("Option A") at an exercise price of $16.43 per share, vesting upon the achievement of a specified thirty-day average closing price of its common stock and the satisfaction of service-based vesting conditions, and an option to purchase 193,400 shares of common stock ("Option B") at an exercise price of $16.43 per share, vesting upon the achievement of a specified thirty-day average closing price of its common stock and the achievement of certain other performance-based vesting conditions. The Company used a Monte Carlo simulation model to estimate the grant-date fair value of the awards. Assumptions and estimates utilized in the model include the risk-free interest rate, dividend yield, expected stock volatility based on a combination of the Company's historical stock volatility since its July 2018 IPO and the historical volatility of a publicly traded set of peer companies and the estimated period to achievement of the market condition. Stock-based compensation expense for Option A is being recognized using the graded-vesting method over the longer of the derived service period from the market condition or the explicit service period required to be completed for each vesting tranche. Stock-based compensation expense for Option B is being recognized using the graded-vesting method over the longer of

the derived service period from the market condition or the estimated achievement of performance-based conditions. For Option B, stock-based compensation expense is recognized when the achievement of each performance-based vesting condition becomes probable regardless of whether the market condition has been achieved. The aggregate grant date fair value of these options was $4.3 million. During the years ended December 31, 2022, 2021 and 2020 the Company recorded stock-based compensation expense on Option A of $0.1 million, $0.2 million and $0.6 million, respectively. During the years ended December 31, 2021 and 2020, the Company recorded stock-based compensation expense on Option B of $1.1 million and $1.1 million, respectively, as a performance-based vesting condition was determined to be probable during each year. No stock-based compensation expense on Option B was recorded during the year ended December 31, 2022.

The Company did not grant market-based stock options during the years ended December 31, 2022, 2021 and 2020. During the years ended December 31, 2022, 2021 and 2020, none of the outstanding stock options with market-based vesting conditions were exercised, forfeited or vested and they had no intrinsic value at December 31, 2022.

***Restricted Stock Units***

The Company has also granted restricted stock units to its employees. During the years ended December 31, 2022 and 2021, the Company granted restricted stock units to employees that were subject to time-based vesting conditions that lapse over four years and three years from the date of grant. No restricted stock units were granted during the year ended December 31, 2020. Restricted stock units with time-based vesting conditions are valued on the grant date using the grant date market price of the underlying shares. The following table summarizes the Company's restricted stock unit activity since December 31, 2022:

| | Shares | Weighted average grant-date fair value |
|---|---|---|
| Unvested restricted common stock as of December 31, 2021 | 794,244 | $ 15.346 |
| Issued | 906,815 | 4.880 |
| Vested | (137,828) | 12.522 |
| Forfeited | (1,130,028) | 9.446 |
| Unvested restricted common stock as of December 31, 2022 | 433,203 | $ 9.728 |

***Stock-Based Compensation***

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations and comprehensive loss (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Research and development expenses | $ 6,863 | $ 12,338 | $ 8,023 |
| General and administrative expenses | 8,920 | 23,272 | 25,642 |
| | $ 15,783 | $ 35,610 | $ 33,665 |

As of December 31, 2022, total unrecognized compensation cost related to unvested stock-based awards was $6.8 million, which is expected to be recognized over a weighted average period of 2.2 years.

**9. Income Taxes**

During the years ended December 31, 2022, 2021 and 2020, the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each year, due to its uncertainty of realizing a benefit from those items.

All of the Company's operating losses since inception have been generated in the United States.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

| | Year ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Federal statutory income tax rate | (21.0)% | (21.0)% |
| State taxes, net of federal benefit | (6.0) | (6.2) |
| Federal and state research and development tax credits | (5.3) | (6.4) |
| Stock-based compensation expense | 0.5 | (1.6) |
| Section 162(m) compensation deduction limitation | 0.1 | 1.6 |
| Other | 0.1 | (0.4) |
| Increase in deferred tax asset valuation allowance | 31.6 | 34.0 |
| Effective income tax rate | — % | — % |

Net deferred tax assets consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 159,691 | $ 145,990 |
| Research and development tax credit carryforwards | 45,478 | 36,161 |
| Accrued expenses | 105 | 2,137 |
| Capitalized intellectual property costs | 2,051 | 1,746 |
| Capitalized research and development expense | 32,007 | 86 |
| Operating lease liabilities | 301 | 10,194 |
| Stock-based compensation expense | 24,454 | 21,483 |
| Depreciation | 74 | — |
| Total deferred tax assets | 264,161 | 217,797 |
| Deferred tax liabilities: | | |
| Operating lease assets | (732) | (9,590) |
| Depreciation and other | — | (1,500) |
| Total deferred tax liabilities | (732) | (11,090) |
| Valuation allowance | 263,429 | 206,707 |
| Net deferred tax assets | $ — | $ — |

As of December 31, 2022, the Company had U.S. federal and state net operating loss ("NOL") carryforwards of $584.8 million and $583.6 million, respectively, which may be available to offset future taxable income. The federal NOLs include $37.2 million which expire at various dates through 2037 and $547.6 million which carryforward indefinitely. The state NOLs expire at various dates through 2042. As of December 31, 2022, the Company also had U.S. federal and state research and development tax credit carryforwards of $29.5 million and $19.9 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2034 and 2026, respectively. During the year ended December 31, 2022, deferred tax assets, before valuation allowance, increased by approximately $46.4 million mainly due to the operating loss incurred by the Company during that period and the capitalization of research and development expenses.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred

or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2022 and 2021. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2022, 2021 and 2020 related primarily to the increase in net operating loss carryforwards and research and development tax credit carryforwards and were as follows (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Valuation allowance as of beginning of year | $ 206,707 | $ 139,877 | $ 85,884 |
| Decreases recorded as benefit to income tax provision | — | — | — |
| Increases recorded to income tax provision | 56,722 | 66,830 | 53,993 |
| Valuation allowance as of end of year | $ 263,429 | $ 206,707 | $ 139,877 |

As of December 31, 2022 and 2021, the Company had no recorded amounts for unrecognized tax benefits. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2022 and 2021, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company's consolidated statements of operations and comprehensive loss. The Company files income tax returns in the U.S., Massachusetts and Rhode Island, as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company is open to future tax examination under statute from 2016 to the present; however, carryforward attributes that were generated prior to January 1, 2016 may still be adjusted upon examination by federal, state or local tax authorities if they either have been or will be used in a future period.

**10. Commitments and Contingencies**

***License Agreement with the Whitehead Institute for Biomedical Research***

The Company has a license agreement with the Whitehead Institute for Biomedical Research ("WIBR"), as amended, under which the Company has been granted an exclusive, sublicensable, nontransferable license under certain patent families related to the development of the Company's red blood cell therapies (as amended, the "WIBR License"). The Company is obligated to pay WIBR annual license maintenance fees of less than $0.1 million, as well as patent-related costs, including legal fees, and low single-digit royalties based on annual net sales of licensed products and licensed services by the Company and its sublicensees. Based on the progress the Company makes in the advancement of products covered by the licensed patent rights, the Company is required to make aggregate milestone payments of up to $1.6 million upon the achievement of specified preclinical, clinical and regulatory milestones. In addition, the Company is required to pay to WIBR a percentage of the non-royalty payments that it receives from sublicensees of the patent rights licensed by WIBR. This percentage varies from low single-digit to low double-digit percentages and will be based upon the clinical stage of the product that is the subject of the sublicense. Royalties shall be paid by the Company on a licensed product-by-licensed product and country-by-country basis, beginning on the first commercial sale of such licensed product in such country until expiration of the last valid patent claim covering such licensed product in such country.

The Company has the right to terminate the WIBR License in its entirety, on a patent-by-patent or country-by-country basis, at will upon three months' notice to WIBR. WIBR may terminate the agreement upon breach of contract or in the event of the Company's bankruptcy, liquidation, insolvency or cessation of business related to the license.

***401(k) Plan***

In January 2018, the Company established a defined-contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company makes matching contributions at a rate of 50% of each employee's contribution up to a maximum employee contribution of 6% of eligible plan compensation. For the years ended December 31, 2022, 2021 and 2020, the Company made matching contributions of $0.9 million, $0.9 million and $0.8 million, respectively. In January 2023, the Company terminated the 401(k) Plan effective December 30, 2022.

***Indemnification Agreements***

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, contract research organizations, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

***Legal Proceedings***

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

**11. Leases**

***Operating Leases***

During the year ended December 31, 2022, the Company leased office and laboratory facilities in Cambridge, Massachusetts under one noncancelable operating lease, which is subject to two expiration dates based on two distinct leased spaces, expiring in January 2027 and August 2028.
In January 2018, the Company entered into a lease for office and laboratory space in Cambridge, Massachusetts (the "Initial Space"). The lease term commenced on January 28, 2019 and was scheduled to expire eight years from the commencement date. The initial annual base rent is approximately $3.8 million, and such amounts increased during the initial term by 3% annually on the anniversary of the commencement date.

In November 2018, the Company entered into a lease amendment for office and laboratory space in the same building (the "Expansion Space"). The lease term for the Expansion Space commenced on August 8, 2019 and was scheduled to expire approximately nine years from the commencement date. The initial annual base rent for the Expansion Space was approximately $2.5 million and such amount increased by 3% annually on the anniversary of the commencement date. The Company was obligated to pay its portion of real estate taxes and costs related to the Expansion Space, including costs of operations, maintenance, repair, replacement and property management.

In December 2022, the Company entered into an Agreement for Termination of Lease (the "Lease Termination Agreement") relating to its two distinct leased spaces for office and laboratory space in Cambridge, Massachusetts (the "Cambridge Facility"). Under the Lease Termination Agreement, the Company's lease for the Cambridge Facility terminated on January 31, 2023. Under the terms of the Lease Termination Agreement, the Company paid the landlord a lease termination payment, inclusive of the full amount of a letter of credit that the landlord held under the lease and rent previously paid by the Company to the landlord for the month of December 2022, of approximately $5.9 million in the fourth quarter of the year ended December 31, 2022, and the Company paid the landlord a subsequent payment of $1.1 million in the first quarter of the year ending December 31, 2023.

The Lease Termination Agreement terminated the lease on January 31, 2023. As the lease termination was effective at a future date, the Company accounted for the change as a lease modification that shortened the lease term. Upon the modification, the Company decreased its operating lease, right-of-use asset by an amount equal to the adjustment of its operating lease liabilities.

The Company evaluated its vendor contracts to identify embedded leases, if any, and noted that an agreement with a contract manufacturing supplier constituted a lease under ASC 842 as the Company has the right to substantially all the economic benefits from the use of the asset and can direct the use of the asset. The Company entered into the agreement during the first quarter of 2019. The lease commenced during March 2019 and was scheduled to expire 22 months from commencement date with no stated option to extend the term. The lease was cancelled prior to expiration during the first quarter of 2020, resulting in derecognition of the lease assets and operating lease liabilities.

As the Company's leases do not provide an implicit rate, the Company utilized its incremental borrowing rate based on information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment. The Company has elected to account for each lease component and its associated non-lease components as a single lease component and, therefore, has allocated all the contract consideration across lease components only. This may result in the initial and subsequent measurement of the balances of the right-of-use asset and lease liability for leases being greater than if the policy election was not applied. Assets under operating lease at December 31, 2022 were $2.7 million. The leases do not include any restrictions or covenants that had to be accounted for under the lease guidance.

As of December 31, 2022, minimum lease payments under the Company's operating leases are as follows (in thousands):

| **Year ending December 31,** | | |
|---|---|---|
| 2023 | $ | 1,100 |
| 2024 | | — |
| 2025 | | — |
| 2026 | | — |
| 2027 | | — |
| Thereafter | | — |
| | | 1,100 |
| Less: imputed interest | | — |
| | $ | 1,100 |

The Company has not entered any material financing leases as of December 31, 2022.

***Lease Portfolio***

The components of lease cost and supplemental balance sheet information for the Company's lease portfolio were as follows (in thousands, except term and discount rate amounts):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Lease cost: | | | |
| Operating lease cost | $ 12,655 | $ 8,173 | $ 9,240 |
| Short-term lease cost | — | 41 | 24 |
| Variable lease cost | 3,058 | 3,723 | 1,916 |
| Sublease income | — | (719) | (1,017) |
| Total lease cost | $ 15,713 | $ 11,218 | $ 10,163 |
| | | | |
| Operating leases: | | | |
| Operating lease, right-of-use-asset | $ 2,679 | $ 35,095 | $ 40,447 |
| Operating lease liabilities | $ 1,100 | $ 9,015 | $ 8,945 |
| Operating lease liabilities, net of current portion | $ — | $ 28,291 | $ 32,762 |
| | | | |
| Other information: | | | |
| Weighted average remaining lease term - operating leases | 0.08 years | 5.80 years | 6.70 years |
| Weighted-average discount rate - operating leases | — % | 7.60 % | 7.60 % |

**12. Net Loss per Share**

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Numerator: | | | |
| Net loss | $ (179,666) | $ (196,547) | (167,731) |
| | | | |
| Denominator: | | | |
| Weighted average common shares outstanding, basic and diluted | 90,305,463 | 87,950,440 | 80,624,608 |
| Net loss per share, basic and diluted | $ (1.99) | $ (2.23) | $ (2.08) |

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares from the periods in the table above, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Unvested restricted common stock | 433,203 | 794,244 | 252,000 |
| Stock options to purchase common stock | 14,453,708 | 17,496,572 | 16,318,124 |
| | 14,886,911 | 18,290,816 | 16,570,124 |

**13. Restructuring and Impairment Charges**

The Company estimates that it will incur approximately $51.9 million in costs to implement the Reorganization Plan and the Strategic Plan, as described in Note 1. The actions associated with the Reorganization Plan and the Strategic Plan commenced in September 2022 and November 2022, respectively, and are expected to be substantially completed by February 28, 2023.

The Reorganization Plan and the Strategic Plan required management to evaluate matters related to involuntary termination benefits provided pursuant to a one-time benefit arrangement, contract termination costs and the impairment of long-lived assets in accordance with generally accepted accounting principles. The recognition of the Company's liability for one-time termination benefits is based on contractual agreements and whether employees are required to render service until they are terminated in order to receive the termination benefits and, if so, whether the employee will be retained to render service beyond a minimum retention period. The Company's contract termination costs represent costs to terminate a contract before the end of its term or costs that will continue to be incurred under a contract for its remaining term without economic benefit to the Company and is recognized at fair value when the contract is terminated or the Company ceases using the right conveyed by the contract. The impairment of long-lived assets is based on the fair value of the Company's long-lived asset group as determined by actual sale transactions.

As a result of these events, the Company incurred the following restructuring and impairment charges, which are recorded in the consolidated statements of operations and comprehensive loss (in thousands):

| | Year Ended December 31, 2022 | Year Ended December 31, 2021 | Year Ended December 31, 2020 |
|---|---|---|---|
| Employee termination benefits | $ 12,929 | $ — | $ — |
| Impairment of property, plant and equipment | 25,841 | — | — |
| Contract termination costs | 12,427 | — | — |
| | $ 51,197 | $ — | $ — |

***Employee Termination Benefits***

Employees affected by the reduction in workforce under the Company's Reorganization Plan and Strategic Plan received involuntary termination benefits that are provided pursuant to a one-time benefit arrangement. For employees who were notified of their termination and have no requirements to provide future service, the Company recognized the liability for the termination benefits in full at fair value in the period in which they were incurred. For employees who are required to render services beyond a minimum retention period to receive their one-time termination benefits, the Company is recognizing the termination benefits ratably over their future service periods. The service periods for the Reorganization Plan began in September 2022 and ended at various dates through December 31, 2022. The service periods for the Strategic Plan began in November 2022 and ended at various dates through January 31, 2023. The Company will incur approximately $13.6 million of employee termination benefits expense to implement the Reorganization Plan and the Strategic Plan of which $12.9 million has been incurred in the year ended December 31, 2022.

The following table shows the liability related to employee termination benefits as of December 31, 2022:

| | Employee Termination Benefits |
|---|---|
| Accrued employee termination benefits beginning balance | $ — |
| Employee termination benefits charges incurred during the period | 12,929 |
| Amounts paid or otherwise settled during the period | (11,528) |
| Accrued employee termination benefits as of December 31, 2022 | $ 1,401 |

***Impairment of Property, Plant and Equipment***

As a result of the Reorganization Plan, the Company determined that sufficient indicators existed to trigger the performance of an interim long-lived asset impairment analysis as of September 30, 2022. In the third quarter of 2022, the Company tested the recoverability of its asset group using entity-specific undiscounted cash flows. Based on these undiscounted cash flows, the Company concluded the undiscounted future cash flows expected to result from the use and eventual disposition of its long-lived assets were less than the carrying value of the asset group. Therefore, the Company measured the long-lived asset impairment as the amount by which the carrying value of the asset group exceeds its fair

value and recorded an impairment of $17.8 million. The loss was allocated to the long-lived assets of the group on a pro rata basis using the relative carrying amounts of those assets, except that the loss allocated to an individual long-lived asset of the group did not reduce the carrying value of that asset below its fair value. The fair value of the asset group was determined from a third-party commercial real estate appraisal which represents a Level 3 fair value measurement.

Additionally, in conjunction with its Reorganization Plan, the Company committed to a plan to actively sell specific assets within its asset group, primarily its laboratory equipment and furniture and fixtures. The laboratory equipment and furniture and fixtures met all of the prescribed criteria required to classify it as held for sale. At December 31, 2022, $4.1 million of laboratory equipment and furniture and fixtures was classified as held for sale as current assets on the consolidated balance sheet as the disposal was expected to be consummated within one year of the balance sheet date and the Company does not expect to use the sale proceeds to reduce any long-term borrowings. The sale was completed by January 31, 2023.

In December 2022, the Company entered into a purchase and sale agreement for the sale of its manufacturing facility and certain related fixtures and personal property for an aggregate purchase price of $18.5 million. The purchase price was less than the carrying amount of the assets sold and the resulting impairment of $8.0 million was recorded within restructuring and impairment charges in the consolidated statements of operations and comprehensive loss.

For the year ended December 31, 2022, the Company recorded long-lived impairment charges of $25.8 million, which were recorded within restructuring and impairment charges on the consolidated statements of operations and comprehensive loss.

***Contract Termination Costs***

The discontinuation of the RTX-240 and RTX-224 clinical trials as part of the Reorganization Plan and of discovery activities and platform development as part of the Strategic Plan resulted in the termination of vendor contracts before the end of their term, as well as costs that continue to be incurred under certain contracts with no future economic benefit to the Company. The Company recognized these contract termination costs in full in the period in which they no longer held an economic benefit to the Company. During the year ended December 31, 2022, the Company incurred $12.4 million of contract termination costs, which it estimates to be the full amount of such costs to be incurred related to the Reorganization Plan.

The following table shows the liability related to contract termination costs as of December 31, 2022:

| | Contract Termination Costs |
|---|---|
| Accrued contract termination costs beginning balance | $ — |
| Contract termination costs incurred during the period | 12,427 |
| Amounts paid or otherwise settled during the period | (11,040) |
| Accrued contract termination costs as of December 31, 2022 | $ 1,387 |

**14. Subsequent Events**

On February 20, 2023, following the conclusion of the Company's review of strategic alternatives, the Company's Board of Directors unanimously approved the dissolution and liquidation of the Company pursuant to a plan of complete liquidation and dissolution, which plan is subject to stockholder approval.

**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**

Our management, with the participation of our Chief Executive Officer (our principal executive officer and principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, our Chief Executive Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Internal Control Over Financial Reporting**

***Management's Report on Internal Control Over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our management conducted an assessment of the effectiveness of our internal control over financial reporting, as of December 31, 2022, based on the criteria described in "Internal Control-Integrated Framework" (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2022, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm.

***Changes in Internal Control Over Financial Reporting***

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We engaged Verdolino & Lowey, P.C. during the quarter ended December 31, 2022 to provide certain services, including accounting services, to the Company. Although the underlying internal controls did not significantly change with this move, the responsibility to perform certain internal controls has transferred to an outsourced service provider.

**Item 9B. Other Information**

None.

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

Not applicable.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

Incorporated by reference from the information in our Proxy Statement to the extent filed with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

### Item 11. Executive Compensation

Incorporated by reference from the information in our Proxy Statement to the extent filed with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

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

Incorporated by reference from the information in our Proxy Statement to the extent filed with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

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

Incorporated by reference from the information in our Proxy Statement to the extent filed with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

### Item 14. Principal Accounting Fees and Services

Incorporated by reference from the information in our Proxy Statement to the extent filed with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

(a) 1. *Financial Statements*

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page 142 of this Annual Report on Form 10-K, incorporated into this Item by reference.

2. *Financial Statement Schedules*

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

3. *Exhibits*

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index below. The exhibits listed in the Exhibit Index are incorporated by reference herein.

**(b) Exhibit Index**

| | |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation of Rubius Therapeutics, Inc. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K (File No. 001-38586) filed on July 23, 2018). |
| 3.2 | Certificate of Amendment of Amended and Restated Certificate of Incorporation of Rubius Therapeutics, Inc. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K (File No. 001-38586) filed on July 7, 2022. |
| 3.3 | Amended and Restated Bylaws of Rubius Therapeutics, Inc. (Incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K (File No. 001-38586) filed on July 23, 2018). |
| 4.1 | Description of Registrant's Securities (Incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-K (File No. 001-38586) filed on March 12, 2020). |
| 4.2 | Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-225840) filed on July 2, 2018). |
| 4.3 | Second Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated February 23, 2018 (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-225840) filed on June 22, 2018). |
| 10.1# | Amended and Restated 2014 Stock Incentive Plan, and form of award agreements thereunder (Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-225840) filed on July 9, 2018). |
| 10.2# | 2018 Stock Option and Incentive Plan, and form of award agreements thereunder (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-225840) filed on July 9, 2018). |
| 10.3# | 2018 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-225840) filed on July 9, 2018). |
| 10.4# | Senior Executive Cash Incentive Bonus Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-225840) filed on June 22, 2018). |

| | |
|---|---|
| 10.5# | Amended and Restated Non-Employee Director Compensation Policy, dated February 24, 2021 (Incorporated by reference to Exhibit 10.5 to the Registrant's Form 10-K (File No. 001-38586) filed on February 25, 2022). |
| 10.6# | Form of Director Indemnification Agreement (Incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-225840) filed on June 22, 2018). |
| 10.7# | Form of Officer Indemnification Agreement (Incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-225840) filed on June 22, 2018). |
| 10.8 | Agreement for Termination of Lease, dated December 12, 2022, by and between Rubius Therapeutics, Inc. and ARE-MA Region No. 58, LLC (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38586) filed on December 14, 2022. |
| 10.9 | Purchase and Sale Agreement, dated December 6, 2022, by and between Rubius Therapeutics, Inc. and DIV Acquisition V, LLC (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38586) filed on December 12, 2022. |
| 10.10^ | Exclusive Patent License Agreement, dated January 28, 2016, by and between Rubius Therapeutics, Inc. and the Whitehead Institute for Biomedical Research (Incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-225840) filed on June 22, 2018). |
| 10.11^ | First Amendment to the Exclusive Patent License Agreement between the Registrant and the Whitehead Institute for Biomedical Research, dated December 12, 2017 (Incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-225840) filed on June 22, 2018). |
| 10.12^^ | Second Amendment to Exclusive Patent License Agreement, dated July 25, 2018, by and between Rubius Therapeutics, Inc. and the Whitehead Institute for Biomedical Research (Incorporated by reference to Exhibit 10.12.1 to Amendment No. 1 to Registrant's Annual Report on Form 10-K (File No. 001-38586) filed on May 15, 2019). |
| 10.13# | Employment Agreement between Rubius Therapeutics, Inc. and Dannielle Appelhans, dated July 26, 2021. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38586) filed on July 29, 2021). |
| 21.1* | List of Subsidiaries of Rubius Therapeutics, Inc. |
| 24.1* | Power of Attorney (included on signature page to this Annual Report on Form 10-K) |
| 31.1* | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1*† | Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, 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 Document. |
| 101.CAL* | Inline XBRL Taxonomy Calculation Linkbase Document. |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase Document. |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase Document. |
| 104* | Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101) |

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* Filed herewith.

\# Indicates a management contract or any compensatory plan, contract or arrangement.

ˆ Confidential treatment has been granted with respect to redacted portions of this exhibit. Redacted portions of this exhibit (indicated by asterisks) have been filed separately with the Securities and Exchange Commission.

ˆˆ Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the SEC.

† This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

**Item 16. Form 10-K Summary**

The company has elected not to include summary information.

## 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.

**RUBIUS THERAPEUTICS, INC.**

February 27, 2023

By: /s/ Dannielle Appelhans
Dannielle Appelhans
Chief Executive Officer

## POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Dannielle Appelhans with full power of substitution and resubstitution, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorney-in-fact and agent or her substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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.

| Signature | Title | Date |
|---|---|---|
| /s/ Dannielle Appelhans<br>Dannielle Appelhans | Chief Executive Officer<br>(Principal Executive Officer, Interim Principal Financial Officer and Interim Principal Accounting Officer) | February 27, 2023 |
| /s/ Pablo J. Cagnoni<br>Pablo J. Cagnoni, M.D. | Chairman of the Board of Directors | February 27, 2023 |
| /s/ Catherine A. Sohn<br>Catherine A. Sohn, Pharm.D. | Director | February 27, 2023 |
| /s/ Jonathan R. Symonds<br>Jonathan R. Symonds, CBE | Director | February 27, 2023 |

**EXHIBIT 21.1**

SUBSIDIARIES

| Subsidiary | Jurisdiction of Incorporation |
| --- | --- |
| Rubius Therapeutics Securities Corporation | Massachusetts |

**EXHIBIT 31.1**

**CERTIFICATION PURSUANT TO SECURITIES AND EXCHANGE ACT OF 1934**
**RULE 13A-14 AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002**

**CERTIFICATION**

I, Dannielle Appelhans, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rubius Therapeutics, 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. The registrant's other certifying officer(s) and I are 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 (the registrant’s fourth fiscal 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. The registrant's other certifying officer(s) and I have disclosed, based on our 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 (or persons performing the equivalent functions):

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

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

Date: February 27, 2023

By: /s/ Dannielle Appelhans

Dannielle Appelhans

Chief Executive Officer and President
(Principal Executive Officer)

**EXHIBIT 31.2**

**CERTIFICATION PURSUANT TO SECURITIES AND EXCHANGE ACT OF 1934**
**RULE 13A-14 AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002**

**CERTIFICATION**

I, Dannielle Appelhans, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rubius Therapeutics, 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. The registrant's other certifying officer(s) and I are 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 (the registrant’s fourth fiscal 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. The registrant's other certifying officer(s) and I have disclosed, based on our 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 (or persons performing the equivalent functions):

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

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

Date: February 27, 2023

By: /s/ Dannielle Appelhans

Dannielle Appelhans

Chief Executive Officer and President
(Principal 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 on Form 10-K of Rubius Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Dannielle Appelhans, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to her knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and

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

Date: February 27, 2023

By: /s/ Dannielle Appelhans

Dannielle Appelhans
Chief Executive Officer and President
(Principal Executive Officer and Principal Financial Officer)