REFINITIV

DELTA REPORT

10-K

TALARIS THERAPEUTICS, INC

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	8855
CHANGES	33
DELETIONS	4737
ADDITIONS	4085

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 20232022

OR

☐ o **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 Number: 001-40384

TALARIS THERAPEUTICS, INC.

Tourmaline Bio, Inc.

(Exact name of Registrant as specified in its Charter)

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Delaware		83-2377352
	8 3 - 2 3 7 7 3 5 2	
Delaware		
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)	
93 Worcester St. Wellesley, MA 27 West 24th Street, Suite 702 New York, NY		02481 10010
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: (502) 398-9250

(646) 481-9832

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

Name

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Title of each class	Trading Symbol(s)		
Common Stock, $0.0001 par value $0.0001 per share	TALS		

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

TRML

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ N Yes o No ☒ x

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ N Yes o No ☒ x

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 YESx ☒ NO ☐ No

o

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 YESx ☒ NO ☐ No

o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Large accelerated filer	o	☐	Accelerated filer	☐ o
Non-accelerated filer	x	☒	Smaller reporting company	☒ x
			Emerging growth company	☒ x

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. ☐ o

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. ☐ o

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. ☐

o

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 officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

o

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO Yes o☒ No x

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

The

As of June 30, 2023 (the last business day of the Registrant's second fiscal quarter), the Registrant's aggregate market value of the its voting and non-voting common stock equity held by non-affiliates of the Registrant, was approximately $89.9 million based on the closing sale price of the shares of common stock $3.04 per share as reported on the The Nasdaq Global Market on June 30, 2022 that date. As of March 15, 2024, was $139,064,898. In determining the market value of non-affiliate common stock, there were 25,646,509 shares of the Registrant's voting and non-voting Registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of March 1, 2023 was 42,015,166.
outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Registrant's definitive proxy statement (the "2024 Proxy Statement") for its 2024 Annual Meeting of Stockholders, which the 2023 annual meeting of stockholders Registrant intends to be filed file pursuant to Regulation 14A within with the Securities and Exchange Commission not later than 120 days after the registrant's Registrant's fiscal year ended December 31, 2022 December 31, 2023, are incorporated by reference in into Part III of this Annual Report on Form 10-K.

Table of Contents

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Item 8.	Financial Statements and Supplementary Data. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.	105101
Item 9.	Controls and Proced	105101

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject

EXPLANATORY NOTE

On October 19, 2023, the Delaware corporation formerly known as “Talaris Therapeutics, Inc.” completed its previously announced merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger, dated as of June 22, 2023 (the “Merger Agreement”), by and among Talaris Therapeutics, Inc. (“Talaris”), Tourmaline Bio, Inc. (“Legacy Tourmaline”) and Terrain Merger Sub, Inc., a direct wholly owned subsidiary of Talaris (“Merger Sub”), pursuant to numerous risks which Merger Sub merged with and uncertainties, including those described into Legacy Tourmaline, with Legacy Tourmaline surviving as a direct wholly owned subsidiary of Talaris and the surviving corporation of the merger (the “Merger”). Additionally, as a result of the Merger, (i) Legacy Tourmaline changed its name from “Tourmaline Bio, Inc.” to “Tourmaline Sub, Inc.”, and (ii) Talaris changed its name from “Talaris Therapeutics, Inc.” to “Tourmaline Bio, Inc.”

On October 19, 2023, in Part II, Item 1A. “Risk Factors” connection with the transactions contemplated by the Merger Agreement, Talaris filed a Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation effecting a 1-for-10 reverse stock split of Talaris’ common stock (the “Reverse Stock Split”). As a result of the Reverse Stock Split, the number of issued and outstanding shares of Talaris’ common stock immediately prior to the Reverse Stock Split was reduced such that every 10 shares of Talaris’ common stock held by a stockholder immediately prior to the Reverse Stock Split were combined and reclassified into one share of common stock after the Reverse Stock Split.

In this Report, unless the context indicates otherwise, the terms “Company,” “we,” “us,” and “our” refer to Tourmaline Bio, Inc. (formerly known as Talaris Therapeutics, Inc.) and its consolidated subsidiaries. Unless otherwise noted, all references to share of common stock and per share amounts in this Annual Report on Form 10-K. The principal risks and uncertainties affecting our business include 10-K have been retroactively adjusted to reflect the following:

- We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate conversion of shares in the fu could have negative consequences.

- Even if we successfully consummate any transaction from our strategic assessment, including, but not limited This Report contains references to an acquisition, merger, a business combination and/or divestiture, we may fail to realize all of the anticipated benefits of the transaction, those benefits may take longer to realize than expected, or we may encounter integration difficulties.

- If we are successful in completing a strategic transaction, we may be exposed trademarks belonging to other operational entities, which are the property of their respe holders. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any c companies.

- If a strategic transaction is not consummated, our board position, business strategy and the plans and objectives of directors may decide management for future operati are forward-looking statements. When used in this Report, words and phrases such as “designed to, pursue a dissolution ” “intended to,” “may,” “might,” “can,” “will,” “to “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “likely,” “continue” and liquidation. In suc event, “ongoing,” or the amount of cash available for distribution to our stockholders will depend heavily on the timing negative of such liquidation terms or other si expressions, as well as the amount of cash that will need they relate to be reserved for commitments and contingent liabilities.

- Our ability to consummate a strategic transaction depends on Any statements in this Report, or incorporated herein, about our ability to retain our employees required to consummate such transaction.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater expected and could disrupt our business.
- We may become involved in litigation, including securities class action litigation, that could divert management's attention and harm the company's business, and insura coverage may not be sufficient to cover all costs and damages.
- Our business substantially depends upon the successful development and regulatory approval of FCR001, our lead product candidate. If we are unable to obtain regula approval for FCR001, our business may be materially harmed.
- We are a late-stage clinical biotechnology company and we have incurred net losses since our inception. We anticipate that we will continue to incur significant net losse the foreseeable expectations, beliefs, plans, objectives, assumptions or future and may never achieve events or maintain profitability.
- We have not yet completed any registrational trials and have no history of commercializing products, which may make it difficult to evaluate the success of our busines date and to assess our future viability.
- Our product candidates represent a novel therapeutic approach that could result in heightened regulatory scrutiny. The regulatory landscape that applies to our Facilit Allo-HSCT Therapy is rigorous, complex, uncertain and subject to change.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the inability to successfully and timely conduct clinical trials and ob regulatory approval for our product candidates would substantially harm our business.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, development of our product candidate may be delayed or prevented, which would ha material adverse effect on our business.
- The results of preclinical studies or earlier clinical trials performance are not necessarily predictive of future results. Our existing product candidates in clinical trials, and other product candidate we advance into clinical trials, may not have favorable efficacy or safety in later clinical trials or receive regulatory approval.
- Interim, "top line" or preliminary data from our clinical trials that we may announce or share with regulatory authorities from time to time may change as more patient become available historical facts and are subject to audit and verification procedures that could result in material changes in the final data.
- Our product candidates, or associated conditioning regimens or treatment protocols, may cause undesirable side effects such as infection or graft vs. host disease, or h other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences follo any regulatory approval.
- Even if our product candidates receive regulatory approval, we will still face extensive ongoing regulatory requirements and continued regulatory review, which may resu significant additional expense, and our products may still face future development and regulatory difficulties.
- We currently operate our own manufacturing facility which would require scale-up to appropriately address our anticipated commercial needs for FCR001, which will req significant resources. We may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.
- Our product candidates are uniquely manufactured for each patient and we may encounter difficulties in production, particularly with respect to scaling our manufactu capabilities.
- If our manufacturing facility is damaged or destroyed or production at our manufacturing facility is otherwise interrupted, our business would be negatively affected.
- We are dependent on a limited number of suppliers and, in some cases sole suppliers, for some of our components and materials used in our product candidates.
- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effec our business and prospects.
- We depend substantially on intellectual property licensed from the ULRF, and termination of this license could result in the loss of significant rights, which would mate harm our business.

- We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipat
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and manufacturing process, or if the scope of the intelle property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.
- Our recent reduction in force may negatively impact employee morale and productivity. Further, uncertainties surrounding the future of our clinical programs may incre retention risk.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within statements. Within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical fact are "forward-looking statements " for purposes of this Annual Report on Form 10-K. In some cases, you can identify, these forward-looking statements by terminology such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative or plural of those terms, and similar expressions.

Forward-looking include statements include, but are not limited to, statements about:

- the success, benefits and timing of a potential strategic transaction, as well as potential alternatives, including but not limited to partnerships or the dissolutio liquidation of the Company;

- our anticipated savings related to our corporate restructuring and the associated headcount reduction, as well as the potential impacts on employee morale and productivity;

- the success, cost and timing of our product development activities, non-clinical studies and clinical trials, including statements regarding the timing of initiation a completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and developme programs;

- the potential for COVID-19 or other pandemic, epidemic or outbreak of an infectious disease, to disrupt our business plans, product development activities, ongoing clinical trials, including the timing and enrollment of patients, the health outcome of our employees current and the strength of our supply chain;

- our expectations regarding the safety or efficacy profile of our product candidates
- our ability to advance any product candidate into or successfully complete any clinical trial;
- our ability to obtain regulatory approval for any of our candidates;
- our ability to successfully manufacture our product candidates for future clinical trials, or for commercial use, if approved;and the reporting of data from those

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

trials;

- the ability to license additional intellectual property relating to any therapeutic potential of TOUR006 and future product candidates and to comply with our existing license agreement;candidates;

•our ability to commercialize our products in light of the intellectual property rights of others;

- the success of competing therapies that are or become available;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our current and future product candidates;candidates, subject to regulatory approvals;

- our ability to attract collaborators with development, regulatory and commercialization expertise;extend our operating capital;

•future agreements with third parties in connection with the development or commercialization potential of our product candidates and any other approved product;

- the size and growth potential of the markets for our product candidates, technologies and our ability to serve those markets;execute on our corporate strategy;

•the rate and degree of market acceptance of our product candidates;

•regulatory and political developments in the United States and foreign countries, including but not limited to the Russia-Ukraine conflict and associated sanctions;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;

- our reliance on third parties to manufacture and conduct preclinical studies and clinical trials of our current and future product candidates;
- the success of competing therapies that are or may become available;
- our ability to obtain regulatory approval for our product candidates and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- the strength and breadth of our patent portfolio;
- our ability to obtain and adequately protect intellectual property rights for our product candidates;
- potential claims relating to our intellectual property;
- our financial performance;
- our ability to develop and maintain our corporate infrastructure, including our ability to design and maintain an effective system of internal controls;
- our ability to remediate the existing material weaknesses in our internal control over financial reporting;
- our ability to attract and retain key scientific, or medical, commercial and management personnel;

•the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

•the impact of laws and regulations; and

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

- our expectations regarding our ability to obtain continue to satisfy the listing requirements of The Nasdaq Stock Market and maintain intellectual property prote for have our product candidates. stock continue to trade thereon; and

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Preclinical* and *requirements including GLPs.

Clinical Development

Prior to beginning the first a clinical trial with a product candidate in the United States, U.S., we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans within a specific defined clinical study or studies. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology, and PD characteristics of the

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

product candidate; CMC information; and any available human data or literature to support the use of the investigational product. An IND must be submitted to the FDA and the FDA must allow the IND to proceed. An IND is an exemption from the FD&C Act that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA allowance that such investigational product may be administered to humans in connection with such trial. Such authorization must be secured prior to interstate shipment and administration. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, must be submitted to the FDA as part of an IND. An IND must become effective cleared before human clinical trials may begin. begin in the US. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold or partial clinical hold. In this case, until the IND sponsor and the FDA must resolve any the outstanding concerns before or questions. The FDA also may impose a partial clinical trials can begin. hold that would limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. Submission of an IND therefore may or may not result in FDA allowance authorization to begin a clinical trial.

Clinical trials involve the administration of the biological investigational product candidate to healthy volunteers or patients human subjects under the supervision of qualified investigators in accordance with GCPs, which generally are physicians not employed by, or under, include the control of the trial sponsor. requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and study, the parameters to be used in monitoring safety and the effectiveness criteria to monitor subject safety, including stopping rules that assure a be evaluated. A separate submission to the existing IND must be made for each successive clinical trial will conducted during product development and for any subsequent protocol amendments. For new indications, a separate new IND may be stopped if certain adverse events should occur.

An required. Furthermore, an independent IRB representing for each institution participating in site proposing to conduct the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to study subjects before it commences the clinical trial begins at that institution, site. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the IRB must conduct continuing review risks to individuals participating in the clinical trials are minimized and reapprove the study at least annually. are reasonable in relation to anticipated benefits. The IRB must review and approve, among other things, monitor the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee (**DSMB**). This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study.

Certain information about certain clinical trials must also be submitted within specific timeframes until completed, including any changes to the NIH for public dissemination on its *clinicaltrials.gov* website.

Clinical trials typically are conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The investigational product study plans while it isRegulatory authorities, the case of some products for severe or life-threatening diseases, especially initially introduced into healthy human subjects and testedwhen the product may be too inherently toxic to ethically administer to healthy volunteers, the initial for safety. In being conducted. human testing is often conducted in patients.
- *Phase 2*. The investigational product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3*. The investigational product is administered to an expanded patient population to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These

clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for approval and product labeling.

In some cases, FDA may require, or firms may voluntary pursue, post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA IRB or the sponsor acting on its own or based on a recommendation from the sponsor's data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if risk, the clinical trial is not being conducted in accordance with the FDA's or IRB's requirements, or if the biological product drug has been associated with unexpected serious harm to patients. subjects or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides advice to the sponsor on whether or not a study should move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Information about some clinical trials, including a description of the trial and trial results,

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if SAEs occur.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, distribution and elimination of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and labeling.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies usually may complete additional animal studies and also must develop additional information about the physical biological characteristics of the biological product as well as candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP and as applicable CGTP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, candidate. In addition, the sponsor must develop and validate analytical methods for testing the identity, strength, quality potency and purity of the final biological product. product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information.

In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review to determine if it is substantially complete before the FDA accepts it for filing. In most cases, the submission of a BLA is subject to a substantial application user fee, although the fee may be waived addition, under certain circumstances. Under the performance goals and policies implemented by the FDA under the Prescription Drug User Fee Act (**PDUFA**) for original BLAs, the FDA targets ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, for its intended use, and whether the product is being manufactured in accordance with cGMP to ensure its continued safety, purity and potency. The FDA may refer applications for novel biological products or biological products that present difficult or novel questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy (**REMS**) is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Where applicable, the FDA also will not approve the product if the manufacturer is not in compliance with the CGTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products (**HCT/Ps**), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human patient. The primary intent of the CGTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

the FDA and, when applicable, to evaluate donors through appropriate screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP, CGTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Under the Pediatric Research Equity Act (**PREA**("PREA"), a BLA or supplement to a BLA for a novel product (e.g., new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the biological product drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product drug for an indication for which orphan designation has been granted.

BLA Submission, Review and Approval

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's CMC and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once the FDA receives an application, it has 60 days to review the BLA to determine if it is substantially complete to permit a substantive review, before it accepts the BLA for filing. If the FDA determines that a BLA is incomplete, the filing may be refused and must be re-submitted for consideration. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months from acceptance of filing in which to complete its initial review of a standard BLA and respond to the applicant, and six months from acceptance of filing for a priority BLA. The FDA does not always meet its PDUFA goal dates. The review process and the PDUFA goal date may be extended by three months or longer if the FDA requests that the BLA sponsor provides additional information or clarification regarding information already provided in the submission before the PDUFA goal date.

After the BLA is accepted for filing, the FDA reviews a BLA to determine, among other things, whether a product is safe and effective, and whether the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued quality, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts any necessary inspections, of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter letter, which indicates that the review cycle is complete, will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product receives regulatory is granted, such approval will be granted for particular indications and may entail limitations on the approval indicated uses for which such product may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, including to subpopulations of patients, which could restrict the commercial value of the product. Further, marketed. For example, the FDA may require that certain contraindications, warnings precautions or interactions be included in approve the BLA with a REMS, to ensure the benefits of the product labeling. The FDA may impose restrictions outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and conditions on product to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase IV 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

Any marketing application for a biologic submitted to the FDA for approval may be eligible for FDA programs intended to expedite the FDA review and approval process, such as priority review, fast track designation, breakthrough therapy and accelerated approval.

A product is eligible for priority review if the FDA determines that it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides additional opportunities for frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and FDA

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the BLA. The review clock does not begin until the final section of the BLA is submitted. The FDA may decide to rescind the fast track designation if it determines that the qualifying criteria no longer apply.

In addition, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are eligible for intensive guidance from the FDA on an efficient development program, organizational commitment to the development and review of the product including involvement of senior managers, and, like fast track products, are also eligible for rolling review of the BLA. Both fast track and breakthrough therapy products may also be eligible for accelerated approval and/or priority review if relevant criteria are met.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. The FDA may require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period, which could adversely impact the timing of the commercial launch of the product.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review and approval will not be shortened. Furthermore, priority review, fast track designation, breakthrough therapy designation, and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, U.S., or more than 200,000 individuals in the United States and U.S. for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug or biological product available in the United States biologic for this type of disease or condition will be recovered from sales of in the product. U.S. for that drug or biologic. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product The orphan drug designation does not convey any advantage in, or automatically shorten the duration of, the regulatory review and or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug many product may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States U.S. may be lost if the FDA later determines that the request for designation was materially defective or as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Orphan drug designation may also entitle a party

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Expedited Development and Review Programs

The FDA has various programs, including Fast Track designation, breakthrough therapy designation, accelerated approval and priority review, that approvals are intended subject to expedite or simplify the process for the development and FDA review of drugs and biologics that are intended for the treatment of serious or life-threatening diseases or conditions. To be eligible for fast track designation, new drugs and biological product candidates must be intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request continuing regulation by the FDA, to designate the drug or biologic as a fast track product at any time during the clinical development of the product. One benefit of fast track designation, for example, is that the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted if certain conditions are satisfied, including, an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Under the FDA's breakthrough therapy program, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more among other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The FDA may take other actions appropriate to expedite the development and review of the product candidate, including holding meetings with the sponsor and providing timely advice to, and interactive communication with, the sponsor regarding the development program.

A product candidate is eligible for priority review if it treats a serious or life-threatening disease or condition and, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Under priority review, the FDA's goal is to review an application in six months once it is filed, compared to ten months for a standard review. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Additionally, a product candidate may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint other than survival or irreversible morbidity, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit, and under the Food and Drug Omnibus Reform Act of 2022 (**FDORA**), the FDA may require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

RMAT Designation

As part of the 21st Century Cures Act, enacted in December 2016, Congress created the Regenerative Medicine Advanced Therapy (**RMAT**) designation to facilitate an efficient development program for, and expedite review of, a product candidate that meets the

following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. A sponsor may request that the FDA designate a drug as a RMAT concurrently with or at any time after submission of an IND. The FDA has 60 calendar days to determine whether the drug meets the criteria. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may, as appropriate, fulfill such requirements through the submission of clinical evidence from clinical trials, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. Like some of FDA's other expedited development programs, RMAT designation does not change the standards for approval but may help expedite the development or approval process.

Post-Approval Requirements

Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements, as well as things, requirements relating to quality control and quality assurance, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. We currently rely, and may continue After approval, most changes to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products approved product, such as adding new indications or other labeling claims, are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Manufacturers also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or identified in patient populations that are not described in the product's an approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, product detentions or refusal to permit the import or export of the product, restrictions on the marketing or manufacturing of the product, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors or other stakeholders, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product BLA. Biologic manufacturers and other entities involved in the manufacture and distribution of approved biological products, and those supplying products, ingredients, and components of them, their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and other laws. documentation requirements upon us and our third-party manufacturers.

Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. Discovery Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, after approval including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, manufacturer, mandated modification of promotional materials or holder issuance of an approved BLA, including corrective information, issuance by FDA or other regulatory authorities of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product, or complete withdrawal of the product from the market. In addition, changes to the manufacturing process market or facility generally require prior FDA approval before being implemented and other types of changes to the approved product such as adding new indications and additional labeling claims, are also subject to further FDA review and approval. recalls;
- fines, warning or untitled letters or holds on post-approval clinical studies;

Marketing Exclusivity •

Depending upon the timing, duration and specifics refusal of the FDA approval to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;

- product seizure or detention, or refusal of the use FDA to permit the import or export of our product candidates, some products; or
- injunctions, consent decrees or the imposition of our United States patents civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. However, manufacturers and third parties acting on their behalf are prohibited from marketing or promoting drugs in a manner inconsistent with the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be eligible for limited patent term extension under the Hatch-Waxman

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up subject to five years as compensation for patent term lost during product development significant liability.

Biosimilars and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. Reference Product Exclusivity

The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the **Affordable Care Act**), signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (**BPCIA**("BPCIA"), which created an abbreviated approval pathway for biological products shown to be that are biosimilar to or interchangeable with an FDA-licensed FDA-approved reference biological product.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial study or trials. studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

FDA will not accept

Under the BPCIA, an application for a biosimilar or interchangeable product based on may not be submitted to the reference biological product FDA until four years after following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensure licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for FDA approves a supplement full BLA for the biological competing product or for a subsequent application by containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency.

and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

In addition to exclusivity under the BPCIA, a biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

U.S. Foreign Corrupt Practices Act, U.K. Bribery Act and

Other Laws

*The U.S. Foreign Corrupt Practices Act of 1977 (**FCPA**) prohibits companies and their employees, agents, and intermediaries from engaging in certain activities to obtain or retain business or secure any improper advantage, or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize, directly or indirectly, the payment of anything of value to any employee or official of a foreign government or public international organization, or political party, political party official, or political candidate in an attempt to obtain or retain business or to otherwise influence the recipient working in an official capacity. The scope of the FCPA*

also includes employees and officials of state- owned or controlled enterprises, which may include healthcare professionals in many countries.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

*Equivalent laws have been adopted in other non-U.S. countries that impose similar obligations, including the U.K. Bribery Act 2010 (**Bribery Act**). As with the FCPA, these laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. The Bribery Act also imposes liability for failing to prevent a person associated with us from committing a bribery offense.*

There also are other laws and regulations governing international operations, including regulations administered by the governments of the United Kingdom and the United States and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as trade control laws.

Failure to comply with the Bribery Act, the FCPA and other anti-corruption laws and trade control laws could subject us to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, where applicable.

Other Healthcare Laws and Compliance Requirements

In the United States, U.S., our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & and Medicaid Services (**CMS**("CMS"), other divisions of the U.S. Department of Health and Human Services (**HHS**("HHS") (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice (**DOJ**("DOJ"), and individual U.S. attorney Attorney offices within the DOJ, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have be subject to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the federal Health Insurance Portability and Accountability Act of 1996 (**HIPAA**("HIPAA"), and similar state laws, each as amended, as applicable:

applicable. our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may be subject to healthcare laws, regulations and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting, and physician sunshine laws. Some of our pre-commercial activities are subject to some of these laws.

- the The federal Anti-Kickback Statute which prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting receiving, offering or paying receiving any remuneration, (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for either the referral of an individual, purchasing, leasing, ordering or arranging for the purchase, lease order, arrangement or recommendation order of any good, facility, item or service for which payment may be made, reimbursable, in whole or in part, under a Medicare, Medicaid or other federal healthcare program, programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Additionally, the intent standard under the Anti-Kickback Statute was amended by the ACA, to a stricter standard such as the Medicare and Medicaid programs; that a person or entity does not need no longer needs to have actual knowledge of the federal Anti-Kickback Statute statute or specific intent to violate it in order to have committed a violation. Violations of the Anti-Kickback Statute can result in significant civil and criminal fines and penalties, imprisonment, and exclusion from federal healthcare programs. In addition, the government may assert ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or ("FCA").

The federal civil money penalties statute;

- the federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalty laws, including the FCA, which imposes significant pena and can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, individuals or entities from know presenting, or causing to be presented, a false or fraudulent claims claim for payment to, or approval by, Medicare, Medicaid, or other the federal government, inclu federal healthcare programs, such as Medicare and Medicaid, knowingly making, using, or causing to be made or used a false record or statement material to a fals fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing making a false statement to improperly avoid, decreas knowingly and improperly avoiding or decreasing or concealing conceal an obligation to pay money to the federal government. Manufacturers can A claim includes request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have b prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. C companies have been prosecuted for causing false claims to be held liable under the False Claims Act even when they do not submit claims directly to governm payors if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblowe bring actions on behalf submitted because of the federal government alleging violations companies' marketing of the False Claims Act

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- the anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or serv for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program; healthcare programs.

- HIPAA which created new additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody control or control custody of, any healthcare benefit program, regardless including private third-party payors, willfully obstructing a criminal investigation of the payor (e.g., public or private) a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements or representations statement in connection with the delivery of or payment for healthcare benefits, items or services

relating to services. Like the Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare matters; similar to the federal Anti-violation. Kickback Statute, fraud statutes under HIPAA such that a person or entity does not need no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (**HITECH**("HITECH"), and their respective its implementing regulations, which impose imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information;information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, which are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity as well as their covered subcontractors. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

- Additionally, the federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act (the "Sunshine Act") within the ACA, and its implementing regulations, which requires applicable require that certain manufacturers of drugs, devices, biologics biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to (with certain exceptions) report annually to the CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these Failure to report accurately could result in penalties. In addition, many states also govern the reporting obligations will extend to include of payments or other transfers of value, made during many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the previous year to certain non-physician providers, including physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives;Sunshine Act, thus further complicating compliance efforts.

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

In addition Many states have similar statutes or regulations to the above on November 20, 2020, the Office of Inspector General (**OIG**) finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. The effective date of the new safe harbors has been delayed by the Biden administration until January 1, 2023. We continue to evaluate what effect, if any, these rules will have on our business.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which that may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar We may also be subject to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed state laws that require pharmaceutical companies to comply with the April 2003 Office pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

drug manufacturers to report information related to payments and other transfers of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/ value to physicians and other healthcare providers, drug pricing or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties. Finally, there are state and foreign expenditures. These laws governing the privacy and security of health information (e.g., the California Consumer Privacy Act), many of which may differ from each other in significant ways and often are may not preempted by HIPAA, thus have the same effect, further complicating compliance efforts.

Because of Additionally, to the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible extent that some we have business operations in foreign countries or sell any of our business activities could products in foreign countries and jurisdictions, including Canada or the E.U., we may be subject to challenge under one or more of such laws.

Violations of fraud and abuse laws additional regulation.

We may develop products that, once approved, may be punishable administered by criminal a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain biopharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or civil sanctions, including penalties, fines, imprisonment and/or exclusion or suspension register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state healthcare programs such as Medicare consumer protection and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these unfair competition laws. Efforts to ensure that our current and future

Ensuring business arrangements with third parties and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. is a costly endeavor. If our operations including our arrangements with physicians and other healthcare providers, are found to be in violation of any of such the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we it may be subject to significant penalties, including without limitation, administrative, civil, and criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), and imprisonment, any of which could adversely affect our ability to operate our business and our financial results. The

approval results of operations.

Coverage, Pricing and commercialization Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the U.S. and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the U.S., third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the U.S., and commercial payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors, which decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that coverage or reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other cell therapies outside third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the United States use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also likely subject provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to foreign equivalents maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develops.

Different pricing and reimbursement schemes exist in other countries. In the E.U., governments influence the price of biopharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to establish their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the U.S. has increased, and we expect will continue to increase, the pressure on healthcare laws mentioned above, pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA"), into law, which among other foreign laws.

If any things, (1) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA includes certain exemptions to the price negotiation program, including a limited exemption for products with orphan drug designation. This exemption applies only to products with one orphan drug designation that is (i) for a rare disease or condition and (ii) is approved for indication(s) for such rare disease or condition.

By limiting price negotiation exemption to products with only one orphan drug designation, the IRA may decrease our interest in pursuing orphan drug designation for our product candidates in multiple indications. The IRA also, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

through a newly established manufacturer discount program. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may first ten drugs that will be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The risk of our being found in violation of these laws is increased by the fact that IRA permits HHS to implement many of these laws provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have not been fully interpreted a significant impact on the pharmaceutical industry.

The ACA has substantially changed healthcare financing and delivery by the regulatory authorities or the courts, both governmental and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. private insurers. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that a healthcare company may violate one or more of the requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial cost.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the Affordable Care Act was enacted, which, ACA, among other things, increased the minimum level of Medicaid rebates owed payable by most manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the Medicaid Drug Rebate Program; introduced manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; extended injected expanded the Medicaid Drug Rebate Program to utilization types of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts entities eligible for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected the 340B drug manufacturers to new annual, nondeductible fees based on pharmaceutical companies' share of sales to federal healthcare programs; imposed a new federal excise tax on the sale of certain medical devices; expanded healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance; discount program; expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; expanded the entities eligible for discounts under the PHS Act's pharmaceutical pricing program, also known as the 340B Drug Pricing Program; created new requirements to report financial arrangements with physicians and teaching hospitals, commonly referred to as the Physician Payments Sunshine Act; programs; created a new requirement to annually report the identity and quantity of drug samples that manufacturers and authorized distributors of record provide to physicians; created a new Patient Centered Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established the a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There

Some of the provisions of the ACA have yet to be implemented, and there have been executive, legal and political challenges to certain aspects of the Affordable Care Act. During his presidency, former President Trump signed several executive orders and numerous other directives designed ACA. In December 2017, Congress repealed the tax penalty for an individual's failure to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act.

Concurrently, Congress considered legislation that would repeal or repeal and replace all or maintain ACA-mandated health insurance as part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. For example, on January 22, 2018, former President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed tax reform bill. Moreover, the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices; however, on December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (**H.R. 1865**), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. The Bipartisan Budget Act of 2018 (**BBA**), among other things, amends amended the Affordable Care Act, ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, the Tax Cuts and Jobs Act of 2017 (**Tax Act**), included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full Affordable Care Act. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial a challenge to on procedural grounds that argued the ACA brought is unconstitutional in its entirety because the "individual mandate" was repealed by several states without specifically ruling on the constitutionality of the ACA. Further, President

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Biden issued an executive order Congress. Prior to initiate a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how other healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives.

For example, on July 24, 2020 and September 13, 2020, former President Trump signed several Executive Orders aimed at lowering drug pricing that seek to implement several of the administration's proposals. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation (**MFN**) Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021, CMS rescinded the Most Favored Nation rule. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed, and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. This deadline was pushed back further to January 1, 2027 by the Bipartisan Safer Communities Act and could potentially be pushed back to January 1, 2032 by the Inflation Reduction Act. Further, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug (**Accumulator Rule**). On May 17, 2022, the U.S. District Court for the District of Columbia granted the Pharmaceutical Research and Manufacturers of America's (**PhRMA**) motion for summary judgement invalidating the Accumulator Rule. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current U.S. presidential administration may reverse or otherwise change these measures, both the current U.S. presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

The Inflation Reduction Act of 2022, or IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The

effects of the IRA on our business and the healthcare industry in general is not yet known. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any cell therapies for which we obtain regulatory approval. In the United States and markets in other countries, sales of any cell therapies for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from payors. Payors include government authorities, managed care providers, private health insurers and other organizations. Patients who are prescribed treatments for their conditions and providers generally rely on these third-party payors to reimburse all or part of the associated healthcare. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a payor not to cover our cell therapies could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development and manufacturing costs. Further, due to the COVID-19 pandemic, millions of individuals have lost employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

In addition, coverage and reimbursement for products can differ significantly from payor to payor. One payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Additionally, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process. Payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product, we may need to conduct expensive evidence generation studies in order to demonstrate the medical necessity and cost-effectiveness of such a product, in addition to the costs required to obtain regulatory approvals. If payors do not consider a product to be cost-effective compared to current standards of care, they may not cover the product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to cover its costs or make a profit.

Employees and Human Capital Resources

We believe our employees are vital to the advancement of our product pipeline, and critical to the safety of patients enrolled in our on-going and future clinical trials. We focus on attracting innovative and collaborative employees who can lead and participate in teams that will advance our Facilitated Allo-HSCT Therapy for the ultimate long-term benefit of patients.

Our People

As of December 31, 2022, we had 129 employees and 13 consultants. In February 2023, we reduced our workforce by approximately one-third. As of March 31, 2023, we had 87 employees and 8 consultants. At that time, a total of 11 employees held doctoral degrees including MD, PhD or PharmD degrees. Within our workforce, 68 employees are engaged in research and development and 19 are engaged in business development, finance, project and information management, and general management and administration. Our human capital resources objectives include identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Diversity and Inclusion

We believe that a diverse workforce fosters innovation and cultivates a culture that leverages the unique perspectives of every team member to advance our pipeline. Our board of directors and executive management team includes diverse individuals based on

gender and race, and benefit from the diverse experiences of our directors and management that individually and collectively create an innovative and productive workplace culture. We also believe diversity and inclusion helps to attract the best talent. Within the broader community, both locally and among our patient communities, we foster diversity and inclusion through our work with charities, patient advocacy organizations, and health related non-profits.

Talent Acquisition, Development and Retention

We have invested in attracting, developing, and retaining our employees. Our philosophy is to communicate a clear organizational mission, purpose and strategy, to set challenging goals, to drive accountability, and to continuously assess, develop, and advance talent. Our Company provides employees opportunities to grow in their current roles as well as to have opportunities to build new skills, while also considering diversity in gender, race, and life experience.

Compensation, Benefits, and Safety

We strive to offer a comprehensive benefits program that provides resources to help employees manage their health, finances and life outside of work. Compensation for our employees includes market competitive salaries and wages, equity participation to drive an ownership culture, comprehensive health and welfare benefits, and retirement plan contributions. Our commitment to the safety of our employees, particularly those who work in our laboratory and manufacturing facilities, is also a priority and we have safety programs at all our properties to facilitate safe working practices.

Corporate Information

We were incorporated under the laws of the state of Delaware in February 2002. Our mailing address is 93 Worcester Street, Wellesley, Massachusetts, and our executive offices are located at 93 Worcester Street, Wellesley, Massachusetts and our telephone number at that address is (502) 398-9250. We maintain an Internet website at the following

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

address: www.talaristx.com. The information on our website is not incorporated by reference in this Annual Report on Form 10-K or in any other filings we make with the Securities and Exchange Commission, or SEC.

Available Information

We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Exchange Act of 1934. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, exhibits and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge the same day we electronically file the information with, or furnish it to, the SEC.

A copy of our Corporate Governance Guidelines, Code of Business Conduct and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are posted on our website, www.talaristx.com, under “Investors – Corporate Governance.”

The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding us and other issuers that file electronically with the SEC. The SEC’s Internet website address is www.sec.gov.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report, including our financial statements and the related notes thereto and the section of this Quarterly Report titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” before you make an investment decision. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. As a result, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock. The risks described below are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition or results of operations.

Risks Related to our Strategic Review Process

We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future could have negative consequences.

In February 2023, we announced that we are undertaking a comprehensive review of strategic alternatives focused on maximizing shareholder value, including, but not limited to, an acquisition, merger, possible business combinations and/or a divestiture of the Company’s cell therapy CMC capabilities. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders.

The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business.

In addition, potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets and our public listing. Further, should we resume the development of our product candidates, the development and any potential commercialization of our product candidates will require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development of our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with us on reasonable terms. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

If we are not successful in setting forth a new strategic path for the Company, or if our plans are not executed in a timely fashion, this may cause reputational harm with our stockholders and the value of our securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of the Company could cause our stock price to fluctuate significantly.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Even if we successfully consummate any transaction from our strategic assessment, including, but not limited to, an acquisition, merger, a business combination and/or divestiture, we may fail to realize all of the anticipated benefits of the transaction, those benefits may take longer to realize than expected, or we may encounter integration difficulties.

Our ability to realize the anticipated benefits of any potential business combination or any other result from our strategic assessment, are highly uncertain. Any anticipated benefits will depend on a number of factors, including our ability to integrate

with any future business partner, our ability to obtain value for our cell therapy CMC capabilities, if divested, and our ability to generate future shareholder value in the technology platform we may elect to pursue. The process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of any potential transaction could adversely affect our business and financial condition.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction.

Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In connection with the evaluation of strategic alternatives and in order to extend our resources, we implemented a restructuring plan that included reducing our workforce by approximately one-third, with remaining employees primarily focused on maintaining the Company's cell therapy CMC capabilities and executing FREEDOM-3, each pending the outcome of our review of strategic alternatives. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining

personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

On February 15, 2023, in connection with the evaluation of strategic alternatives and in order to extend its resources, the Board of Directors of the Company approved a restructuring plan (the "Plan") that includes reducing the Company's workforce by approximately one-third, with remaining employees primarily focused on maintaining the Company's cell therapy CMC capabilities and executing FREEDOM-3. In addition, the Plan includes a discontinuation of the Company's FREEDOM-1 and FREEDOM-2 clinical development programs and further prioritization of the Company's resources as it assesses strategic alternatives. The Company estimates that it will incur approximately $2.9 million for retention, severance and other employee termination-related costs in the first and second quarters of 2023. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employees. Employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business.

Our workforce reduction activities may also yield unintended consequences, such as attrition beyond our reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. For example, the workforce reduction may negatively impact our clinical, regulatory, technical operations, and commercial functions, should we choose to continue to pursue them, which would have a negative impact on our ability to successfully develop, and ultimately, commercialize our product candidates. Our future financial performance and our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be.

We may become involved in litigation, including securities class action litigation, that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, litigation, including securities class action litigation, has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the SEC. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Risks Related to Our Business and Product Candidates

Risks Related to Clinical Development

Our business substantially depends upon the successful development and regulatory approval of FCR001, our lead product candidate. If we are unable to obtain regulatory approval for FCR001, our business may be materially harmed.

We currently have no products approved for sale and are investing substantially all of our efforts and financial resources in the development of our Facilitated Allo-HSCT Therapy, specifically in our lead product candidate, FCR001. Successful continued development and ultimate regulatory approval of FCR001 for any potential indications is critical to the future success of our business. We will need to raise sufficient funds for, and successfully enroll and complete, our clinical development programs of FCR001 for severe autoimmune diseases or any additional indications.

There is no guarantee that any of our product candidates will proceed in clinical development or achieve regulatory approval. The process for obtaining marketing approval for any product candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval as planned or, if at all. The potential regulatory approval of FCR001 or any other product candidate we may develop is subject to a number of risks, including the following:

- successful initiation and completion of clinical trials;
- successful patient enrollment in clinical trials;
- successful data from our clinical trials that supports an acceptable risk-benefit profile of our product candidates in the intended populations; and
- receipt and maintenance of marketing approvals from applicable regulatory authorities.

Furthermore, negative results in the development of FCR001, such as the patient death in our FREEDOM-1 trial, may impact our ability to obtain regulatory approval of FCR001 for other current and potential indications since the underlying platform, manufacturing process, development process, and cell therapy is the same for all of our current programs in development. Accordingly, a failure in any one program may affect the ability to obtain regulatory approval to continue or conduct our other clinical programs. Specifically, in February 2023, we announced the termination of our FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001's ability to induce durable tolerance in LDKT recipients. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones in those programs. Should we continue clinical development of our product candidates, we may face enrollment challenges in our clinical trials, such as those faced in our LDKT trials.

In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidate and our current indications, we may forgo or delay pursuit of opportunities with other future product candidates and indications that later prove to have greater commercial potential. Our resource

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidate or indication, we may relinquish valuable rights to those future product candidates or indications through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates or indications.

Many of these risks are beyond our control, including the risks related to clinical development, our proprietary manufacturing process and the regulatory submission process. If we are unable to develop and receive regulatory approval for FCR001 for the indications we are developing it for, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

We may not successfully identify, develop or commercialize new indications for FCR001 or identify any additional product candidates and may be unable to expand our product pipeline through acquisition or in-licensing.

In the event that FCR001 does not receive regulatory approval or is not successfully commercialized in our currently planned indications, then the success of our business will depend on our ability to expand FCR001 into additional indications or our product pipeline to include other product candidates through our own internal research and discovery efforts, in-licensing or other acquisitions. We may be unable to identify relevant product candidates or indications. If we do identify such product candidates or indications, we may be unable to develop these programs for a number of reasons, including insufficient capital or other resources.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the inability to successfully and timely conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical

trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate to assure safety, purity and potency.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and clinical trials.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the study designs and substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or conduct of our clinical trials;
- failure to demonstrate to the satisfaction of regulatory agencies that FCR001, our lead product candidate, is safe and effective, or has a positive benefit/risk profile for its proposed indications;
- failure of clinical trials to meet the level of statistical significance required for approval;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a Biologics License Application ("BLA") or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes, our own manufacturing facility, or facilities of third-party manufacturers with whom we may in the future contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

If we experience delays or difficulties in the enrollment of patients in clinical trials, development of our product candidate may be delayed or prevented, which would have a material adverse effect on our business.

In February 2023, we announced the termination of our FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001 in LDKT. This decision wasprimarily attributable to the pace of enrollment and the associated timeline to critical milestones. While we continue to believe FCR001 should be assessed in our FREEDOM-3 clinical trial in severe scleroderma, we may not be able to initiate or continue clinical trials for our product candidate if we or a potential future sponsor are unable to locate and enroll a sufficient number of eligible patients to participate in these continuing trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. In particular, because

certain of our clinical trials are focused on indications with relatively small patient populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates.

Furthermore, because we are investigating the treatment of complex indications that require specialized medical care by means of an HSCT procedure, which is itself a complex procedure performed by specialized physicians and treatment centers, we face inherent challenges in recruiting clinical trial sites to participate in our trials and to complete our trials on a timely basis. For example, in LDKT, each site that participated in our trials needed to identify a lead clinician from each of the solid organ transplant and HSCT departments, who are willing and able to coordinate closely on the care and follow-up of our patients. We have historically relied on our relationships with transplant centers of excellence to assist in identifying eligible patients and carrying out our clinical trials, and any inability to secure or deterioration of those relationships could impede our ability to successfully enroll patients in a timely manner, if at all.

Patient enrollment may also be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- patient eligibility criteria for the trial in question;
- nature of the trial protocol;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- perceived risks and benefits of the product candidate under study;
- the occurrence of adverse events attributable to our lead product candidate;
- efforts to facilitate timely enrollment in clinical trials;
- the number and nature of competing products or product candidates and ongoing clinical trials of competing product candidates for the same indication;
- patient referral practices of physicians;
- risk that enrolled subjects will drop out or die before completion;
- competition for patients from other clinical trials;
- the ability to monitor patients adequately during and after treatment;
- travel restrictions and other potential limitations by federal, state, or local governments affecting the workforce or affecting clinical research site policies implemented in response to the COVID-19 pandemic;

- delays in or temporary suspension of the enrollment of patients in our ongoing and planned clinical trials due to the ongoing and evolving COVID-19 pandemic;
- proximity and availability of clinical trial sites for prospective patients; and
- continued enrollment of prospective patients by clinical trial sites.

Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete. Any delays in completing our clinical trials will increase our costs, delay or prevent our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any delays in completing our clinical studies for our product candidates may also decrease the period of commercial exclusivity. Any of these occurrences may significantly harm our business, financial condition and prospects.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunities will be significantly impacted if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are less expensive or obtain more significant acceptance in the market than any product candidates that we develop. Additionally, our commercial opportunities will be significantly impacted if novel upstream products or changes in treatment protocols reduce the overall incidence or prevalence of diseases in our current or future target population. Competition could result in reduced sales and pricing pressure on our product candidates, if approved by applicable regulatory authorities. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates.

While there are currently no FDA- or European Medicines Agency ("EMA") approved cell-based therapies for the indications we are currently targeting, other approved or commonly used drugs and therapies for our current or future target diseases, such as nintedanib to slow the rate of decline in lung function in patients with scleroderma-associated interstitial lung disease, are more well established and are accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and other drugs are available on a generic basis. Insurers and other third-party payors may encourage the use of generic products or specific branded products. In addition, a number of companies, academic institutions and government agencies are seeking to address limitations of existing therapies that we are also seeking to address. For example, a number of third parties, such as Jasper Therapeutics, Inc., bluebird bio, Inc. and Magenta Therapeutics, Inc., are seeking to develop conditioning regimens for HSCT that have lower toxicities, morbidities and mortalities than the current standard of care. Similarly, Johns Hopkins University and the Fred Hutchinson Cancer Center have previously administered non-myeloablative conditioning treatments. A number of other companies are also seeking to decrease the incidence and severity of graft versus host disease (“GvHD”) in HSCT. If any of these endeavors prove to be successful, the anticipated advantages of our Facilitated Allo-HSCT Therapy in comparison to the then existing standard of care could be eliminated and the demand for our Facilitated Allo-HSCT Therapy could be materially impacted.

We expect that, if our one-time investigational therapy is approved, it will be priced in a manner that will reflect its long-term clinical, economic, and humanistic value. Such a pricing model may entail a single upfront cost or multiple installments contingent upon demonstration of continued benefit that will likely be more expensive than the upfront cost or initial annual costs of competitive generic products that must be taken chronically. Absent differentiated and compelling clinical evidence, pricing premiums may impede the adoption of our products over currently approved or commonly used therapies, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our products continue in clinical development. Many of our competitors or potential competitors have significantly greater market presence, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements or mergers with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, commercial and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to, which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop products that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or noncompetitive before we can recover the expenses of development and commercialization.

Delays in the clinical development or delays in or our ability to achieve regulatory approval, if at all, and commercialization of our product candidates, if approved, would have a material adverse effect on our business.

We may experience delays in our ongoing or future clinical trials and we do not know whether clinical trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all, such as on account of the ongoing COVID-19 pandemic and its impact at clinical trials sites or on the third-party service providers on whom we rely. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on the design and implementation of clinical trials;
- delay or failure in obtaining authorization to commence a trial, including the delay or ability to generate sufficient preclinical data to support initiation of clinical trials, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a trial;
- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the inability of CROs to perform under these agreements, including due to impacts from the COVID-19 pandemic on their workforce;
- delay or failure in obtaining institutional review board (“IRB”) approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in subjects completing a trial or returning for post-treatment follow-up;
- inability to identify and maintain a sufficient number of trial sites, including because potential trial sites may not have the capabilities required for the indication that we are treating;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- failure of our third-party clinical trial managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- delay or failure in adding new trial sites, including due to changes in policies of the clinical research sites or local IRBs;
- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;

- feedback from the FDA, the IRB, data safety monitoring boards ("DSMBs") or comparable foreign authorities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a trial;
- unacceptable benefit/risk profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a product candidate;
- lack of adequate funding to continue a trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials or increased expenses associated with the services of our CROs and other third parties; or
- changes in governmental regulations or administrative actions, failure by us or third parties to comply with regulatory requirements, or lack of adequate funding to continue a clinical trial.

Furthermore, clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, including as a result of clinical sites, investigators or other third parties deviating from the trial protocol, failing to conduct the trial in accordance with regulatory and contractual requirements, and/or dropping out of a trial.

In addition, disruptions caused by the COVID-19 pandemic, including any current or future emerging variants of the virus, may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a DSMB for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects including a suspected unexpected serious adverse reaction ("SUSAR"), such as the recent death of a patient in our FREEDOM-1 trial, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Risks Related to the Results of our Preclinical Studies and/or Clinical Trials

The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our existing product candidates in clinical trials, and any other product candidate we advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical studies and earlier clinical trials does not ensure that later clinical trials will generate findings consistent with our earlier clinical trials, including adequate data to demonstrate the efficacy and safety of FCR001 or any of other product candidates we may develop. Likewise, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials. Despite the results reported in earlier preclinical studies or clinical trials for our product candidates, to date, results may not be replicated in subsequent trials, and we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval of FCR001 or any future product candidates we develop. Inaccuracies in our earlier clinical data and deviations from our clinical trial protocols can impact the integrity of those data, including safety data, and could impact the ability of those data to support regulatory approval. Additionally, certain of our clinical trial endpoints also may not be adequately powered in a particular subpopulation of our trial population. For example, our Phase 2 trial was a "single arm" trial for which there was no comparator arm to permit a comparison of our investigational therapy against standard of care treatment. Furthermore, all of our ongoing and planned clinical trials to date have been or will be open-label trials. This means that both the patient and investigator know whether the patient is receiving our FCR001 therapy or standard of care therapy. Open-label clinical trials can be subject to various limitations that may exaggerate any therapeutic effect, as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias." Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new

treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Given that each of our planned and ongoing clinical trials include an open-label dosing design, while we believe our trials utilize objective assessment measures for measuring our primary endpoints and therefore are unlikely to be influenced in any manner by patient or investigator bias, our trials may utilize secondary endpoint patient reported outcome measures and, it is unknown whether the open-label design may not be predictive of future clinical trial results with this or other product candidates for which we conduct an open-label clinical trial when studied in a controlled environment or with only objective endpoints. In addition, clinical data obtained from a clinical trial with an allogeneic product candidate such as FCR001 may not yield the same or better results on certain relevant outcome measures as compared to an autologous product candidate. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, which risk may be heightened in open-label trials where outcomes are subject to patient and investigator bias, and many companies that believed their product candidates performed satisfactorily in such trials nonetheless failed to obtain FDA, EMA or other necessary regulatory agency approval.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, no therapies for inducing immune tolerance to a transplanted organ or restoring tolerance to self in an autoimmune disease have been approved to date, and the FDA or other regulatory authorities may not agree with our interpretation and may require that we conduct additional clinical trials to support the regulatory approval of our product candidates. If we fail to obtain results in our planned and future preclinical and clinical activities and studies sufficient to meet the requirements of the relevant regulatory agencies, the development timeline and regulatory approval and commercialization prospects for any potential product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Interim, "top line" or preliminary data from our clinical trials that we may announce or share with regulatory authorities from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we expect to announce clinical updates or share with regulatory authoritiesinterim "top line" or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In particular, additional data from existing or subsequent patients may not be comparable or positive with respect to efficacy, safety or target engagement. For example, in June 2022, we announced interim results from our FREEDOM-1 Phase 3 clinical trial, including limited efficacy and safety data for the first seven patients dosed. Subsequently, in October 2022, we reported that one of the first seven patients, who had experienced GvHD symptoms that were treatment responsive and resolved in June 2022, had been hospitalized with grade IV GvHD that was complicated by serious infections leading to respiratory and renal failure, and ultimately death.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. These data and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of interim, "top line" or preliminary data, and we may not have received or had the opportunity to fully and carefully evaluate all data.

As a result, the top-line or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Preliminary or "top line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced. As a result, interim, "top-line," and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary, "top-line," or interim data and final data could impact the regulatory approval of, and significantly harm the prospects for any product candidate that is impacted by the applicable data.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be

deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the clinical updates, or the interim, "top-line," or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Risks Related to Potential Side Effects and the Safety and Efficacy Profile of our Product Candidates

Our product candidates, or associated conditioning regimens or treatment protocols, may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Undesirable side effects caused or risks exacerbated by our product candidates or associated conditioning regimens or treatment protocols could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of safety or toxicity issues that we may experience in our clinical trials, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects, or side effects outweighing the benefits of our product candidates. Such side effects could include known side effects or safety risks that are exacerbated by the combination of HSCT and LDKT in our clinical trials. In such an event, our trials could be delayed, suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Additionally, during the course of our product development programs, FDA or comparable foreign regulatory authority review teams may change and new agency personnel may view the risk-benefit profile of any product candidates we may develop differently than prior agency review teams. Any negative views as to the risk-benefit profile of FCR001 or any product candidates we may develop in the future could lead FDA or comparable foreign regulatory authorities to require that we conduct additional clinical trials or could require more onerous clinical trial designs for any ongoing or future clinical trials. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, while we note the summary of safety findings we have gathered to date, certain populations of patients receiving our Facilitated Allo-HSCT Therapy may experience side effects in greater frequency or severity than others who may receive our product candidates and additional clinical research is planned to more fully understand the safety profile of our product candidates in our patient

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

populations and indications of focus. Furthermore, we or others may later identify undesirable side effects caused by our products, including during any long-term follow-up observation period, such as that involved in our previous trials of FCR001.

In particular, LDKT and HSCT involve certain known potential post-procedure complications that may manifest several weeks or months after a transplant and which may be more common in certain patient populations. For example, up to 20% of patients with inherited metabolic diseases treated with HSCT experience primary engraftment failure, resulting in severe complications, including death. GvHD also accounts for approximately 10% of deaths following allogeneic HSCT. In June 2022, we reported three cases of low-grade acute GvHD in our FREEDOM-1 clinical trial, all of which had responded to treatment and were resolved. One of the three aGvHD patients was subsequently diagnosed with moderate chronic GvHD and was also responding to treatment at the time of the June 2022 update. In October 2022, we reported that the patient who had been diagnosed with chronic GvHD had died. The patient had been hospitalized with grade IV GvHD that was complicated by serious infections leading to respiratory and renal failure, and ultimately death. This event triggered a pre-specified, temporary stopping requirement and review by the FREEDOM-1 DMC. After their review of this case, the DMC determined that trial enrollment and dosing could continue. We also reported the event and the DMC's recommendation to the FDA.

If these or other serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any of our product candidates, it may be difficult to determine whether these complications were or were not related to our investigational therapy, and we may need to limit, delay or abandon our further clinical development of those product candidates, even if such events, effects or characteristics were potentially the result of HSCT, LDKT or related procedures generally, and not directly or specifically caused or exacerbated by our product candidates. All serious adverse events or unexpected side effects are continually monitored per the clinical trial's approved protocol. If serious adverse events are determined to be directly or specifically caused or exacerbated by our product candidates, we would follow the trial protocol's requirements, which include certain pre-specified stopping requirements, and which call for our DSMB to review all available clinical data in making a recommendation regarding the trial's continuation. However, there may be a failure by trial sites to effectively execute our clinical trial protocols, including during any long-term follow-up period for our clinical trials during the conduct of future clinical trials or following any product approval we may receive. In addition, HSCT is associated with an increased risk of cancer. Among the likely causes of this increased risk is the total body irradiation and high-dose chemotherapy used in myeloablative conditioning regimens. We believe non-myeloablative conditioning regimens have

the potential to help obviate this increased risk, however, patients receiving Facilitated Allo-HSCT Therapy in clinical trials after non-myeloablative conditioning have developed cancer after transplant. For example, a patient, a lifelong smoker, in our Phase 2 clinical trial developed non-small cell carcinoma of the lung approximately four years after HSCT.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused or risks exacerbated by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or decide to remove the product form the marketplace;
- regulatory authorities may withdraw or change their approvals of that product;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or to sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and the outcome is uncertain. Despite preclinical and early clinical trial data, any product candidate can unexpectedly fail at any stage of further development. The historical failure rate for product candidates is high. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. In particular, we have conducted a Phase 2 trial of FCR001 in LDKT. We do not know whether FCR001 will perform in our subsequent clinical trials, including in dSSc, as it has performed in our initial LDKT Phase 2 trial. In addition, if our

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

clinical results are not successful, we may terminate clinical trials for a product candidate and abandon any further research or studies of the product candidate. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

Risks Related to Combination Therapies

We intend to develop FCR001, and potentially future product candidates, in other indications and in combination with other therapies, which exposes us to additional risks. Combination therapies and additional indications involve additional complexity and risk that could delay or cause our programs to stall or fail; development of such programs may be more costly, may take longer to achieve regulatory approval and may be associated with unanticipated adverse events.

We intend to develop FCR001, and may develop future product candidates, for use in combination with nonmyeloablative conditioning and related conditioning drugs. Clinical development and commercialization of combination therapies involve additional complexity and risk, including without limitation, those involving drug-drug interactions, dose selection, unanticipated adverse events, clinical design and approvals of regulatory bodies and therapeutic development networks of patient advocacy groups. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. If we are unable to manage the additional complexities and risks of the development and commercialization of combination therapies, the development of FCR001 or any other current or future product candidate could be delayed, halted or otherwise fail to receive or maintain approval and may be less successful commercially.

We may develop FCR001 or related product candidates for a number of different indications, including solid organ transplant, severe autoimmune diseases and other severe disorders for which allo-HSCT has previously been observed to provide potential clinical benefit. Depending on the indication, patients may manifest a variety of differing co-morbidities, may be more or less vulnerable to our conditioning regimen, and may be more or less susceptible to certain severe adverse events or complications in the near or longer term, including cancer, infection, blood disorders and other life-threatening conditions. If any of these conditions or complications were to affect a patient who is participating in one of our clinical trials, it may be difficult or impossible to determine whether these adverse events or complications are related to the original or underlying condition or to our Facilitated Allo-HSCT Therapy. Given that our trials enroll a relatively small number of patients, even a small number of severe adverse events or serious complications could result in the delay or halt of development of our product candidates in one or more of our targeted indications.

Risks Related to Regulatory Matters and Approvals

Our product candidates represent a novel therapeutic approach that could result in heightened regulatory scrutiny. The regulatory landscape that applies to our Facilitated Allo-HSCT Therapy is rigorous, complex, uncertain and subject to change.

Given that our single-dose cell therapy represents a novel combination of nonmyeloablative conditioning, our investigational FCR001 product, and stem cell transplant-oriented treatment protocols, developing and commercializing our product candidates subjects us to a number of challenges, including obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of stem cell therapies.

Regulatory requirements governing the development of cell therapy products have changed frequently and may continue to change in the future. In 2016, the FDA established the Office of Tissues and Advanced Therapies ("OTAT") within the Center for Biologics Evaluation and Research ("CBER"), to consolidate the review of cell therapy, and related products, and to advise the CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products ("OTP") and elevation of OTP to a "Super Office" to meet its growing cell and gene therapy workload. Moreover, serious adverse events or developments in clinical trials of cell therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual cell therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. Adverse developments in preclinical studies or clinical trials conducted by others in the field of cell therapy may cause the FDA, the EMA, and other regulatory bodies to amend the requirements for approval of any product candidates we may develop or limit the use of products utilizing cell therapies, either of which could harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Further, as we are developing novel potential treatments for conditions in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or other regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. Regulatory agencies administering existing or future regulations or legislation may not allow

production and marketing of products utilizing cell therapies in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for biologics or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

In response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities while local, national and international conditions warrant. Since March 2020, when foreign and domestic inspections have largely been on hold, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

We may not be able to maintain orphan drug designation for FCR001 or obtain orphan drug designation for our future product candidates, or to obtain and maintain the benefits associated with orphan drug designation.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs or therapies for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. In the European Union, the prevalence of the condition must not be more than five in 10,000. The FDA has granted FCR001 orphan drug designation for the prophylaxis of organ rejection without the need for chronic immunosuppression in patients receiving LDKT. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

If a product that has orphan drug designation from the FDA subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same indication, for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was designated. Even if we or our collaborators obtain orphan designation to a product candidate, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. The scope of exclusivity is limited to the scope of any approved indication, even if the scope of the orphan designation is broader than the approved indication. Additionally, exclusive marketing rights may be limited if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if a product obtains orphan drug exclusivity, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a product with the same active moiety for the same condition if the FDA concludes that the later product is safer, more effective, or makes a major contribution to patient care. Furthermore, the FDA can waive orphan exclusivity if we or our collaborators are unable to manufacture sufficient supply of the product. The FDA may further reevaluate the Orphan Drug Act and its regulations and

policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Similarly, in Europe, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141/2000. This applies to products that are intended for a life-threatening or chronically debilitating condition and either (1) such condition affects no more than five in 10,000 persons in the E.U. when the application is made, or (2) the product, without the benefits derived from orphan status, would be unlikely to generate sufficient returns in the E.U. to justify the necessary investment. Moreover, in order to obtain orphan designation in the E.U. it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the E.U. or, if such a method exists, the product will be of significant benefit to those affected by the condition. In the E.U., orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and applicants can benefit from specific regulatory assistance and scientific advice. Products receiving orphan designation in the E.U. can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the E.U. for pediatric studies. However, the ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation-for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- the first applicant consents to a second orphan medicinal product application; or
- the first applicant cannot supply enough orphan medicinal product.

If we do not receive or maintain orphan drug designation to product candidates for which we seek such designation, it could limit our ability to realize revenues from such product candidates.

The incidence and prevalence of the target patient population for FCR001 are based on estimates and third-party sources. If the market opportunity for FCR001 or our other product candidates is smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations based on various third-party sources and internally generated analysis. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity for FCR001 in any given indication will depend on, among other things, acceptance of FCR001 by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with FCR001, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects.

We may never obtain FDA approval for any of our product candidates in the United States, and even if we do, we may never obtain approval for or commercialize any of our product candidates in any other jurisdiction, which would limit our ability to realize their full market potential.

In addition to regulations in the United States, to market and sell our product candidates in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. The approval procedure varies among countries and can involve additional testing and validation and additional administrative review periods. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the United States require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or

jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the European Union, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

Even if our product candidates receive regulatory approval, we will still face extensive ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense, and our products may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and product listing, as well as continued compliance by us and/or any future contract manufacturing organizations ("CMOs") and CROs for any post-approval clinical trials that we conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a REMS, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of cell therapies and their facilities are subject to initial and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices ("cGMP"), Good Clinical Practices ("GCP"), current good tissue practices ("cGTP"), and other regulations. For certain commercial prescription and biologic products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such products;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, withdraw or modify regulatory approval;
- suspend or modify any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or

- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

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

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice ("DOJ"), the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services ("HHS"), state attorneys general, members of the U.S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any current or future product candidate. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or to the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained. Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

Risks Related to Healthcare Legislation and Reform

Our relationships with customers, third-party payors, physicians and healthcare providers will be subject to applicable anti-kickback, fraud and abuse, and other laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Physicians, hospitals and third-party payors are often slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our products. Patients are unlikely to use our product candidates unless insurance coverage is provided, and reimbursement is adequate, to cover a significant portion of the cost of our product candidates because patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is (i) a covered benefit under the payor's health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational.

Because our product candidates have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. Based on these and other factors, hospitals, physicians and payors may decide that the benefits of this new therapy do not or will not outweigh its costs. Our current and future arrangements with third-party payors and customers may expose us to broadly applicable federal and varied state fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research as well as market, sell and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are, and will be, applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include, but are not limited to, the following:

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

- the federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, paying or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, arrangement, or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other;
- federal civil and criminal false claims laws, including the False Claims Act, and the civil monetary penalties law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery;
- the federal beneficiary inducement statute, includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular supplier of items or services reimbursable by a federal or state governmental program;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”) and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information as well as their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “ACA”), including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (“CMS”) information related to payments or other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. As of January 1, 2022, these reporting obligations now extend to include transfers of value by manufacturers that are made to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require pharmaceutical companies to comply with the industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; and state laws that require drug

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals.

Efforts to ensure that our current and future business arrangements with third parties, and our business generally, continue to comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with any such laws and regulations. If our operations, including our arrangements with physicians and other healthcare providers, are found to be in violation of any such laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, reputational harm, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, additional reporting requirements, and/or the curtailment or restructuring of our operations, as well as additional reporting obligations oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to similar penalties.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of

cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

For example, in March 2010, the Affordable Care Act ("ACA") was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are that the ACA: made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on average manufacturer price, or AMP, on most branded prescription drugs and adding a new rebate calculation for "line extensions" (*i.e.*, new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP; imposed a requirement on manufacturers of branded drugs to provide a 50% point-of-sale discount (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the coverage gap (*i.e.*, "donut hole") as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D;

- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded the entities eligible for discounts under the 340B Drug Discount Program;
- established a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, ir instilled, implanted, or injected;
- imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according t market share in certain government healthcare programs, and
- established the Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with f for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products. Th established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spe potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation through 2019.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect that there will be additional challenges and amendments to the ACA in the future. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling, on the constitutionality of the ACA. Prior to the Supreme Court's decision, January 28, 2021, President Biden issued an executive order to initiate that initiated a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how possible that the ACA and IRA may be subject to judicial or Congressional challenges in the future.

We anticipate that the ACA, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reform measures reforms may prevent us from being able to generate

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Further legislation or regulation could be passed that could harm our business, financial condition and results of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business. In addition, other operations. Other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- On August 2, 2011, enacted. For example, in August 2011, President Obama signed into law the U.S. Budget Control Act of 2011, which, among other things, in aggregate reductions of to Medicare payments to providers of 2% per fiscal year, which remain went into effect beginning on April 1, 2013 and, due to subsequent leg amendments, will stay in effect through 2031, with 2032 unless additional Congressional action is taken. In January 2013, the exception of a temporary suspensio May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the suspension, a 1% payment reduction began April 1, 2022 and continued throug 30, 2022, and the 2% payment reduction resumed on July 1, 2022. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting fr American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.
- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several ty providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpaym providers from three to five years.

- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
-

On Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.
- On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Additionally, there has been increasing legislative and enforcement interest in the United States U.S. with respect to drug pricing practices. Specifically, there has have been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs.

- programs, and reform government program reimbursement methodologies for drugs. At the federal level, in an executive order, the administration of President Biden an Executive Order on July 9, 2021 affirming the administration's expressed its intent to pursue certain policy initiatives to (i) support legislative reforms that would lov prices of prescription drugs and biologics, including by allowing Medicare to negotiate reduce drug prices by imposing inflation caps, and, by supporting the developr response, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and market entry sets out a variety of cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS po legislative policies that Congress could pursue to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic lower drug chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implem importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates.
- On November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation ("MFN") Model under which Medicare Part B reimbursement rates have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Develo countries with a similar gross domestic product per capita. However, on December 29, 2021, CMS rescinded the Most Favored Nations rule.
- Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sp under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor fo reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between

pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legi imposed a moratorium on implementation of the rule until January 1, 2026. This deadline was pushed back further to January 1, 2027 by the Bipartisan Safer Comm

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Act and could potentially be pushed back to January 1, 2032 by the Inflation Reduction Act.

- Further, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is p on prices. In response to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug. On May 17, 2022, th District Court for the District of Columbia granted the Pharmaceutical Research and Manufacturers of America's ("PhRMA") motion for summary judgment invalidat accumulator adjustment rule
- The Inflation Reduction Act of 2022, or IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of- spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer fi liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and bi without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until Jan 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan dru exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is f disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemptio effects of the IRA on our business and the healthcare industry in general is not yet known.
- In February 2023, HHS also issued a proposal in response to an Biden administration's October 2022 executive order, from President Biden that includes on Febru 2023, HHS released a proposed prescription drug pricing model that report outlining three new models for testing by the CMS, Innovation Center which will test be eva on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether targeted Medicare payment adjustments the mod sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these an proposed be utilized in any health reform measures may require authorization through additional legislation to become effective, and in the future. Further, on Decem 2023, the Biden administration may reverse or otherwise change these measures, both announced an initiative to control the Biden administration price of prescription through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Congress Technology published for com Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agen use when deciding to exercise march-in rights. While march-in rights have indicated not previously been exercised, it is uncertain if that they will continue to seek un new legislative measures to control drug costs.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products, if licensed;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

framework. Individual states in the United States U.S. have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological biopharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on

The U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), prohibits any individuals and entities from paying, providing, offering, or authorizing payment amounts by third-party payors or other restrictions could harm our business, financial condition, results provision of operations and prospects. In addition, regional healthcare authorities and individual hospitals money or anything of value, directly or indirectly, to any officer, employee, agent, or representative of any non-US government or public international organization, or any political party or candidate for the purpose of influencing any act or decision of the foreign governmental entity in order to obtain or retain business. The FCPA also obligates companies whose securities are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included listed in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Risks Related to Privacy and Data Security Laws

We are subject to stringent and changing privacy and data security laws, contractual obligations, self-regulatory schemes, government regulation, and standards related to data privacy and security. The actual or perceived failure by us, our collaborators, vendors or other relevant third parties U.S. to comply with such obligations could harm our reputation, subject us accounting provisions requiring the maintenance of books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to significant fines devise and liability, or otherwise adversely affect our business, operations and financial performance.

We collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect and share personal information and other information, including information we collect about patients and healthcare providers in connection with clinical trials.

There are numerous federal, state, local and maintain an adequate system of internal accounting controls for international laws, regulations and guidance regarding privacy, information security and processing, the number and scope of which is changing, subject to differing applications and interpretations, and which may be inconsistent among

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

jurisdictions, or in conflict with other rules, laws or data protection obligations. Data protection laws and data protection worldwide is, and is likely to remain, uncertain for the foreseeable future, and our failure or perceived failure to address or comply with these laws could: increase our compliance and operational costs; expose us to regulatory scrutiny, actions, fines and penalties; result in reputational harm; lead to a loss of customers; reduce the use of our products; result in litigation and liability; and otherwise result in other material harm to our business.

For example, in the United States, HIPAA, as amended by HITECH, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and, if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according operations.

Additional Regulation

In addition to the Federal Trade Commission ("FTC"), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Federal Trade Commission Occupational Safety and Health Act, ("FTCA"), 15 U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable the Resource Conservancy and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, Recovery Act and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations.

Additionally, U.S. States have begun introducing privacy legislation. For example, California recently enacted the California Consumer Privacy Toxic Substances Control Act, ("CCPA"), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA, which went into effect on January 1, 2020, requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches that may increase our risk to data breach class action litigation. The CCPA will be expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 ("CPRA") becomes fully operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal information, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law. The CCPA and the CPRA could substantially impact our business.

Additionally, some observers have noted that the CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business. Already, These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, the United States, we have witnessed significant developments at the state level. For example, in 2021, Virginia and Colorado enacted state legislation that becomes effective January 1, 2023. In 2022, Utah and Connecticut also enacted privacy legislation. With bills proposed in many other jurisdictions, it remains quite possible that other states will follow suit. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could wastes generated by, our operations. If our operations result in increased contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that it is in material compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country will make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

The increasing number and complexity of regional, country and U.S. state data protection with applicable environmental laws and other changes in laws or regulations across the globe, especially those associated with the enhanced protection of certain types of sensitive data could lead to government enforcement actions and significant penalties against us and could that continued compliance therewith will not have a material adverse effect on our business, financial condition or results of operations.

business. We may also be subject to additional privacy restrictions cannot predict, however, how changes in various foreign jurisdictions around the world in which we operate or process personal information. The collection, use, storage, disclosure, transfer, or other processing of personal information regarding individuals in the European Economic Area ("EEA"), including personal health data, is subject to the General Data Protection Regulation 2016/679 ("GDPR"). The GDPR is wide-ranging and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

In addition, further to the UK's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Complying with these laws if enacted, would require significant resources and leave us vulnerable to possible fines and penalties if we are unable to comply.

In addition, GDPR prohibits the transfer of personal data from the EU to the U.S. and other countries in respect of which the European Commission or other relevant regulatory body has not issued a so-called "adequacy decision" (known as "third countries"), unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards used for transfers of personal data to the U.S. was the EU-U.S. Privacy Shield framework administered by the U.S. Department of Commerce. However, certain recent EU court decisions cast doubt on the ability to use one of the primary alternatives to the EU-U.S. Privacy Shield, namely the European Commission's Standard Contractual Clauses, to lawfully transfer personal data to the U.S. and other third countries. In addition, the European Commission has recently published new versions of the Standard Contractual Clauses, which must be used for all new transfers of personal data from the EEA to third countries (including the United States) as of September 2021, and all existing transfers of personal data from the EU to third countries relying on the existing versions of the Standard Contractual Clauses must be replaced by December 2022. The implementation of the new Standard Contractual Clauses will necessitate significant contractual overhaul of our data transfer arrangements with customers, sub-processors and vendors. Use of both the existing and the new Standard Contractual Clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals, and additional supplementary technical, organizational and/or contractual measures and/or contractual provisions may need to be put in place.

At present, there are few if any viable alternatives to the Standard Contractual Clauses, and there remains some uncertainty with respect to the nature and efficacy of such supplementary measures in ensuring an adequate level of protection of personal data. As supervisory authorities issue further guidance on personal data export mechanisms (including circumstances where the Standard Contractual Clauses can and cannot be used) and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines. In addition, if we are unable to transfer personal data between and among countries and regions in which we operate and/or engage providers and/or otherwise transfer personal data, this could affect the manner in which we receive and/or provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results and generally increase compliance risk as a result. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of operating our business.

Furthermore, following Brexit, the relationship between the U.K. and the EEA in relation to certain aspects of data protection law remains somewhat uncertain. In June 2021, the European Commission issued an adequacy decision under the GDPR which allows transfers (other than those carried out for the purposes of U.K. immigration control) of personal data from the EEA to

the U.K. to continue without restriction for a period of four years. After that period, the adequacy decision may be renewed only if the U.K. continues to ensure an adequate level of data protection. During these four years, the European Commission will continue to monitor the legal situation in the U.K. and could intervene at any point if the U.K. deviates from the level of data protection in place at the time of issuance of the adequacy decision. If the adequacy decision is withdrawn or not renewed, transfers of personal data from the EEA to the U.K. will require a valid "transfer mechanism" and we may be required to implement new processes and put new agreements in place, such as Standard Contractual Clauses, to enable transfers of personal data from the EEA to the U.K. to continue, which could disrupt our future operations.

In addition, while the U.K. data protection regime currently permits data transfers from the U.K. to the EEA and other third countries covered by a European Commission adequacy decision, and currently includes a framework to permit the continued use of the existing version of the Standard Contractual Clauses for personal data transfers from the U.K. to third countries, this is subject to change in the future, and any such changes could have implications for our transfers of personal data from the U.K. to the EEA and other third countries. In particular, the U.K. Information Commissioner's Office has stated that it is working on its own bespoke version of the Standard Contractual Clauses and it is not clear whether the new Standard Contractual Clauses published by the European Commission will be accepted as a valid mechanism to permit the transfer of personal data from the U.K. to third countries and/or whether any U.K. version of the Standard Contractual Clauses will supersede the existing and/or new EU version of the Standard Contractual Clauses. This could necessitate the implementation of both U.K. and EU versions of Standard Contractual Clauses, which would require significant resources and result in significant cost to implement and manage.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the terms future.

Employees and Human Capital Resources

As of March 15, 2024, we had 44 full-time employees, including 8 who hold Ph.D. or M.D. degrees. Of these full-time employees, 31 employees are engaged in research and development and 13 employees are engaged in management or general and administrative activities. None of our external and internal privacy and security policies,

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

representations, certifications, standards, publications and frameworks, and contractual obligations employees are subject to third parties related a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to privacy, information security and processing.

With applicable data protection laws, privacy policies and data protection obligations imposing complex and burdensome obligations, and with substantial uncertainty over the interpretation and application of these requirements, we have faced and may face additional challenges in addressing and complying with them, and making necessary changes to our privacy policies and practices, and may incur material costs and expenses in an effort to do so, any of which could materially adversely affect our business operations and financial results, and may reduce the overall demand for our products.

be good.

Core Values

We strive to comply with applicable data protection laws, privacy policies and data protection obligations to the extent possible, but live by our core values every day: (1) we may at times fail to do so, or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our personnel, collaborators or vendors do not comply with applicable data protection laws, privacy policies and data protection obligations. Any failure or perceived failure by us or our collaborators, service providers and contractors to comply with federal or foreign laws or regulation, our internal policies and procedures, representations or our contracts governing the processing of personal data could result in negative publicity, disruptions or interruptions in our operations, fines, penalties, lawsuits, liability, inability to process personal data, diversion of time and effort, proceedings against us by governmental entities, or other adverse effects to our business.

Risks Related to Our Dependence on Third Parties

We are dependent on a limited number of suppliers and, in some cases sole suppliers, for some of our components and materials used in our product candidates.

Our manufacturing process, like that of a number of other cell therapy companies, is characterized by limited numbers of suppliers, and in some cases sole source suppliers, with the manufacturing capabilities and know-how to create or source the reagents, materials and equipment necessary for the production of our product candidates. For example, like many other cell therapy companies, our manufacturing process for FCR001 depends on certain cell manipulation equipment and related reagents, all of which are available from Miltenyi Biotec ("Miltenyi") as the sole supplier.

We cannot be sure that our suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that decides not to continue producing these materials for us. Additionally, during a public health emergency, there is a potential for certain manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, which may make it more difficult to obtain materials or reagents passion for our current and any future product candidates for our clinical trials or for commercial production, if approved, which could lead to delays in these trials or issues with our commercial supply. Our use of a sole or a limited number of suppliers of raw materials, components and finished goods exposes us to several risks, including disruptions in supply, price increases, late deliveries and an inability to meet customer demand. While we try to mitigate these risks by purchasing excess supplies, some of these components, such as reagents, typically expire after approximately four to six months. This short expiration period means that

stocking the reagents in large quantities for future needs would not be an effective strategy to mitigate against the risk of shortage due to disruption of the supply chain or termination of our business relationship. We also pursue multiple sources for the critical components of our manufacturing process, but there are, in general, relatively few alternative sources of supply for these components and we may not be successful in securing these additional sources at all or on a timely basis. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. For example, the FDA or EMA could require additional supplemental data, manufacturing data and comparability data up to and including clinical trial data if we rely upon a new supplier. Any disruption in supply from any supplier or manufacturing location, including as a result of or impact from the COVID-19 pandemic, could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects. If we are required to switch to a replacement supplier, the manufacture and delivery of our product candidates could be interrupted for an extended period, adversely affecting our business. Establishing additional or replacement suppliers may not be accomplished quickly. While we seek to maintain adequate inventory of the components and materials used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to conduct our clinical trials and, if our product candidates are approved, to meet the demand of our customers and cause them to cancel orders.

In addition, as part of the FDA's approval of our product candidates, the FDA must review and approve the individual components of our production process, which includes raw materials, the manufacturing processes and facilities of our suppliers and CMOs. Some of our current suppliers may not have undergone this process, and may not have had any components included in any product approved by the FDA.

Our reliance on external suppliers subjects us to a number of risks that could harm our reputation, business, and financial condition, including, among other things:

- the interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term commercial supply arrangements for key components with our suppliers;
- the inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- a delay in delivery due to our suppliers prioritizing other customer orders over ours; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

If any of these risks materialize, costs could significantly increase and our ability to conduct our clinical trials and, if our product candidates are approved, to meet demand for our products could be impacted. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production of our product candidates.

We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development

programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct all aspects of our clinical trials ourselves. As a result, we are, and expect to remain, dependent on third parties to conduct our ongoing clinical trials and any future clinical trials of our product candidates, including but not limited to governmental agencies and university laboratories, CMOs, CROs, distribution and supply (logistics) services organizations, contract testing organizations ("CTOs"), consultants or consultant organization with specialized knowledge-based expertise. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators, and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs, CTOs, and other third parties does not relieve us of our regulatory responsibilities. For example, we rely on a single third-party investigator to provide ongoing data from our Phase 2 clinical trial. We, our CROs and clinical sites are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our current product candidates and any future product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs, and in particular, our single third-party investigator for our Phase 2 company-sponsored trial, or clinical trial sites fail to adhere to our clinical trial protocols or to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of our product candidates.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. Further, the performance of our CROs has been, and may again in the future be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. In August 2022, a software vendor, which is responsible for providing logistics support for apheresed material from the donor to our manufacturing facility and back to the clinical site, shutdown operations. As there are few alternative vendors providing similar services, we may be required to utilize a manual, paper-based chain of custody process that could add risk to our manufacturing process.

If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our current product candidates and any future product candidates.

We may not realize the benefits of strategic alliances that we may form in the future or of potential future product acquisitions or licenses.

We may desire to form strategic alliances, create joint ventures or collaborations, enter into licensing arrangements with third parties or acquire products or businesses, in each case that mission; (2) we believe will complement or augment our existing business. These relationships or transactions, or those like them, may require us respect and inclusion are core to incur nonrecurring and other charges, increase our near- and

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

long-term expenditures, issue securities that dilute our existing stockholders, reduce the potential profitability of the products that are the subject of the relationship or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and transactions and the negotiation process is time-consuming and complex and there can be no assurance that we can enter into any of these transactions even if we desire to do so. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate a positive risk profile. Any delays in entering into new strategic alliances agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

If we license products or acquire businesses, we may not be able to realize the benefit of these transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following an acquisition or license, we will achieve the financial or strategic results that would justify the transaction.

Risks Related to Manufacturing

Risks Related to our Manufacturing Facility

We currently operate our own manufacturing facility which would require scale-up to appropriately address our anticipated commercial needs for FCR001, which will require significant resources. We may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.

We operate our own dedicated cGMP cell processing facility, located on the campus of the University of Louisville, where we manufacture our product candidates for our current and planned clinical trials. Although we are currently operating our manufacturing facility, our operations remain subject to review and oversight by the FDA, and the FDA could object to our use of our manufacturing facility or the processes used therein.

We had begun to scale-up our manufacturing and processing approaches to appropriately address our anticipated commercial needs for FCR001 for LDKT. While those scale-up efforts have been deferred, in order to scale-up our manufacturing capabilities and facility in the future to support our anticipated commercial needs, we will require substantial additional funds and will need to hire and retain significant additional personnel and comply with extensive cGMP regulations applicable to a commercial facility. If we fail to complete any construction in an efficient manner, recruit the required personnel and generally manage our growth effectively, the development and production of our product candidates could be curtailed or delayed. Our manufacturing facility would also need to be licensed for the production of our product candidates by the FDA. Even if our manufacturing facility is approved by the FDA, we would be subject to ongoing periodic unannounced inspection by the FDA, corresponding state agencies and potentially third-party collaborators to ensure strict compliance with cGMPs and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review.

We expect to use the same manufacturing process and starting material for future programs as those that we have used in our Phase 2 and Phase 3 trials of FCR001 for LDKT, except that our starting materials and process may be different for programs where we derive our component cells from a deceased donor. However, our use of this manufacturing process in our Phase 2 and Phase 3 trials may not be successfully replicated in subsequent trials, which could adversely affect our ability to scale-up our manufacturing processes or obtain or maintain the requisite licenses and approvals from the FDA to commercialize our product candidates.

We believe that our manufacturing processes can be scaled-up to address our commercial needs. However, there can be no assurance that we will not encounter difficulties in scaling out our manufacturing processes. Significant scale-up of manufacturing may result in unanticipated technical challenges and may require additional FDA approvals. We may encounter difficulties in scaling out production, including problems involving raw material suppliers, production yields, technical difficulties, scaled-up product characteristics, quality control and assurance, shortage of qualified personnel, capacity constraints, compliance with FDA and foreign regulations, environmental compliance, production costs and development of advanced manufacturing techniques and process controls. The actual cost to manufacture and process our product candidates could also be greater than we expect and could materially and adversely affect the commercial viability of our product candidates. Any of these difficulties, if they occur and are not overcome to the satisfaction of the FDA or other regulatory agency, could lead to significant delays and possibly the termination of the development program for such product candidate. These risks become more acute as we scale-up for commercial quantities, where a reliable source of product becomes critical to commercial success. The commercial viability of any of our product candidates, if approved, will depend on our ability to

produce our personalized cell therapy at a large scale. Failure to achieve this level of supply could jeopardize the successful commercialization of our therapy.

The manufacture of a cell therapy is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, shortages of raw materials, as well as compliance with strictly enforced federal, state and foreign regulations. For example, in late 2021, we were required to undertake an additional apheresis of a donor when quality testing revealed that the product prepared from that donor's stem cells was contaminated. While there can be no assurance at what point the donor blood product was contaminated, whether at the point of apheresis or during the manufacturing process, we nonetheless have reviewed and enhanced our quality control procedures and believe the risk of future contamination to be low. Furthermore, if contaminants are discovered in our cell therapy or in the

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot ensure that any stability or other issues relating to the manufacture of our product candidates will not occur in the future.

We may fail to manage the logistics of collecting and shipping donor cell material to the manufacturing site and shipping the product candidate to the patient. Logistical and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could cause breakage or contamination of our products and prevent or delay the delivery of product candidates to patients. Additionally, we have to maintain a complex chain of identity and chain of custody with respect to donor material as it moves to the manufacturing facility, through the manufacturing process, and to the recipient. Failure to maintain chain of identity and chain of custody could result in patient death, loss of product or regulatory action.

Though our supply chain has not been materially impacted by the COVID-19 pandemic to date, our manufacturing capabilities could be affected by cost-overruns, resource constraints, unexpected delays, equipment failures, labor shortages or disputes, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy, jeopardize our ability to provide our product candidates to patients, and have a material adverse effect on our business, financial condition, results of operations and prospects.

If our manufacturing facility is damaged or destroyed or production at our manufacturing facility is otherwise interrupted, our business would be negatively affected.

Damage to our manufacturing facility or disruption to our operations for any reason, including due to natural disaster (such as earthquake, wildfires and other fires or extreme weather), power loss, communications failure, cyberattack, unauthorized entry or other events, such as a flu or other health epidemic (such as the COVID-19 pandemic, including any current and future variants), could affect our manufacturing processes.

In particular, our manufacturing facility, located on the Health Science Center campus of the University of Louisville, supplies all of our clinical needs, and any damage or disruption to that facility could cause a loss of products or materials or otherwise adversely affect our ability to manufacture our current and any future product candidates in support of our clinical trials. It may require substantial lead time to repair, and we may not have control over such repairs. The property damage and business interruption insurance coverage on our facility that we maintain might not cover all losses under such circumstances, and we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs.

Any damage or disruption to the University of Louisville's operations, including the foregoing events, may also adversely affect our business. For example, disruption to any of the utilities provided to our facility by University of Louisville (HVAC, electrical, water, etc.) could inhibit or prevent us from being able to manufacture our product candidates. Moreover, if we are unable to obtain key inputs used in our manufacturing process, disinfectants or other materials required to maintain "clean room" sterility in our manufacturing facility, we may be unable to manufacture products entirely. Any failure of our building systems could also adversely affect our operations, including but not limited to equipment malfunctions, failure to follow specific protocols and procedures, and issues relating to air handling and other utilities. Any significant disruption to our manufacturing facility or processes would likely have an adverse impact on our business.

Any adverse developments affecting manufacturing operations for our current and any future product candidates may result in lot failures, inventory shortages, shipment delays, product losses or other interruptions in the supply of our product candidates for an undetermined period of time. We may also have to write off raw material and drug product inventory, incur other charges and expenses for key manufacturing inputs that fail to meet specifications, undertake costly remediation efforts, or seek more

costly manufacturing alternatives. Inability to meet the clinical demand for our product candidates could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics.

Our manufacturing process needs to comply with regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals. Further, as our preclinical and clinical programs and the manufacture of our product candidates are dependent on human donor material, we are or could be subject to additional regulations and requirements.

The FDA, EMA and comparable foreign regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP, cGTP and similar jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA and comparable foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards, including for the manufacture, packaging or testing of biological products.

We may encounter difficulties in achieving quality control and quality assurance or meeting regulatory expectations. Our facilities are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP, cGTP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, packaging, or storage of our product candidates as a result of our failure to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

In addition, our clinical programs and the manufacture of our product candidates are dependent on human donor material. Procurement of certain human organs for transplantation is subject to the National Organ Transplant Act of 1984 (“NOTA”), which prohibits the acquisition, receipt, or transfer of any human organ for valuable consideration for use in human transplantation. We depend on third parties who arrange for living donor kidney transplants ("LDKT") to comply with applicable NOTA requirements and we do not know whether any failure by such third parties to comply with NOTA requirements could impact the integrity or usability of data in our clinical trials.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

team; (3) we overcome obstacles to deliver results for patients; and (4) we push the envelope.

Conduct and Ethics

At Tourmaline, we are committed to fostering a culture of integrity and ensuring each of our employees is equipped with resources to help them do the right thing. We believe it is imperative that the board of directors and senior management strongly support a no-tolerance stance for workplace harassment, biases and unethical behavior. All employees are subject required to numerous environmental, review and agree to abide by our company’s Code of Conduct, whistleblower policy, anti-corruption policy, insider trading policy, and other corporate policies upon hire and on an annual basis thereafter.

Retention, Training and Development

The development, attraction and retention of our employees is a critical success factor for Tourmaline. We cultivate a culture of learning and offer formal and informal training and development opportunities for employees at all levels. We actively promote from within and continue to fill our team with strong and experienced talent.

Diversity and Inclusion

At Tourmaline, diversity means making a conscious effort to reflect the many experiences and identities of the world outside, while treating each other with fairness and without bias. Inclusion is the choice we make every day to foster an environment where people of all backgrounds not only belong but excel, so that together, as a company, we can succeed. Tourmaline strives to foster an inclusive community, both inside and out of the office.

Compensation and Benefits

An important part of attracting and retaining key talent is competitive pay and benefits. To ensure our compensation programs are competitive, we engage a nationally recognized outside compensation consulting firm to independently evaluate the effectiveness of our programs and to provide benchmarking against our peers within the industry. Our pay for performance philosophy seeks to motivate and reward employees while accomplishing our short and long-term strategic goals. As part of our performance management process, employees are evaluated both on what they accomplished and on their experience managing and mentoring other employees. Annual salary increases and incentive bonuses are based on market data and merit, and include individual and corporate performance factors.

To encourage our employees to think like owners and share in our company’s success, all employees are granted stock options. Employees are eligible for health insurance, a retirement plan, and safety life and accidental death and dismemberment coverage.

Corporate Information

Our common stock is listed on The Nasdaq Global Select Market under the symbol “TRML”.

We were incorporated under the laws of the State of Delaware in February 2002. Legacy Tourmaline was incorporated under the laws of the State of Delaware in September 2021. Following the Merger with Tourmaline Sub, Inc. (formerly Tourmaline Bio, Inc.) on October 19, 2023, we changed our name from Talaris Therapeutics, Inc. to Tourmaline Bio, Inc. Our principal executive offices are located at 27 West 24th Street, Suite 702, New York, New York 10010 and regulations, including those governing laboratory procedures our telephone number is (646) 481-9832.

Available Information

Our website address is www.tourmalinebio.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports which we have filed or may in the handling, use, storage, treatment future file pursuant to

Sections 13(a) and disposal 15(d) of hazardous materials and wastes. Our operations involve the use Exchange Act are made available free of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract charge on or through our website as soon as reasonably practicable after such reports are filed with, third parties for or furnished to, the disposal of these materials and wastes. We cannot eliminate SEC. The information contained on, or that can be accessed through, our website is not incorporated by reference into this Report or in any other report or document we file with the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, SEC, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries references to our employees resulting from website are intended to be inactive textual references only.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the use risks and uncertainties described below, together with all of hazardous materials with a policy limit the other information contained in this Annual Report on Form 10-K, including our audited consolidated financial statements and related notes hereto, before deciding to invest in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, this insurance are not material, may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims also become important factors that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could adversely affect our business, financial condition, results of operations and prospects.

The process for treatment using cell therapies is subject to human and systemic risks.

The "vein-to-vein" cycle for treating patients using our Facilitated Allo-HSCT Therapy and other cell-based targeted therapies typically takes approximately four to twelve weeks and involves a large number of steps, as well as human participants. In the United States, samples of the final product are subjected to several release tests which must fulfill specified criteria for the drug product to be released for infusion. These include sterility, identity, purity, potency and other tests. We are subject to stringent regulatory and quality standards in the course of our cell therapy treatment process. us. We cannot assure you that our quality control and assurance efforts will be successful or that the risk of human or systemic errors in these processes can be eliminated. Our cell therapies are uniquely manufactured for each recipient, so they must be administered only to the recipient matched to the donor from which the cellular source material was collected. While we implement specific identifiers, lot numbers and labels with cross checks for our products and operations from collection of cellular source material, through manufacture of drug product, transport of product to the clinical site up to thawing and administration any of the product, it is possible that a product may be administered into the wrong patient. If our cell therapies were to be administered into the wrong recipient, the recipient could suffer harm, including experiencing a severe adverse immune reaction and this event, should it happen, could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Manufacturing of our Product Candidates

Our product candidates are uniquely manufactured for each patient and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities.

The manufacturing process used to produce our product candidates is novel and has not been validated for commercial production. Our product candidates comprise a composition of hematopoietic stem cells ("HSCs"), facilitating cells ("FCs") and Alpha Beta T-cell Receptor Cells ("αßTCR+ T cells"), the dose of each of which is tailored to the recipient using our proprietary manufacturing process. Due to the personalized nature of the product candidate, we expect the cost to manufacture our product candidates to be high.

Although we have qualified and obtained positive initial FDA feedback on our potency assays for each of our active cell components in FCR001, we must validate the potency assays prior to submission of a marketing application for FCR001. Potency assays have traditionally proven difficult to develop for cell-based products and must be validated prior to approval. There can be no assurance that we will be able to validate our potency assays to FDA's satisfaction, or that FDA events discussed below will not want us to develop different or alternative potency assays for FCR001 or other product candidates. Any such development could delay or prevent approval of FCR001 or our other product candidates.

There is a risk of manufacturing issues associated with the differences in donor starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, and variability in product characteristics. Even minor deviations from our normal manufacturing processes could result in reduced production yields, lot failures, product defects, product delays, product recalls, product liability claims and other supply disruptions. If for any reason we lose a donor's starting material or one of our custom-manufactured products at any point in the process, the manufacturing process for that recipient will need to be restarted and the resulting delay may adversely affect that recipient's outcome. Because our product candidate is manufactured for each particular patient, we will be required to maintain a chain of identity with respect to materials as they move from the donor to the manufacturing facility, through the manufacturing process and on to the patient. Further, as our product candidate is developed through preclinical to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered in an effort to optimize processes and results. If we make these types of changes, we may not achieve our intended objectives and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials.

Although we continually attempt to optimize our manufacturing process, doing so is a difficult and uncertain task and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials. If we are unable to adequately validate or scale-up our manufacturing processes, we may encounter lengthy delays in commercializing our product candidates. We may continue to manufacture our product ourselves or we may ultimately decide to outsource our manufacturing to a third party CMO. We may not be successful in transferring our production system to such manufacturer, or the manufacturer(s) on whom we rely may not have the necessary capabilities to complete the implementation and development process. If we are able to adequately validate and scale-up the manufacturing processes for our product candidates with a contract manufacturer, we will still need to negotiate an agreement for commercial supply with that contract manufacturer and it is not certain we will be able to come to agreement on terms acceptable to us. As a result, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are approved and commercialized.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority approval processes and, if we choose to outsource our commercial production, we will need to contract with manufacturers who we believe can meet applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we are unable to reliably produce our cell therapy candidate to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize our products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or any CMOs we may contract with in the future will be able to manufacture the approved product to specifications and under cGMPs acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements. Our inability to do so could have a material adverse effect on our business, financial condition, prospects and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures.

In addition, the FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any personalized product lot, together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a specific product lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing process could restrict our ability to meet market demand for our products.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

Our product candidate requires specific shipping, storage, handling and administration at the clinical sites, including cold-chain logistics, which could subject our product candidates to risk of loss or damage.

Our product candidates are sensitive to temperature, storage and handling conditions. They must be stored at very low temperatures in specialized freezers or specialized shipping containers until immediately prior to use. For administration, the cryopreserved product container must be carefully removed from storage, and rapidly thawed under controlled temperature conditions in an area proximal to the patient's bedside and administered into the patient. The handling, thawing and administration of the cryopreserved therapy product must be performed according to specific instructions, typically using specific disposables, specific bags and in some steps within specific time periods. Failure to correctly handle our product, including the potential breakage of the cryopreservation bags or to follow the instructions for thawing and administration and or failure to administer our product within the specified period post-thaw could negatively impact the efficacy and or safety of our product, or cause a loss of product.

In addition, our product candidates must be cryopreserved/frozen using specialized equipment and following specific procedures in order to be stored without damage in a cost-efficient manner and without degradation. We may encounter difficulties in further optimization of freezing and thawing methodologies, and also in obtaining the necessary regulatory approvals for using such methodologies in treatment. If we cannot adequately demonstrate similarity of our frozen product to the unfrozen or thawed form to the satisfaction of the FDA, we could face substantial delays in our regulatory approvals. If we are unable to freeze FCR001 or other cell-based therapies we may develop for storage and shipping purposes, our ability to promote adoption and standardization of our products, as well as achieve economies of scale by centralizing production facilities, will be limited.

Even if we are able to successfully freeze and thaw FCR001 without damage in a cost-efficient manner and without degradation to the satisfaction of the FDA to support regulatory approval, we will still need to scale-up a cost-effective and reliable cold-chain distribution and logistics network, which we may be unable to accomplish. Failure to effectively scale-up our cold-chain supply logistics, by us or third parties, could in the future lead to additional manufacturing costs and delays in our ability to

supply required quantities for commercial supply. For these and other reasons, we may not be able to manufacture FCR001 or other cell-based therapies we may develop at commercial scale or in a cost-effective manner.

The process of manufacturing cell therapies is inherently susceptible to contamination. If microbial, viral or other contaminations are discovered in any product candidate or in our manufacturing facility, our manufacturing facility may need to be closed for an extended period of time to allow us to investigate and remedy the contamination. Because our cell therapy product candidates are manufactured from the cells of third-party donors, the process of manufacturing is susceptible to the availability of the third-party donor material. The process of developing products that can be commercialized may be particularly challenging, even if they otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

or unusable product. These types of contaminations could result in manufacturing delays which could result in delays in the development of our product candidates. These contaminations could also increase the risk of adverse side effects.

Risks Related to Our Intellectual Property

Risks Related to our Intellectual Property Licensed from ULRF

We depend substantially on intellectual property licensed from the ULRF, and termination of this license could result in the loss of significant rights, which would materially harm our business.

We depend substantially on the ULRF License for our intellectual property, data and know-how. The ULRF License imposes, and we expect that future license agreements will impose, various development, diligence, commercialization and other obligations on us. This license may be terminated upon certain conditions. Any termination of this license could result in the loss of significant rights and could harm our ability to commercialize our product candidate. In the future, we may also enter into additional license agreements that are material to the development of our product candidates.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those related to:

- *the scope of rights granted under the license agreement and other interpretation-related issues;*
- *whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;*
- *our right to sublicense patent and other rights to third parties under collaborative development relationships;*
- *our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and*
- *the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators.*

If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. In addition, the resolution of any such disputes 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.

We may rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in

---

which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect such licensed intellectual property, our ability to commercialize products could suffer.

Risks Related to our Intellectual Property Protection

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and manufacturing process, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.

We rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements that we own or possess or that are owned or possessed by our collaborators that are in-licensed to us under licenses, including the ULRF License, to protect the intellectual property related to our technology and product candidates. When we refer to "our" technologies, inventions, patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we in-license, many of which are critical to our intellectual property protection and our business. For example, our product candidates and Facilitating Allo-HSCT Therapy are protected by patents or patent applications of ULRF that we have licensed and as confidential know-how and trade secrets. Additionally, our earlier stage product candidates are not yet protected by any patents or patent applications. If the intellectual property that we rely on is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have.

The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is highly uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U.S. Patent and Trademark Office ("USPTO") and non-U.S. patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

There is no assurance that all potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. Further, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Thus, we may be unaware of prior art that could be used to invalidate an issued patent or prevent a pending patent application from issuing as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries.

Even if patents have issued or do successfully issue from patent applications, and even if these patents cover our product candidates, third parties may challenge the validity, ownership, enforceability or scope thereof, which may result in these patents being narrowed, invalidated, circumvented, or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable.

Even if unchallenged, our patents and patent applications or other intellectual property rights may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. The possibility exists that others will develop products on an independent basis which have the same or similar effects as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product candidates is threatened, it could jeopardize our ability to commercialize our product candidates and dissuade companies from collaborating with us.

We may also desire to seek a license from a third party who owns intellectual property that may be necessary or useful for providing exclusivity for our product candidates, or for providing the ability to develop and commercialize a product candidate in an unrestricted manner. There is no guarantee that we will be able to obtain a license from such a third party on commercially reasonable terms, or at all.

Obtaining and enforcing biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain patents licensed from third parties. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

We and our collaborators have filed a number of patent applications covering our product candidates or methods of using or making those product candidates. We cannot offer any assurances about which, if any, patents will be issued with respect to these pending patent applications, the breadth of any such patents that are ultimately issued or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our collaborators were the first to file any patent application related to a product candidate. We or our collaborators may also become involved in proceedings regarding our patents, including patent infringement lawsuits, interference or derivation proceedings, oppositions, reexaminations, and inter partes and post-grant review proceedings before the USPTO, the European Patent Office and other non-U.S. patent offices.

Even if granted, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent generally occurs 20 years after the earliest U.S. non-provisional application is filed. Although various extensions may be available if certain conditions are met, the life of a patent and the protection it affords is limited. If we encounter delays in our clinical trials or in obtaining regulatory approvals, the period of time during which we could exclusively market any of our product candidates under patent protection, if approved, could be reduced. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be vulnerable to competition from biosimilar products, as we may be unable to prevent competitors from entering the market with a product that is similar or identical to our product candidates.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the European Union, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights". March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. Some of our licensed patents are subject to the provisions of the Bayh-Dole Act.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive. Our intellectual property rights in certain countries outside the United States may be less extensive than those in the United States. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our future collaborators may not be able to prevent

third parties from practicing our inventions in countries outside the United States, or from selling or importing infringing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where we do not have exclusive rights under the relevant patents to develop their own products and, further, may export otherwise-infringing products to territories where we and our collaborators have patent protection but where enforcement is not as strong as that in the United States. These infringing products may compete with our product candidates in jurisdictions where we or our future collaborators have no issued patents or where we do not have exclusive rights under the relevant patents, or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our collaborators to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our future collaborators. We or our future collaborators may not prevail in any lawsuits that we or our collaborators initiate, and even if we or our collaborators are successful, the damages or other remedies awarded, if any, may not be commercially meaningful.

In some jurisdictions, including European Union countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our future collaborators are forced to grant a license to third parties under patents relevant to our business, or if we or our future collaborators are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our technology could be materially adversely affected and our business could be harmed.

In addition to seeking the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and other elements of our technology, discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our product candidates, thus eroding our competitive position in the market.

Trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, collaborators, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to our competitors. In addition, our competitors may otherwise gain access to our trade secrets or independently develop substantially

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

equivalent information and techniques. occur. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the United States. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could materially adversely affect following risks actually occurs, our business, prospects, operating results of operations and financial condition.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. condition could suffer materially. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over such event, the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Risks Related to Potential Third Party Claims

If we are sued for infringing the intellectual property rights of third parties, the resulting litigation could be costly and time-consuming and could prevent or delay our development and commercialization efforts.

Our commercial success depends, in part, on us and our future collaborators not infringing the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, reexaminations, and inter partes and post-grant review proceedings before the USPTO and non-U.S. patent offices. Numerous U.S. and non-U.S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights, as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. For example, we are aware of certain issued patents that may cover some of our product candidates, and while we believe these patent claims are not valid and would not establish a basis for our operations to be enjoined, we may be subject to litigation and be obligated to pay reasonable royalties to the patent owners. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

Third parties may assert infringement claims against us based on existing or future intellectual property rights, alleging that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacturing of our product candidates that we failed to identify. For example, patent applications covering our product candidates could have been filed by others without our knowledge, since these applications generally remain confidential for some period of time after their filing date. Even pending patent applications that have been published, including some of which we are aware, could be later amended in a manner that could cover our product candidates or their use or manufacture. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent

---

and the patent's prosecution history. In addition, we may have analyzed patents or patent applications of third parties that we believe are relevant to our activities and believe that we are free to operate in relation to any of our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which may block our efforts or potentially result in any of our product candidates or our activities infringing their claims.

If we or our future collaborators are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult and even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. If any issued third-party patents were held by a court of competent jurisdiction to be valid and enforceable and cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

the relevant patent expires. Alternatively, we may desire or be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us. Additionally, in the event of a successful intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product candidates, which may be impossible or technically infeasible, or require substantial time and monetary expenditure. In addition to paying monetary damages, we may lose valuable intellectual property rights or personnel and the parties making claims against us may obtain injunctive or other equitable relief, which could impose limitations on the conduct of our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who are or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. In particular, our founder and Senior Scientific Advisor, Suzanne T. Ildstad, MD, is the Jewish Hospital Distinguished Professor of Transplantation Research, Director of the Institute for Cellular Therapeutics, and a Professor in the Department of Surgery with associate appointments in the Departments of Physiology & Biophysics and Microbiology & Immunology at the University of Louisville School of Medicine. Our Chief Technology Officer, Michael Zdanowski, and certain other employees or consultants were previously employed at Medeor Therapeutics, Inc., which is developing a cell therapy similar to ours. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may face claims that we misappropriated, or otherwise acted unjustly or in bad faith with respect to, the confidential information or trade secrets of third parties, including collaborators or former collaborators. If we are found to have misappropriated a third party's trade secrets, or otherwise to have acted unjustly or in bad faith with respect to such trade secrets, we may be prevented from further using these trade secrets, which could limit our ability to develop our product candidates, or may be otherwise subject to monetary damages.

We may face claims that we misappropriated, or otherwise acted unjustly or in bad faith with respect to, the confidential information or trade secrets of third parties, including collaborators or former collaborators. Defending against intellectual property claims could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle before a final judgment, any litigation could burden us with substantial unanticipated costs. Parties making claims against us may be able to sustain the costs of litigation more effectively than we can because they have substantially greater resources. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation and these announcements may have negative impact on the perceived value of our product candidates, programs or intellectual property. Any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of

operations, financial condition and prospects. As a result of all of the foregoing, any actual or threatened intellectual property claim, including claims that we acted unjustly or in bad faith with respect to the intellectual property of others, could prevent us from developing or commercializing a product candidate, subject us to monetary damages, or force us to cease some aspect of our business operations.

We cannot ensure that additional patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

We have issued and pending U.S. and foreign patent applications in our portfolio, however, we cannot predict:

- *if and when additional patents may issue based on our patent applications;*
- *the scope of protection of any patent issuing based on our patent applications;*
- *whether the claims of any patent issuing based on our patent applications will provide protection against competitors;*
- *whether or not third parties will find ways to invalidate or circumvent our patent rights;*
- *whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;*
- *whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and*
- *whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.*

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may obtain. Even if the patents are issued based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. Our patent applications cannot be enforced against third parties practicing the technology claimed in these applications unless and until a patent issues from the applications, and then only to the extent the issued claims cover the technology. In the future, we or our collaborators may elect to initiate legal proceedings to enforce or defend our or our collaborators' intellectual property rights, to protect our or our collaborators' trade secrets or to determine the validity, ownership, enforceability or scope of our intellectual property rights. Any claims that we or our collaborators assert against perceived infringers could also provoke these parties to assert counterclaims against us or our collaborators alleging that we or our collaborators infringe their intellectual property rights or that our intellectual property rights are invalid or unenforceable.

Interference or derivation proceedings provoked by third parties, brought by us or our collaborators, or declared by the USPTO may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We or our collaborators may also become involved in other proceedings, such as reexamination or opposition proceedings, inter partes review, post-grant review or other pre-issuance or post-grant proceedings before the USPTO or in non-U.S. jurisdictions relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any of these proceedings could result in us losing our valuable intellectual property rights, require us or our collaborators to cease using the related technology and commercializing our product candidates, or require us to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our collaborators a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our collaborators. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Any intellectual property proceedings can be expensive and time-consuming. Our or our collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our collaborators can. Accordingly, despite our or our collaborators' efforts, we or our collaborators may not be able to prevent third parties from infringing upon or misappropriating our intellectual property rights, particularly in countries where the laws may not protect our rights as fully as in the United States. Even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. In addition, in an infringement proceeding, a court may decide that one or more of our patents is invalid or unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

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. 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 view these announcements in a negative light, the trading price of our common stock could be adversely affected.

Risks Related decline and you might lose all or part of your investment.

SUMMARY OF RISK FACTORS

An investment in our common stock involves various risks, and prospective investors are urged to Intellectual Property Laws and Regulations

Some intellectual property has been discovered through government-funded programs and thus may be subject to federal regulations such as certain reporting requirements, a preference for U.S.-based companies, and carefully consider the possibility of "march-in" rights. Compliance with such regulations or the inability to obtain a waiver for meeting such requirements may limit our ability to contract with non-U.S. manufacturers, or, matters discussed in the unlikely event of the government exercising their "march-in" rights, may limit section titled "Risk Factors" prior to making an investment in our exclusive rights.

Some of our intellectual property rights were generated through the use of U.S. government funding and common stock. These risks include, but are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in certain of our current or future product candidates pursuant not limited to, the Bayh-Dole Act of 1980 ("Bayh-Dole Act"). These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

under federal regulations (also referred to as “march-in rights”). To our knowledge, however, the U.S. government has, to date, not exercised any march-in rights on any patented technology that was generated using U.S. government funds. The U.S. government also has the right to take title to these inventions if we or the applicable grantee fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future following:

•

intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

Changes in U.S. or foreign patent laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the “America Invents Act”), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor’s patents or patent applications.

The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affects patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review and, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Risks Related to Our Financial Condition and Capital Needs

We are a late-stage clinical biotechnology company and we have incurred net losses every year since our inception. We anticipate that we will continue to incur significant net losses for the foreseeable future, inception and may never achieve or maintain profitability.

We are a late-stage clinical biotechnology company with a limited operating history. 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 to date, and we will continue to incur significant research and development and other expenses related to our clinical development and ongoing operations. As a result, we are not profitable and have incurred net losses in each period since our inception. Since our inception, we have devoted substantially all source of our resources to developing our product candidate, FCR001, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. Our financial condition and operating results, including net losses, may fluctuate significantly from quarter to quarter and year to year. Accordingly, you should not rely upon the results of any

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

quarterly or annual periods as indications of future operating performance. Additionally, net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net loss was $73.7 million and $47.8 million for the years ended

December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $164.5 million. revenue. We expect to continue to incur net significant operating losses for and may never become profitable.

- Our business is highly dependent on the foreseeable success of TOUR006 as well as any other potential future and we expect our research and development expenses, general and administrative expenses and capital expenditures to continue to increase.

We anticipate that our expenses will increase substantially if and as we:

- continue to conduct clinical trials for our product candidate, FCR001;
- seek to identify additional product candidates and initiate research, preclinical and clinical development efforts for any future product candidates;
- seek regulatory approvals for FCR001 or any future product candidates that successfully complete clinical development;
- scale our in-house manufacturing process to address anticipated commercial needs;
- seek to meet regulatory requirements for our in-house manufacturing process;
- add operational, financial and management information systems and personnel, including personnel to help us comply with our obligations as a public company;
- hire and retain additional personnel, such as clinical, quality control, scientific, manufacturing, commercial and administrative personnel, to support our product candidate development;
- maintain, expand and protect our intellectual property portfolio;
- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize any product candidates for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- add equipment and physical infrastructure to support our research and development; and
- acquire or in-license other product candidates and technologies.

Our expenses could increase beyond our expectations if product candidates. If we are required by the FDA unable to successfully complete clinical development of, obtain regulatory approval for, or commercialize, TOUR006 or any other regulatory authorities to perform clinical trials in addition to those that we currently expect, if there are any delays in establishing appropriate manufacturing arrangements for our potential future product candidates, or if we experience delays in the initiation or completion doing so, our business will be materially harmed.

- We will need significant additional capital to proceed with development and commercialization of our clinical trials or the development of TOUR006 and any of our potential future product candidates for any reason, including and our other operations. We may not be able to access sufficient capital on acceptable terms, if at all, and, as a result, we may be required to delay, scale back or discontinue development of the COVID-19 pandemic. such product candidates or other operations.

-

We have not yet completed any registrational trials a limited operating history and have no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

-

We were first formed in February 2002 under the name Regenerex LLC, and engaged in operations with non-dilutive funding, or in collaboration with Novartis International AG ("Novartis") from 2013 to 2016, until October 2018 when we closed our first external financing round, converted into a corporation and changed our name to Regenerex, Inc. and subsequently to Talaris Therapeutics, Inc. Since we commenced our operations, we have devoted substantially all of our resources to raising capital, organizing and staffing our company, business planning, conducting discovery and research activities, establishing and protecting our intellectual property portfolio, developing and progressing FCR001 and preparing for clinical trials, and manufacturing initial quantities of FCR001. As an organization, we have not yet demonstrated an ability to successfully complete any Phase 3 clinical trials, obtain regulatory approval, consistently manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for the successful commercialization

of any of our product candidates. In addition, our Facilitated Allo-HSCT Therapy is novel and has only been evaluated in a limited number of patients to date. Any predictions about our future success, performance or viability, particularly in view of the rapidly evolving immunotherapy field, may not be accurate given the limits of our operating history and lack of approved products.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

In addition, given the limits of our operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities and may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, our financial results for any quarterly or annual periods may not be indicative of future operating performance.

We will require substantial incur additional funding to develop costs and commercialize our product candidates and identify and invest in new product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product discovery and development programs or commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect to continue to spend substantial amounts of capital to continue the preclinical and clinical development of our current and future programs. If we are able to gain marketing approval for any product candidate we develop, including for any indication for which we are developing or may develop FCR001, we will require substantial additional funding in order to launch and commercialize such product candidates, to the extent that such launch and commercialization are not the responsibility of a collaborator that we may contract with in the future. We may also invest in preparations for launch and commercialization in advance of receiving regulatory approval for a product candidate, and such approval may not be received on a timely basis or at all. In addition, other unanticipated costs may arise in the course of our development efforts. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. Additionally, any COVID-19-related program setbacks or delays due to changes in federal, state, or local laws and regulations or clinical site policies could impact the timing and cost of the development of our product candidates. Under the terms of the ULRF License Agreement, we are also obligated to make payments increased demands upon the achievement of certain development, regulatory and commercial milestones.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing FCR001 for our current indication, as well as any other product candidates we may develop, including any COVID-19-related delays or other effects on our development programs;
- the timing of, and the costs involved in, obtaining marketing approvals for FCR001 for our current indication, and any other product candidates we may develop;
- if approved, the costs of commercialization activities for FCR001 for any approved indications, or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of a collaborator that we may contract with in the future, including the costs and timing of scaling our manufacturing and establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of FCR001 for any approved indications or any other product candidates;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our research and development, increase our office space, and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the ongoing costs of operating as a public company.

As of December 31, 2022, we had cash, cash equivalents and marketable securities of approximately $181.3 million. We cannot be certain that additional funding will be available on acceptable terms, or at all. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are

unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Any of our current or future license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements.

We believe that our cash, cash equivalents and marketable securities as of December 31, 2022 will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from the issuance date of this Annual Report on Form 10-K. Our estimate may prove to be wrong, and we could use our available capital resources earlier than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds earlier than planned.

Raising capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on terms that are unfavorable to us.

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, including incurring additional debt, making capital expenditures, entering into licensing arrangements or declaring dividends. If we raise additional funds from

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that are not favorable to us. Market volatility resulting from the COVID-19 pandemic or other factors may further adversely impact our ability to access capital as and when needed. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidates, grant to others the rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or take other actions that are adverse to our business.

Risks Related to Our Business, Growth and Industry

Risks Related to the COVID-19 Pandemic

Our business has been adversely affected by the ongoing COVID-19 pandemic, and could be further adversely affected by the effects this and other of public health epidemics in regions where we, or third parties on which we rely have significant research, development or production facilities, concentrations of clinical trial sites or other business operations.

Our business has been adversely affected by the ongoing COVID-19 pandemic, and could be further adversely affected by this and other public health epidemics in regions where we, and third parties on which we rely, such as CROs or suppliers, have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of those third-parties, and adversely affect our business. For example, enrollment in our Phase 3 FREEDOM-1 clinical trial, prior to being discontinued, consistently lagged both our original and revised enrollment projections, significantly limiting the data which we were able to report at periodic medical conferences. In November 2021, when we provided the first interim data in connection with the American Association of Nephrology meeting, we reported data on five dosed patients, only three of whom had met the three-month post-transplant milestone. We believe the COVID-19 pandemic significantly impacted the ability of our clinical trial sites to attract and enroll clinical trial subjects, which contributed to our decision to discontinue the clinical trial. Furthermore, the performance of our CROs may also be delayed or disrupted by the ongoing COVID-19 pandemic and current and future variants of the virus, including due to travel or quarantine policies, availabilities of staff, exposure of CRO staff to COVID-19 or re-prioritization of CRO resources management as a result of complying with the pandemic. laws and regulations applicable to public companies.

•

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could impact personnel at our manufacturing facilities, including our ability to manufacture FCR001, or the availability or cost of materials, which would disrupt our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and manufacturing activities.

In addition, our clinical trials have been and may be further affected by the ongoing COVID-19 pandemic, particularly as viral variants, such as the COVID-19 omicron variant and associated sub-variants, continue to proliferate in areas where we have clinical trials. Clinical site initiation and patient enrollment has been and may be further delayed due to prioritization of healthcare system resources toward the ongoing COVID-19 pandemic. For example, some of our patients We may not be able to comply obtain and maintain the relationships with clinical trial protocols third parties that are necessary to develop, commercialize, and follow-ups if quarantines impede patient movement, interrupt healthcare services,

reduce patient access to trial investigators, hospitals manufacture TOUR006 and trial sites, and limit on-site personnel support at various trial sites. Similarly, COVID-19 and current and evolving variants may adversely impact our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, thereby adversely impacting our clinical trial operations and enrollment timelines.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the any potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. product candidates.

•

The global ongoing COVID-19 pandemic continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these potential effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Risks Related to Employee and Growth Matters

We are highly dependent rely completely on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. While we expect to engage in an orderly transition process as we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

from business concerns, failure to retain other key personnel or loss of institutional knowledge. In addition, the loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product contract development and harm our business.

We conduct our main operations at our cell processing facility in Louisville, Kentucky, we maintain a corporate office in Wellesley, Massachusetts manufacturing organizations ("CDMOs") for the manufacture and a laboratory in Houston, Texas. Competition for skilled personnel, particularly in the rapidly growing cell testing of TOUR006 and gene therapy any potential future product candidates under current good manufacturing practices ("CGT" cGMP") market, is intense, particularly in Massachusetts, which serves as headquarters to many other biopharmaceutical companies and many academic and research institutions, and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Changes to U.S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U.S. citizens.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. It may be difficult or time-consuming to recruit all the qualified personnel that we need in order to scale-up our manufacturing operations in Louisville.

Our recent reduction in force may negatively impact employee morale and productivity. Further, uncertainties surrounding the future of our clinical programs may increase retention risk.

In connection with the evaluation of strategic alternatives that we announced in February 2023, and in order to extend our resources, we implemented a restructuring plan that included reducing our workforce by approximately one-third. In order to retain remaining employees primarily focused on maintaining the Company's cell therapy CMC capabilities and executing FREEDOM-3, we offered assurance of severance arrangements and retention benefits to certain remaining personnel. There

can be no assurance that these programs will allow us to retain the personnel necessary to implement our strategic assessment plans, or continue our FREEDOM-3 clinical program and CMC manufacturing capabilities.

In addition, we may take additional restructuring steps in the future as we seek to realize operating synergies, optimize our operations to achieve our target operating model and profitability objectives, respond to market forces or better reflect changes in the strategic direction of our business. Disruptions in operations may occur as a result of taking these actions. Taking these actions may also result in significant expense for us, including with respect to workforce reductions, as well as decreased productivity due to employee distraction and unanticipated employee turnover. Substantial expense or business disruptions resulting from restructuring and reorganization activities could adversely affect our operating results. In addition, if there are unforeseen expenses associated with such realignments in our business strategies, and we incur unanticipated charges or liabilities, then we may not be able to effectively realize the expected cost savings or other benefits of such actions which could have an adverse effect on our business, operating results and financial condition.

Our employees, principal investigators, consultants and collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee and third party fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, litigation and serious harm to our reputation. It is not always possible to identify and deter employee and third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, , and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, many manufacturing risks, any of which could substantially increase our costs and limit supply of any potential product candidates and any future products. Additionally, any difficulties in the transfer of drug substance or drug product to or from manufacturing facilities could materially adversely affect our ability to operate our business, financial condition, and results of operations.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Risks Related to Business Disruptions

If our security measures are compromised now, or Our manufacturing and testing of bulk drug substance for TOUR006 currently takes place in China through a global CDMO with facilities in China and around the world. Our manufacturing and testing of drug product for TOUR006 occurs in facilities in Austria and the U.S. Our drug product is packaged in Germany and the U.S. A significant disruption in the future, operation of these manufacturing facilities, a trade war, or the security, confidentiality political unrest could materially adversely affect our business, financial condition, and results of operations.

- We may seek to establish business development arrangements ("BD Arrangements"), and, if we are not able to establish them on commercially reasonable terms, or integrity or availability at all, we may have to alter our development and commercialization plans.

- TOUR006 and any other of our information technology, software, services, communications future product candidates must undergo rigorous clinical trials before seeking regulatory approvals, and clinical trials may be delayed, suspended, or data terminated at any time for many reasons, any of which could delay or prevent regulatory approval and, if approval is compromised, limited, granted, commercialization of our product candidates.

- If clinical trials of TOUR006 or fails, this could result any potential future product candidates fail to timely initiate, enroll, complete, or produce positive results, or if such clinical trials fail to demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration (the "FDA") or comparable health authorities or sufficiently to demonstrate differentiation from other approved therapies or therapies in a materially adverse impact, including without limitation, damage to our reputation, significant financial and legal exposure, breach or triggering of data protection laws, privacy policies and data protection obligations, disruption to our clinical trial or administrative activities, or loss of customers or collaborators.

  We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our business, development, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information, as well as intellectual property, trade secrets, and proprietary business information owned incur additional costs or controlled by ourselves experience delays in completing, or other parties.

  Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors, consultants and relevant third parties are vulnerable ultimately be unable to several threats, including without limitation damage from computer viruses, unauthorized access, terrorism, war, natural disasters, and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, phishing attacks, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. Although we have not, to our knowledge, experienced a material security

incident, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches.

We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our services, software, operations or information technology in an effort to protect against security breaches and to mitigate, detect, and remediate actual and potential vulnerabilities. Applicable data protection laws, privacy policies and other data protection obligations may require us to implement specific security measures or use industry-standard or reasonable measures to protect against security breaches.

If we, our service providers, collaborators, or other relevant third parties have experienced or in the future experience, any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent disclosure of sensitive information or compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, legal liability, government investigations an inability to conduct our clinical trials, regulatory investigations, enforcement actions, indemnity obligations, the disruption of our operations, delays to complete, the development and commercialization of our product candidates, negative publicity and financial loss. A failure by us candidates.

- If we experience delays or relevant third parties to detect, anticipate, measure or detect such security incidents could result difficulties in similar material adverse impacts.

  Additionally, applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders the enrollment of security breaches, including affected individuals, customer and regulators. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to material adverse impacts, including without limitation, negative publicity, a loss of customer confidence patients in our products or security measures or a breach of contract claim. There can be no assurances that the limitations of liability in our contract would be enforceable or adequate or would otherwise protect us from liabilities or damages.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions in our operations and adversely impact the confidentiality, integrity and availability of sensitive or confidential information. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future preclinical studies and clinical trials, could result in delays in our regulatory approval efforts and significantly increase our costs to recover development of TOUR006, or reproduce the data.

While we maintain general liability insurance coverage and coverage for errors or omissions, we cannot assure that such coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or other material adverse impacts arising out of our privacy and security actions we may experience, or that such coverage will continue to be available on acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or that results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any potential future claim.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our manufacturing operations, and those of our CROs, suppliers and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

Market conditions such as inflation, volatile energy costs, geopolitical issues, unstable global credit markets and financial conditions could lead to periods of significant economic instability, diminished liquidity and credit availability, diminished expectations for the global economy and expectations of slower global economic growth going forward. Our business and operations product candidates, may be adversely affected by such instability, including any such inflationary fluctuations, economic downturns,

volatile business environments and continued unstable delayed or unpredictable economic and market conditions. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive.

Failure to secure any necessary financing in a timely manner and on favorable terms could prevented, which would have a material adverse effect on our growth strategy, financial performance business.

- Even if we obtain approval to market TOUR006 or other potential future product candidates, these products may become subject to unfavorable pricing regulations, reimbursement practices from third-party payors or healthcare reform initiatives in the United States (“U.S.”) and stock price and abroad, which could require us harm our business.
- We expect to delay or abandon expand our clinical development, plans. In addition, there is a risk that one or more manufacturing, and regulatory capabilities and potentially implement sales, marketing, and distribution capabilities, including significant growth in the number of our current service providers, manufacturers employees, and other collaborators as a result, we may not survive these difficult economic times, encounter difficulties in managing our growth, which could directly affect disrupt our operations.
- Healthcare reform may negatively impact our ability to attain our operating goals on schedule profitably sell TOUR006 and on budget. any potential future product candidates, if approved.
-

Furthermore, our stock price Our international operations may decline due in part expose us to the volatility business, regulatory, political, operational, financial, pricing, and reimbursement risks associated with doing business outside of the stock market U.S.

- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit development and commercialization of any products that we may develop.
- Our relationships with healthcare providers, customers, and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.
- Our business could be materially and adversely affected in the general economic downturn.

Global economic uncertainty and weakening product demand caused by political instability, changes in trade agreements and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business and financial performance.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Economic uncertainty in various global markets caused by political instability and conflict and economic challenges caused future by the COVID-19 pandemic has resulted, and may continue to result, in weakened demand for our products and services and difficulty in forecasting our financial results and managing inventory levels. Political developments impacting government spending and international trade, including current or potential government-imposed sanctions, potential government shutdowns and trade disputes and tariffs, may negatively impact markets and cause weaker macro-economic conditions. The effects of these events may continue due to potential U.S. government shutdowns disease outbreaks, epidemics, and the transition in administrations, and the United States' ongoing trade disputes with China and other countries. The continuing effect of any or all of these events could adversely impact demand for our products, harm our operations and weaken our financial results. pandemics.

Risks Related to Laws and Regulations that May Affect our Business •

Legislation or other changes in U.S. 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 us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Our ability to use our U.S. net operating loss carryforwards and certain other U.S. tax attributes may be limited.

•

Our ability to use We have identified material weaknesses in our U.S. federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses.

Under current law, unused U.S. federal net operating losses generated for tax years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. Such U.S. federal net operating losses generally may not be carried back to prior taxable years, except that, net operating losses generated in 2018, 2019 and 2020 may be carried back to each of the five tax years preceding the tax years of such losses. Additionally, the amount of net operating loss carryforwards generated in taxable years beginning after December 31, 2017 that internal control over financial reporting. If we are permitted unable to deduct in a taxable year beginning after December 31, 2020, is limited to 80% of our taxable income in each such taxable year to which the net operating loss carryforwards are applied. In addition, both our current and our future unused U.S. federal net operating losses and tax credits may be subject to limitations under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), remediate these material weaknesses, or if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period. We may have experienced such ownership changes in the past, and we may experience ownership changes identify additional material weaknesses in the future as a result of shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law. As of December

31, 2022, otherwise fail to maintain effective internal control over financial reporting, we had U.S. federal net operating loss carryforwards of approximately $96.9 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us.

We are subject to U.S. anti-corruption laws and regulations and can face serious consequences for violations.

We are subject to anti-corruption laws, including the U.S. domestic bribery statute contained in 18 U.S.C. 201, the U.S. Travel Act, and the U.S. Foreign Corrupt Practices Act of 1977, as amended. These anti-corruption laws generally prohibit companies and their employees, agents, and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to recipients in the public or private sector. We can be held liable for the corrupt or illegal activities of our agents and intermediaries, even if we do not explicitly authorize or have actual knowledge of such activities. Violations of anti-corruption laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Likewise, any investigation of potential violations of anti-corruption laws could also have an adverse impact on our reputation, our business, results of operations and financial condition.

If product liability lawsuits are brought against, we may incur substantial liabilities and may be required to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to study subjects or patients;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop; and
- a decline in our share price.

We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost accurately or in an amount adequate to satisfy any liability that timely report our financial condition or results of operations, which may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidate in development, but we may be unable to obtain commercially

reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Risks Related to Ownership of Our Common Stock

Risks Related to our Common Stock

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Quarterly Report, these factors include:

- 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 cell therapy 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;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- changes in the structure of health care payment systems;
- general political and economic conditions, including impacts from the COVID-19 pandemic; and
- other events or factors, many of which are beyond our control.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

In addition, 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. 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 and a diversion of management's attention and resources, which would harm our business, financial condition, results of operation and future prospects.

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

Our executive officers, directors, and 5% stockholders beneficially owned approximately 68.7% of our outstanding voting common stock as of December 31, 2022. The voting power of this group financial reporting may increase to not meet the extent they convert shares of non-voting common stock they hold into common stock. Therefore, 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 you may feel are in your best interest as one of our stockholders.

Our business is affected standards required by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. For instance, rising interest rates have impacted the Company's net income. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on the Company's product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials for our product candidates.

Risks Related to our Filer Status

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years following the completion of our offering in May 2021, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock and non-voting common stock that are held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to not "opt out" of this exemption from complying with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies

adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, and reduced disclosure obligations regarding executive compensation failure to achieve and maintain effective internal control over financial reporting in our periodic reports and proxy statements.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions applicable to emerging growth companies and smaller reporting companies. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks Related to our Certificate of Incorporation and Bylaws

Anti-takeover provisions under our certificate of incorporation and bylaws 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 our 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 board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- 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 accordance with 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 and other stockholders to elect directors of your choosing or cause us to take other corporate actions you 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 bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein (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 federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act (the "Federal Forum Provision"). 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 provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, 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 were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States 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.

General Risk Factors

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.

Adverse developments involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB"), was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC"), as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. The Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money, including funds held in uninsured deposit accounts, after only one business day of closure. The U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee, however, that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

We do not hold cash deposits or securities at SVB and have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations. However, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets and termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, a critical vendor, CDMO, or business partner could be adversely affected by any of the liquidity or other risks that are described above as factors, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any CDMO, business partner, or supplier bankruptcy or insolvency, or any breach or default by a CDMO, business partner, or supplier, or the loss of any significant supplier relationships, could result in material adverse impacts on our current and/or projected business operations and financial condition.

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

Our results of operations could be adversely affected by economic and political changes in the location in which we, or our suppliers and vendors, maintain operations. For example, out business may be generally exposed to the impact of political or civil unrest or military action, including the current conflict between Russia and Ukraine and, while we do not have direct exposure to Ukraine, we do have interests in securing regulatory approval in Europe. The approval process may be impacted based upon the events taking place there. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

As a public company, we will 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 (the "Exchange Act"), which will require, among other things, that we file with the Securities and Exchange Commission (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 Global Market to implement provisions 404 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

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Reform and Consumer Protection Act (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. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our initial public offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. 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.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to 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 decrease share price.

- Failure or perceived failure to comply with laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our net income business.Compliance or

the actual or perceived failure to comply with such obligations could increase our net loss costs and otherwise negatively affect our operating results and business.

Risks Related to Our Financial Condition and Capital Needs

We have a limited operating history and no history of commercializing products which may require us make it difficult for an investor to reduce costs in other areas evaluate the success of our business to date and to assess our future viability.

We are a biotechnology company with a limited operating history and a single product candidate, TOUR006, in development to date. Legacy Tourmaline was formed in 2021 and commenced operations in 2022. To date, we have not yet demonstrated our ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a product on a commercial scale or increase the prices of arrange for a third-party to do so on our products behalf, or services. For example, we expect these rules conduct sales and regulations to make it more difficult and more expensive marketing activities necessary for us to obtain director and officer liability insurance successful commercialization, and we may not be required successful in doing so in the future. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, technical or regulatory challenges, or unanticipated delays in development timelines. We will eventually need to transition from a company with a clinical development focus to a company, if TOUR006 or any potential future product candidates are approved, capable of supporting commercial activities. We may not be successful in such a transition.

We have incurred net losses every year since our inception and have no source of product revenue. We expect to continue to incur substantial significant operating losses and may never become profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. Legacy Tourmaline has incurred losses in each year since it commenced operations.

We expect to continue to incur significant research and development ("R&D") costs and other expenses related to maintain our ongoing operations for the same or similar coverage. foreseeable future, particularly to fund R&D of, and seek regulatory approvals for, TOUR006 and any potential future product candidates. We cannot predict or estimate also expect to continue to incur significant operating losses over the next several years as our research, development, manufacturing, preclinical study, clinical trial and related activities grow. We expect our accumulated deficit will also increase in future periods. The size of our future net losses will depend, in part, on the amount or timing of additional costs we may incur our expenses and our ability to respond generate revenue. Our prior losses and expected future losses have had, and will continue 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.

Actions of activist stockholders could cause us to incur substantial costs, divert management's attention and resources, and have, an adverse effect on our business.

Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. From time to time, we may be subject to proxy solicitations or proposals by activist stockholders urging us to take certain corporate actions, or otherwise effect changes or assert influence on our board of directors stockholders' deficit and management. For example, volatility in the price of our common stock or other reasons may in the future cause us to become the target of stockholder activism. If activist stockholder activities ensue, our business could be adversely affected because responding to proxy contests and reacting to other actions by activist stockholders can be costly and time-consuming, disrupt our operations and divert the attention of management and our employees. For example, we may be required to retain the services of various professionals to advise us on activist stockholder matters, including legal, financial and communications advisors, the costs of which may negatively impact our future financial results. working capital.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist stockholder initiatives may result in the loss of potential business opportunities, harm our ability to enter into strategic transactions, harm our ability to attract new investors, customers, employees and joint venture partners and cause our stock price to experience periods of volatility or stagnation.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have begun the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as a public company.

Implementing not be able to generate product revenue unless and until TOUR006, or any appropriate changes to our internal controls may distract our officers potential future product candidate, successfully completes clinical trials, receives regulatory approval, and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, is successfully commercialized or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

generates revenues through business development activities. We do not intend expect 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 development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent receive product revenue from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

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 product candidates for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. In the event one or more of the analysts who cover 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 may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our cell therapy manufacturing facility is located in Louisville, Kentucky, where we lease and occupy 20,705 square feet of office and laboratory space. The current term of our Louisville lease expires in November 2023 with an option to extend the term by five successive one-year renewal periods in each case upon three months' prior written notice. We also lease additional corporate space in Louisville, Kentucky, where we lease and occupy 6,130 square feet of office space. The current term of this lease expires in November 2023. We maintain our corporate offices in Wellesley, Massachusetts, where we currently lease 7,410 square feet. The current term of this lease expires in September 2025. We lease additional space in Houston, Texas, where we lease and occupy 6,000 square feet of office and laboratory space. The current term of our Houston lease expires in January 2025. We believe our existing facilities in Louisville, Wellesley and Houston are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

From time to time, we may become involved in litigation or other legal proceedings. As of December 31, 2022, we are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business, financial position, results of operations or cash flow. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not Applicable.

PART II

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

Market for Common Stock

On May 7, 2021, our common stock began trading on the Nasdaq Global Market under the symbol "TALS". Prior to such time, there was no public market for our common stock.

Stockholders

As of March 1, 2023, there were 20 stockholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We have never paid or declared any cash dividends on our common stock and do not intend to pay cash dividends to our stockholders 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.

Unregistered Sales of Equity Securities and Use of Proceeds

During the year ended December 31, 2022, we did not issue or sell any unregistered securities not previously disclosed in an Annual Report on Form 10-K or in a Current Report on Form 8-K.

Use of Proceeds from Initial Public Offering

On May 11, 2021, we completed our IPO, in which we issued and sold 8,825,000 shares of common stock, $0.0001 par value per share, at a price to the public of $17.00 per share. The offer and sale of the shares in the IPO was registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-255316) that was filed with the Securities and Exchange Commission (the "SEC") on May 3, 2021 and declared effective on May 6, 2021. The underwriters of the offering were Morgan Stanley & Co. LLC, SVB Leerink LLC, Evercore Group L.L.C. and Guggenheim Securities, LLC. Our IPO commenced on May 7, 2021.

We raised approximately $137.2 million in net proceeds after deducting underwriting discounts and commissions of $10.5 million and other offering expenses of approximately $2.4 million payable by us. No underwriting discounts and commissions or offering expenses were paid directly or indirectly to any of our directors or officers (or their affiliates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

We are holding a significant portion of the balance of the net proceeds in a variety of capital preservation investments, including money market funds, short-term investment-grade, interest bearing instruments and U.S. government securities. Since our IPO through February 2023, there had been no material change in the planned use of proceeds, as described in our final prospectus filed with the SEC on May 10, 2021 pursuant to Rule 424(b) under the Securities Act. In February 2023, we announced a comprehensive review of strategic alternatives focused on maximizing stockholder value, including, but not limited to, an acquisition, merger, possible business combinations and/or a divestiture of our cell therapy CMC capabilities. The planned use of our remaining net proceeds from our IPO will be dependent on the resolution of this review of strategic alternatives. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, years, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value, or that we will make any additional cash distributions to our stockholders.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Item 6. [Reserved].

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

You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected Financial Data" section of this prospectus and our financial statements and the related notes appearing elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this prospectus.

Overview

We are a late-clinical stage, cell therapy company developing an innovative method of allogeneic hematopoietic stem cell transplantation ("allo-HSCT") that we believe has the potential to transform the standard of care in solid organ transplantation, certain severe autoimmune diseases and certain severe blood, immune and metabolic disorders. In the organ transplant setting, which is our initial focus, we believe our proprietary therapeutic approach, which we call "**Facilitated Allo-HSCT Therapy**", could prevent organ rejection without the morbidity and mortality that has been associated with the use of lifelong immunosuppression. Beyond the organ transplant setting, our Facilitated Allo-HSCT Therapy also has the potential to treat a range of severe blood, immune and metabolic disorders, in each case with potential for similar outcomes to what has previously been observed with HSCT, while mitigating the toxicities, morbidities and extended hospital stay associated with the fully myeloablative conditioning typically required by HSCT. We believe that these indications, individually and collectively, represent a significant unmet need and commercial opportunity.

We were incorporated as Regenerex, Inc. in 2018 under the laws of the State of Delaware, having converted from a limited liability company under the name Regenerex LLC. In 2019, we changed our corporate name from Regenerex, Inc. to Talaris Therapeutics, Inc.

Since our inception, we have devoted substantially all of our resources to developing our lead product candidate, FCR001, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. To date, we have principally financed our operations through private placements of convertible preferred stock, payments under a former research collaboration with Novartis, Inc., research grants and most recently, our IPO. Through December 31, 2022, we had received net proceeds of $186.2 million from sales of our convertible preferred stock and net proceeds of $137.2 million, after deducting underwriting discounts and commissions and other expenses, from our IPO.

In February 2023, we announced the discontinuation of our FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001's ability to induce durable tolerance in living donor kidney transplant ("LDKT") recipients. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones.

In February 2023, we also announced a comprehensive review of strategic alternatives focused on maximizing stockholder value, including, but not limited to, an acquisition, merger, possible business combinations and/or a divestiture of the Company's cell therapy CMC capabilities. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value, or that we will make any additional cash distributions to our stockholders. In March 2023, pending the outcome of our review of strategic alternatives, we voluntarily paused enrollment in our FREEDOM-3 Phase 2 clinical trial, while continuing to evaluate patients for potential future enrollment.

In connection with the evaluation of strategic alternatives and in order to extend our resources, we implemented a restructuring plan that included reducing our workforce by approximately one-third, with remaining employees primarily focused on maintaining our cell therapy CMC capabilities and executing FREEDOM-3.

We have incurred significant operating losses since inception. ever.

Our ability to generate any product revenue sufficient to achieve profitability will depend heavily on the successful development from TOUR006 and eventual commercialization of our product and any potential future product candidates and/ also depends on a number of additional factors, including our ability, or the outcome ability of the strategic reassessment announced in February 2023. Our net losses were $73.9 million any potential future third-party partner, to successfully:

- complete research and $47.8 million for the years ended December 31, 2022 and 2021. As of December 31, 2022, we had an accumulated deficit of $164.7 million. We expect to continue to incur net losses for the foreseeable future. In particular, based on the outcome of the strategic reassessment that we announced in February 2023, we expect our expenses may increase as we continue our clinical development of current and seek regulatory approvals for, any future product candidates as well as hire additional personnel, pay fees and obtain regulatory approval for those product candidates;

- establish and maintain supply and manufacturing relationships, and ensure adequate, scaled-up, and legally-compliant manufacturing of bulk drug substances and drug products to outside consultants, lawyers maintain sufficient supply;

- launch and accountants, commercialize TOUR006 or any potential future product candidates for which marketing approval is obtained, if any, and, incur other increased costs associated with being if launched independently by us without a public company. Furthermore, we expect partner, successfully establish a sales force and marketing and

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

distribution infrastructure;

- demonstrate the necessary safety data (and, if accelerated approval is obtained, verify the clinical benefit) post-approval to incur additional costs ensure continued regulatory approval;
-

associated with operating as a public company, obtain coverage and adequate product reimbursement from third-party payors, including significant legal, accounting, investor relations, compliance and other expenses that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, government payors, for any approved products;

- achieve market acceptance for any approved products;
- enter into collaboration, partnering, licensing, or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or similar arrangements when needed on economically favorable terms, or at all. If we fail to raise capital or enter into such agreements as terms;
- establish, maintain, protect and when needed, we may have to significantly delay, reduce enforce our intellectual property rights; and/or eliminate the development
- attract, hire and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. retain qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, including that TOUR006 and any potential future product candidates may not advance through development or be approved for commercial sale, we are unable to predict the timing or amount of increased expenses if or when or if we will be able to generate product revenue or achieve or maintain profitability.

Even if we are able to generate successfully complete development and obtain health authority approval for commercialization for any product sales, candidates that we may not become profitable. take forward, we anticipate incurring significant costs associated with launching and commercializing any products. If we fail to become profitable or are unable to do not sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate cease operations.

Our business is highly dependent on the success of TOUR006 as well as any other potential future product candidates. If we are unable to successfully complete clinical development of, obtain regulatory approval for, or commercialize, TOUR006 or any other potential future product candidates, or if we experience delays in doing so, our operations.

Based upon our current operating plan, we believe that our existing cash and cash equivalents and marketable securities of $181.3 million as of December 31, 2022 business will be sufficient materially harmed.

Our future success and ability to fund our operating expenses and capital expenditure requirements for more than twelve months generate revenue from the date of issuance of this Annual Report on Form 10-K. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Impact of COVID-19 on Our Business

The COVID-19 pandemic has caused significant disruptions to the U.S., regional and global economies and has contributed to significant volatility and negative pressure in financial markets.

We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. We have a mandatory COVID-19 vaccination policy in place for our workforce, and to the extent necessary, we limit access to our facility to those employees and vendors who are vaccinated or have received negative COVID-19 tests before entering our site. We will continue to monitor and follow masking and other COVID-19 related guidance from state and local authorities in the jurisdictions in which we operate.

The future impact of the COVID-19 pandemic on our industry, the healthcare system and our current and future operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of the pandemic, the impact of new strains of the virus, the effectiveness and availability of vaccines and antiviral medications, the pace of these efforts, the actions taken to contain the pandemic or mitigate its impact, any additional preventative and protective actions that governments may direct, and the direct and indirect economic effects of the pandemic and containment measures, among others. See “Item 1A. Risk Factors” for a discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

License Agreement

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

In October 2018, we entered an amended and restated exclusive license agreement ("ULRF License Agreement") with University of Louisville Research Foundation ("ULRF") related to certain licensed patent rights and know-how related to human facilitating cells for our Facilitated Allo-HSCT Therapy approach. Pursuant to the ULRF License Agreement, ULRF granted us an exclusive, worldwide license under such patents and a nonexclusive royalty-bearing, worldwide license for such know-how to research, develop, commercialize and manufacture FCR001 and products containing FCR001 in all fields, without limitation. ULRF also granted us the right to grant sublicenses in accordance with the ULRF License Agreement. Under the terms of the ULRF License Agreement, the Company is obligated to compensate ULRF three percent of net sales of all licensed products sold, one third of any non-royalty sublicensing income, and up to $1.625 million in regulatory and sales milestones on each licensed product upon the occurrence of specific events as outlined in the ULRF License Agreement; and annual license maintenance fees. As of December 31, 2022, we have paid ULRF $0.1 million in milestone payments and $0.2 million in annual maintenance fees, for a total of $0.3 million.

In addition, upon execution of the ULRF License Agreement, we granted contingent equity consideration equal to 65,186 shares of common stock to ULRF. Pursuant to the ULRF License Agreement, on or prior to our first underwritten public offering TOUR006 or any transaction that is treated as a deemed liquidation event, potential future product candidates, which we are required to either issue to ULRF the 65,186 shares in common stock or make a cash payment equal to the 65,186 shares of common stock multiplied by either the price per share of common stock in the underwritten public offering or by the price per share of common stock received in connection with such deemed liquidation event. Coincident with the completion of our IPO in May 2021, we issued to ULRF 48,889 shares of common stock in addition to $0.3 million in a cash payment to fully satisfy the contingent stock liability to ULRF (see Note 8 in the accompanying financial statements). As of

---

December 31, 2022 and December 31, 2021, we had no liability to ULRF for contingent common stock (see Note 3 in accompanying audited financial statements).

Components of Our Results of Operations

Revenue

We have not generated any revenue since our inception and do not expect will occur for several years, if ever, is dependent on our ability to generate any revenue from successfully develop, obtain regulatory approval for and commercialize one or more product candidates. We have identified thyroid eye disease (“TED”) as the sale of products lead indication for TOUR006. We submitted an investigational new drug application (“IND”) in the future, if at all. U.S. to support initiation of a Phase 2b trial of TOUR006 in first-line TED. This IND was cleared by the FDA in August 2023, and we initiated the aforementioned Phase 2b trial in September 2023, which we refer to as the spiriTED trial. Further, we expect to commence a pivotal Phase 3 trial of TOUR006 in first-line TED in 2024. If TOUR006 encounters undesirable safety signals, insufficient efficacy results, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

Our second indication for TOUR006 is expected to be atherosclerotic cardiovascular disease (“ASCVD”). As previously announced in January 2024, we have reached alignment with the FDA on the ASCVD clinical development program, including a Phase 2 trial evaluating the reduction of C-reactive protein (“CRP”), a validated biomarker for inflammation, with quarterly and monthly dosing of TOUR006 in patients with elevated cardiovascular risk. This trial is targeted to commence in the first half of 2024. TOUR006 for ASCVD is in an earlier stage of development and will require substantial additional investment for clinical development, prior to potentially being submitted for regulatory review and approval in one or more jurisdictions. If our product candidates we are currently developing and that we may develop in the future are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from Phase 2 CRP biomarker trial is unsuccessful, our development plans for a combination of product sales or payments from such collaboration or license agreements.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection Phase 3 ASCVD trial would be significantly harmed.

We will need significant additional capital to proceed with the development and research of our novel cell therapy, as well as unrelated discovery program expenses. We expense research and development costs as incurred. These expenses include:

- *employee-related expenses, including salaries, related benefits and stock-based compensation expense, for employees engaged in research and development func*
- *external research and development expenses incurred under arrangements with third parties, such as CROs, investigational sites, and consultants;*
- *the cost of acquiring, developing, and manufacturing clinical study materials;*
- *costs associated with preclinical and clinical activities and regulatory operations;*
- *costs incurred in development of intellectual property; and*
- *an allocated portion of facilities and other infrastructure costs associated with our research and development activities.*

We enter into consulting, research, and other agreements with commercial entities, researchers, universities, and others for the provision of goods and services. Such arrangements are generally cancelable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the respective vendors, including our clinical sites. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of us. Depending upon the timing of payments to the service providers, we recognize prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. We monitor each of these factors and adjust estimates accordingly.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

The successful clinical development and subsequent commercialization of product candidates is highly uncertain. This is due to the numerous risks TOUR006 and uncertainties with product development and commercialization, including significant variations in our clinical development costs as well as the following factors:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the length of hospitalization of patients in our clinical trials
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;

- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates. the timing and progress of nonclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- raising necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development program and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign reg authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance and drug product for use in production of our product candidate;
- the development of commercial scale manufacturing and distribution processes for our product candidates;
- establishing and maintaining agreements with third-party manufacturers for commercial manufacturing, if we pursue a third party manufacturing strategy outside United States, and if our product candidate is approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidate, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our product candidate, if approved, by patients, the medical community and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our therapies following approval.

We may never succeed in obtaining regulatory approval for any of our current and potential future product candidates including FCR001. and our other operations. We may obtain unexpected results from our clinical trials. We may elect not be able to discontinue, delay or modify clinical trials of some product candidates or focus access sufficient capital on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials for FCR001 beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of any preclinical studies or execution or enrollment in clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development. A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to decrease in the near future as we have discontinued our FREEDOM-1 and FREEDOM-2 clinical trials and have voluntarily paused enrollment in our FREEDOM-3 clinical trial, pending the outcome of our review of strategic alternatives.

We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates. Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, including fees paid to consultants, contractors and

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

CROs in connection with our development activities and the cost of acquiring, developing, and manufacturing clinical study materials. At this time, we do not fully allocate personnel costs to individual programs as many of our personnel are deployed across multiple programs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, corporate and business development, human resources and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters, professional fees for accounting, auditing, tax and administrative consulting services, insurance costs and other operating costs, including an allocated portion of facilities and other infrastructure costs associated with our general and administrative activities.

We anticipate that our general and administrative expenses may increase in the future as we explore strategic alternatives, including potential legal, accounting and advisory expenses and other related charges. We also anticipate that we will continue to incur accounting, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Other Income (Expense), Net

Other income (expense), net is comprised of interest income earned on cash reserves in our operating account and on our marketable securities, amortization expense and accretion income on our marketable securities and expense incurred in relation to the change in fair value of our contingent stock liability with ULRF.

Results of Operations

Comparison of Years Ended December 31, 2022 and 2021

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

	Years ended December 31,		
	2022	2021	Change
		(in thousands)	
Operating expenses			
Research and development	$ 57,005	$ 34,245	$ 22,760
General and administrative	19,472	13,262	6,210
Total operating expenses	76,477	47,507	28,970
Loss from operations	(76,477)	(47,507)	(28,970)
Interest and other income (expense), net	2,583	(326)	2,909
Net loss	$ (73,894)	$ (47,833)	$ (26,061)

Research and development expenses

	Years ended December 31,		
	2022	2021	Change
		(in thousands)	
Direct research and development program expense:			
FCR001 clinical and pre-clinical programs	$ 15,990	$ 8,843	$ 7,147
Indirect research and development expenses:			
Personnel related (including stock-based compensation)	28,462	18,140	10,322
Facilities and other operating costs	12,553	7,262	5,291
Total research and development expenses	$ 57,005	$ 34,245	$ 22,760

Research and development expenses were $57.0 million for the year ended December 31, 2022, compared to $34.2 million for the year ended December 31, 2021. The increase of $22.8 million was primarily due to:

- An increase of $10.3 million in personnel costs related to the need for additional staff to conduct our FREEDOM-1 Phase 3 clinical trial, progress our FREEDOM FREEDOM-3 Phase 2 clinical trials, and to advance other pre-clinical activities. We also incurred additional personnel costs as we invested in hiring medical affa process development personnel to further advance our pipeline programs and increased stock compensation expense stemming from additional option and unit gra
- An increase of $7.1 million in direct clinical trial expenses related to our FREEDOM-1 Phase 3 trial as additional clinical sites were activated and additional subject enrolled. This increase also includes direct clinical trial expenses in our

FREEDOM-2 and FREEDOM-3 Phase 2 clinical trials as additional clinical sites were activated and increase process development to further advance our pipeline; a

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

- An increase of $5.3 million in external consulting, medical affairs, and patient advocacy related costs in support of ongoing and planned clinical trials. This increas includes facilities-related costs in support of our process development.

General and Administrative Expenses

The following table summarizes our general and administrative expenses to support our business activities for the years ended December 31, 2022 and 2021:

	Years ended December 31,		
	2022	2021	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$ 10,142	$ 5,525	$ 4,617
Professional and consulting fees	3,352	2,859	493
Facility-related and other	5,978	4,878	1,100
Total general and administrative expenses	$ 19,472	$ 13,262	$ 6,210

General and administrative expenses were $19.5 million for the year ended December 31, 2022, compared to $13.3 million for the year ended December 31, 2021. The increase in general and administrative costs of $6.2 million was primarily due to:

- An increase of $4.6 million in personnel costs primarily due to the hiring of personnel in our human resources, IT and other administrative functions to support the g organization, and increased stock compensation expense stemming from additional option and unit grants;
- An increase of $1.1 million in facility-related costs as well as other operating costs, primarily increased director and officer insurance expense and rent expense; and
- An increase of $0.5 million of professional fees primarily due to increased legal fees and accruals.

Other Income (Expense), Net

Other income, net in the year ended December 31, 2022 was comprised of $1.7 million of net accretion income on our marketable securities and $0.9 million in interest income from our marketable securities and operating cash balance. Other expense, net in the year ended December 31, 2021 was comprised of $0.8 million in interest income from our marketable securities and operating cash balance, $(0.4) million of net amortization expense on our marketable securities and $(0.7) million in expense related to a fair value adjustment of our contingent stock liability.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, acceptable terms, if at all. Since 2018, we have funded our operations primarily with proceeds from the sale of our convertible preferred stock. Through December 31, 2022, we had received net proceeds of $186.2 million from sales of our convertible preferred stock and net proceeds of $137.2 million, after deducting underwriting discounts and commissions and other expenses, from our IPO.

Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. As of December 31, 2022, we had cash and cash equivalents of $13.7 million and marketable securities of $167.6 million.

Contractual Obligations

We are currently a party to four operating leases for our manufacturing facility in Louisville, Kentucky, laboratory space in Houston, Texas, corporate office space in Wellesley, Massachusetts, and additional corporate office space in Louisville, Kentucky. The future minimum lease obligations for these leases total $3.2 million over the next four years.

Furthermore, as described above, we are party to the ULRF License Agreement. Under the terms of the ULRF License Agreement, the Company is obligated to compensate ULRF three percent of net sales of all, licensed products sold, one third of any non-royalty

sublicensing income, and up to $1.625 million in regulatory and sales milestones on each licensed product upon the occurrence of specific events as outlined in the ULRF License Agreement; and annual license maintenance fees.

We have also entered into other contracts in the normal course of business with certain CROs and other third parties for nonclinical research studies and testing, as well as clinical trials. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior notice and, as a result, are not included we may be required to delay, scale back or discontinue development of such product candidates or other operations.

Our operations have consumed substantial amounts of cash since inception, and we will require substantial additional capital to finance our operations and pursue our product development strategy, both in the table short- and the long-term, and the amount of contractual obligations and commitments above. Payments due upon cancellation consist only funding we will need depends on many factors, including:

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- the rate of payments for services provided and expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation.

Cash Flows

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

	Years ended December 31,		
	2022	2021	Change
	(in thousands)		
Net cash used in operating activities	$ (60,857)	$ (39,988)	$ (20,869)
Net cash provided by (used in) investing activities	55,671	(96,387)	152,058
Net cash provided by financing activities	242	137,400	(137,158)
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (4,944)	$ 1,025	$ (5,969)

Cash Flow from Operating Activities

During the year ended December 31, 2022, operating activities used $60.9 million of cash, due to our net loss of $73.9 million, partially offset by non-cash charges of $11.9 million and net cash provided by changes in our operating assets and liabilities of $1.1 million. Non-cash charges primarily consisted of $11.2 million of stock-based compensation expense, $2.2 million of depreciation on fixed assets and amortization of right-of-use assets, and $0.2 million of expense related to the impairment of fixed assets, offset by $1.6 million of accretion income of marketable securities. Net cash provided by changes in our operating assets and liabilities primarily consisted of a $3.4 million increase in accounts payable and accrued expenses related to timing, offset by a $1.8 million increase in prepaids and other current assets driven by prepaid clinical trial expenses, $0.6 million decrease in operating lease liability, and a $0.1 million increase in other liabilities.

During the year ended December 31, 2021, operating activities used $40.0 million of cash, due to our net loss of $47.8 million, partially offset by non-cash charges of $5.5 million and net cash provided by changes in our operating assets and liabilities of $2.3 million. Non-cash charges primarily consisted of $3.8 million of stock-based compensation expense, $1.0 million of depreciation on fixed assets and amortization of marketable securities and $0.7 million of expense related to the fair value adjustment of our contingent stock liability. Net cash provided by changes in our operating assets and liabilities primarily consisted of a $3.7 million increase in accounts payable and accrued expenses related to timing, offset by a $1.3 million increase in prepaids and other current assets driven by director and officer insurance premiums and a $0.1 million increase in other assets driven by security deposits for new leases.

Cash Flow from Investing Activities

During the year ended December 31, 2022, investing activities provided $55.7 million of cash, due to maturities of marketable securities of $250.3 million, offset by purchases of marketable securities of $191.6 million and purchases of property and equipment of $3.0 million.

During the year ended December 31, 2021, investing activities used $96.4 million of cash, due to purchases of marketable securities of $275.9 million and purchases of property and equipment of $2.4 million, partially offset by maturities of marketable securities of $181.9 million.

Cash Flow from Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $0.2 million, consisting of $0.1 million in proceeds from exercise of stock options and $0.1 million of proceeds from purchases of shares in our Employee Stock Purchase Plan.

During the year ended December 31, 2021, net cash provided by financing activities was $137.4 million, primarily consisting of net proceeds after deducting underwriting discounts and commissions, of $139.5 million from our IPO, $0.3 million of proceeds from exercise of stock options and $0.2 million of proceeds from purchases of shares in our Employee Stock Purchase Plan, partially offset by $2.4 million paid for other IPO expenses $0.3 million paid in partial satisfaction of ULRF contingent stock liability.

Future Funding Requirements

We currently expect our expenses to decrease progress in the near term due to our decision to discontinue our FREEDOM-1 and FREEDOM-2 clinical trials and conduct workforce reductions while we explore strategic alternatives. Pending the outcome of our review of strategic alternatives, should we decide to continue to advance the clinical development of TOUR006 and our other potential future product candidates, we expect to incur additional costs in connection with such activities. The timing and amount of such operating expenditures will depend largely on: candidates;

- the outcome, success, timing, and cost of any strategic transactions, business combinations or divestiture;
- the initiation, progress, timing, delays, costs, and results of preclinical studies and clinical trials for our TOUR006 and any potential future product candidates;
- the number and development requirements of product candidates or any future product candidates that we may develop; pursue;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- the outcome, timing, and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory health authorities, including the potential for such authorities to require that we perform more preclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;expect;

- the cost to establish, maintain, expand, enforce, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights;

- the cost and timing of selecting and auditing a manufacturing site for later-stage clinical and commercial-scale manufacturing;

- the cost and timing of performing manufacturing process validation sufficient to meet regulatory expectations and requirements;

- the effect of competing technological products that may compete with TOUR006 and any potential future product candidates or other market developments;

- the costs of continuing to grow our business, including hiring key personnel and maintaining or acquiring operating space;

- market acceptance of any approved product candidates, including product pricing as well as and product coverage and the adequacy of reimbursement by third-pa payors;

- the cost of potentially acquiring, licensing, or investing in additional businesses, products, product candidates and technologies; and

- the cost and timing of selecting, auditing and potentially validating or expanding a manufacturing site for commercial-scale manufacturing;

- the cost of establishing sales, marketing, and distribution capabilities for TOUR006 and any potential future product candidates for which we may receive regulat approval and that we determine decide to commercialize; and

- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We believe that our existing cash and cash equivalents and marketable securities as of December 31, 2022, working capital will enable us be sufficient to fund our operating expenses and capital expenditure requirements for more than at least twelve months from the date of issuance of this Annual Report on Form 10-K. Moreover, based on our current development plans and related assumptions, we believe our cash, cash equivalents and investments are sufficient to fund our operations into 2027. We have based these estimates on plans and assumptions that may prove to be insufficient or inaccurate (for example, with respect to anticipated costs, timing, or success of certain activities), and we could utilize our available capital resources sooner than we currently expect. In addition, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially as a result of a number of factors.

We plan to finance our future cash needs through public or private equity or debt offerings, BD Arrangements, or a combination of these potential financing sources. For example, we may seek BD Arrangements in the future to facilitate clinical development that requires significantly more capital and resources that may otherwise not be available to us on acceptable terms or at all, such as large cardiovascular outcome trials of TOUR006 in patients with ASCVD. Additional capital may not be available in sufficient amounts, on reasonable terms, or when we need it, if at all. In addition, our ability to obtain financing may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from geopolitical tensions, such as the ongoing war in Ukraine and hostilities in the Middle East, global pandemics, inflation, rising interest rates, and liquidity concerns at, and failures of, banks and other financial institutions. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in economic growth, increases in inflation rates, higher interest rates and uncertainty about economic stability. If the financial market disruptions and economic slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our financial condition and our ability to pursue our business strategy.

If adequate funds are not available from public or private equity or debt offerings, or BD Arrangements on acceptable terms when needed, in order to continue the development of TOUR006 or any of our potential future product candidates we may need to:

- seek strategic alliances for R&D programs when we otherwise would not, at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or

- enter into BD Arrangements that could require us to relinquish, or license, on potentially unfavorable terms, our rights to intellectual property, product candidates, or products that we otherwise would develop or seek to commercialize ourselves.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

We may not be able to raise adequate additional capital on a timely basis, on acceptable terms or at all. If we are unable to do so, we may need to significantly delay, scale back or discontinue development of or abandon TOUR006 or any potential future product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects, or we may be required to cease operations altogether.

We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations applicable to public companies.

We will incur significant legal, accounting and other expenses as a public company that we did not incur as a private company, including costs associated with public company reporting obligations under the Exchange Act. Our management team consists of the executive officers of Legacy Tourmaline prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Once we are no longer an emerging growth company, a smaller reporting company, or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly, and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as an emerging growth company, we may take advantage of exemptions from various requirements, such as an exemption from the requirement to have our independent auditors attest to our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002, as well as an exemption from the "say on pay" voting requirements pursuant to the Dodd-Frank Act. After we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which may allow us to take advantage of some of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Even after we no longer qualify as an emerging growth company, we expect to still qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, in at least the near term, which will allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in periodic reports and proxy statements. Once we are no longer an emerging growth company, a smaller reporting company, or otherwise qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline, or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Risks Related to Our Dependence on Third Parties

We may not be able to obtain and maintain the relationships with third parties that are necessary to develop, commercialize and manufacture TOUR006 and any potential future product candidates.

We expect to depend on third parties, including contract research organizations ("CROs"), clinical data management organizations, clinical investigators, and CDMOs and other third-party partners and service providers to support our development efforts, to conduct our clinical trials and certain aspects of our research and preclinical studies, to manufacture clinical and commercial-scale quantities of our drug substances and drug products under cGMP and to market, sell and distribute any products we successfully develop and for which we obtain regulatory approval. Any problems we experience with any of these third parties could delay the development, manufacturing or commercialization of TOUR006 or any potential future product candidates, which could harm our results of operations.

We cannot guarantee that we or, as applicable, any of our partners will be able to successfully negotiate agreements for, and maintain relationships with, third-party partners and service providers on favorable terms, if at all. If we or any of our partners are unable to obtain and maintain these agreements, we may not be able to clinically develop, manufacture, obtain regulatory approvals for or commercialize TOUR006 or any potential future product candidates, which will, in turn, adversely affect our business. If we or any of our partners need to enter into alternative arrangements, it could delay our product development and, if applicable, commercialization activities and such alternative arrangements may not be available on terms acceptable to us.

We expect to continue to expend substantial time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, our reliance on these third parties for development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that our clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and we remain responsible for ensuring that manufacturing activities are conducted under cGMP. However, we cannot control the amount or timing of resources our partners will devote to our programs, TOUR006 or potential future product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct their clinical trials or other R&D activities in accordance with regulatory requirements, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for TOUR006 or any potential future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize any approved products. In addition, we base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf and, if their estimates are not accurate, it could negatively affect the accuracy of our financial statements.

Any agreements we have or may enter into with third-party partners and service providers may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over contract interpretation, rights to ownership or use of intellectual property, the scope and direction of our programs, the approach for regulatory approvals or commercialization strategy. Any disputes or commercial conflicts could lead to the termination of our agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights, result in increased financial obligations for us or result in costly and time-consuming arbitration or litigation.

We rely completely on CDMOs for the manufacture and testing of TOUR006 and any potential future product candidates under cGMP, and we are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of any potential product candidates and any future products. Additionally,

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

any difficulties in the transfer of drug substance or drug product to or from manufacturing facilities could materially adversely affect our business, financial condition, and results of operation.

We require the services of third-party CDMOs to provide process development, analytical method development, formulation development, and manufacturing. We do not have, and do not currently plan to acquire or develop, the facilities or capabilities to manufacture and test bulk drug substance or filled drug product for use in clinical trials or commercialization. As a result, we rely completely on CDMOs, which entails risks to which we would not be subject if we manufactured TOUR006 or any potential future product candidates or products ourselves, including risks related to reliance on third parties for availability of drug product to use in our clinical trials and for regulatory compliance and quality assurance with respect to such drug product, the possibility of breach of the manufacturing agreement by third parties because of factors beyond our control (including a failure to manufacture TOUR006 and any potential future product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of agreements by third parties, based on their own business priorities, at a time that is costly or damaging to us.

TOUR006 is a biologic, and the manufacture and testing of biologic products is complex, highly regulated and requires significant expertise and capital investment, including the development of advanced manufacturing techniques, process controls, and advanced analytical testing capability. As a result, the manufacture and testing of our product candidate is subject to many risks, including the following, some of which we may experience:

- product loss or other negative consequences due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, shortages of qualified personnel or improper delivery or storage conditions;
- difficulties with product yields, quality control release testing, including challenges related to analytical method development and the qualification and implementation of those methods for release testing, which can delay availability of clinical trial materials;
- challenges with long-term stability of our product candidate and products at reasonable and expected storage conditions;
- challenges with comparability of product made following changes in the manufacturing process such as a change in the manufacturing facility, scale-up, changes in the storage container used for drug product, or other changes;
- the negative consequences of failure to comply with strictly enforced federal, state and foreign regulations;
- major deviations from normal manufacturing processes, which may result in reduced production yields, product defects and other supply disruptions;
- the presence of microbial, viral or other contaminants discovered in our product candidate or in the manufacturing facilities in which it is made, which can necessitate closure of facilities for an extended period of time to investigate and eliminate the contamination;
- the negative consequences of our CDMOs' failure to be approved for commercial production following an audit by regulatory authorities, by us or by our partners;
- Our CDMOs' changing strategies and business priorities, which can affect the availability of facilities where we intend to manufacture our product candidate; and
- Our CDMOs' manufacturing facilities being adversely affected by labor, raw material and component shortages, turnover of qualified staff or financial difficulties of their owners or operators, including as a result of natural disasters, power failures, local political unrest or other factors.

We cannot ensure that issues relating to the manufacture or testing of our product candidates, such as those described above, will not occur or continue to occur in the future. If we or our CDMOs experience any such issues there could be a shortage of drug substance or drug product for use in our clinical trials, which could delay clinical and regulatory timelines significantly and have an adverse effect on our business.

In addition, to date, TOUR006 has been manufactured and tested by our drug substance and drug product CDMOs solely for clinical trials. We intend to continue to use CDMOs for these purposes, and also for the supply of larger quantities that may be required to conduct accelerated or expanded early clinical trials or larger, later clinical trials and for commercialization if we advance any of our product candidates through regulatory approval and to commercialization. These manufacturers may not have sufficient manufacturing capacity and may not be able to scale up the production of drug substance or drug product in the quantities we need and at the level of quality required in a timely or effective manner, or at all. In particular, there is increased competition in the biotechnology industry for CDMO manufacturing slots and other capabilities generally, which has had, and may continue to have, a negative impact on the availability of manufacturing capacity and therefore our ability to supply clinical trial materials for planned, ongoing or expanded clinical trials or commercialization.

The scale up and validation of the manufacturing processes in the CDMOs' facilities to manufacture larger quantities or different formats such as a pre-filled syringe involve complex activities and coordination. Scale up and process validation activities entail risks such as process reproducibility and robustness, stability of in-process intermediates, product quality consistency and other technical challenges. We may be unable to scale up or validate our manufacturing processes, which can be expensive and time-consuming and could delay the initiation or completion of our clinical trials.

Similarly, we or our CDMOs may make changes to our manufacturing processes at various points in product development for many reasons, including changing manufacturing facilities, scaling up, facility fit, raw material or component availability, improving process robustness and reproducibility, decreasing processing times, changing the storage container, or others. In some circumstances, we may fail to demonstrate that the product from the new process is comparable to product from the prior process and we may be required to perform additional bridging studies, animal or human studies to demonstrate that the product used in earlier clinical trials are comparable to the product we intend to use in later trials or later stages of an ongoing trial. These efforts are expensive and there is no assurance that they will be successful, which could impact our ability to continue or initiate clinical trials in a timely manner, or at all, and could require the conduct of additional clinical trials.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Any future adverse developments affecting manufacturing operations or the scale up or validation of manufacturing processes for TOUR006 or any of our future product candidates may result in shipment delays, lot failures, clinical trial delays or discontinuations, or, if we are commercializing products, inventory shortages, product withdrawals or recalls or other interruptions in supply. We may also have to record inventory write-offs and incur other charges and expenses for drug substance or drug product that fail to meet specifications or cannot be used before its expiration date. In addition, for out of specification materials, we may need to undertake costly remediation efforts or manufacture new batches at considerable cost and time delays or, in the longer run, seek more expensive manufacturing alternatives.

We currently have a single source of supply for our drug substance and for our drug product. Single sourcing minimizes our leverage with our CDMOs, who may take advantage of our reliance on them to increase the pricing of their manufacturing services or require us to change our intended manufacturing plans based on their strategies and priorities. Single sourcing also imposes a risk of interruption or delays in supply in the event of manufacturing, quality or compliance difficulties and/or other difficulties in timely supplying us with materials. We do not currently have arrangements in place for redundant supply for drug substance or drug product. If one of our suppliers fails or refuses to supply us for any reason or we otherwise choose to engage a new supplier for TOUR006 or any of our future product candidates, including a second-source supplier to mitigate the risks of single-source supply, it may take a significant amount of time and cost to implement and execute the necessary technology transfer to, and qualification of, a new supplier. The FDA or comparable foreign health authority must approve manufacturers of commercial drug substance and drug product. If there are any delays in qualifying new suppliers or facilities or a new supplier is unable to meet the requirements of the FDA or comparable foreign health authority for approval of production of our commercial supply, there could be a shortage of drug substance or drug product with respect to the affected product candidates.

If our CDMOs are unable to source certain raw materials and components from their supplier and if they must obtain such materials from a different supplier, additional testing, and regulatory approvals, may be required, which may negatively impact manufacturing timelines. Any significant delay in the acquisition or decrease in the availability of these materials, components or other items, or failure to successfully qualify alternative materials or components, could considerably delay the manufacture of our product candidates, which could adversely impact the timing or completion of any ongoing and planned trials or the timing of regulatory approvals, if any, of our product candidates.

In addition, our CDMOs' facilities and operations may be adversely affected by labor, raw material and component shortages, high turnover of staff and difficulties in hiring trained and qualified replacement staff and the operations of our CDMOs may be requisitioned, diverted or allocated by U.S. or foreign government orders such as under emergency, disaster and civil defense declarations. Changes in economic conditions, supply chain constraints, labor, raw material and component shortages and steps taken by governments and central banks could also lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs.

If any CDMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We would also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a

CDMO may possess technology related to the manufacture of our product candidate that such CDMO owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another CDMO manufacture our product candidates.

Our manufacturing and testing of bulk drug substance for TOUR006 currently takes place in China through a global CDMO with facilities in China and around the world. Our manufacturing and testing of drug product for TOUR006 occurs in facilities in Austria and the U.S. Our drug product is packaged in Germany and the U.S. A significant disruption in the operation of these manufacturing facilities, a trade war or political unrest could materially adversely affect our business, financial condition and results of operations.

We currently contract manufacturing operations to third parties. TOUR006 bulk drug substance for clinical studies is manufactured by a third-party facility in China. TOUR006 drug product is manufactured in Austria and the U.S. and packaged in Germany and the U.S. Any disruption in production or inability of our manufacturers in those countries to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue development of our product candidates. Furthermore, since bulk drug substance is produced in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic conditions in China. Any of these matters could materially and adversely affect our business and results of operations. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. Furthermore, any recall of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currencies. Future appreciation of the local currencies could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in such countries.

Additionally, we plan to transfer manufacturing and testing of TOUR006 bulk drug substance to a facility in the U.S. that is licensed for commercial production. We intend to use this U.S. facility to produce TOUR006 bulk drug substance for late-stage clinical studies and commercial supply. We may encounter difficulties transferring the manufacture and testing process. Furthermore, our process at the new facility may result in the production of TOUR006 that is not comparable to the current TOUR006 clinical trial material produced at the facility in China. Also, we plan to conduct manufacturing and testing of TOUR006 drug product at a facility in Europe that is licensed for commercial production, through a global CDMO. TOUR006 drug product produced at the commercial facility may not be comparable to the current TOUR006 drug product that is being used in our clinical studies.

We may seek to establish BD Arrangements, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Our product development programs and the potential commercialization of TOUR006 or any of our future product candidates will require substantial additional cash to fund expenses. For TOUR006 or any of our future product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a BD Arrangement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's own evaluation of a potential collaboration. Such factors a potential collaborator will use to evaluate a BD Arrangement may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a BD Arrangement could be more attractive than one with us for our product candidate. The terms of any additional BD Arrangements or other arrangements that we may establish may not be favorable to us.

We may in the future be restricted under our current BD Arrangements from entering into potential future BD Arrangements on certain terms with potential collaborators. BD Arrangements are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate BD Arrangements on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

In addition, any future BD Arrangements that we enter into may not be successful. The success of our BD Arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a BD Arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the BD Arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. BD Arrangements with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We have no experience in sales, marketing and distribution and may have to enter into agreements with third parties to perform these functions, which could prevent us from successfully commercializing TOUR006 or any potential future product candidates.

We currently have no sales, marketing or distribution capabilities. To commercialize TOUR006 or any potential future product candidates we must either develop our own sales, marketing and distribution capabilities or make arrangements with third parties to perform these services for us. If we decide to market or distribute any of our products on our own, we will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all. If we are not able to establish and maintain successful arrangements with third parties or build our own sales and marketing infrastructure, we may not be able to commercialize our product candidates, which would adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates

TOUR006 and any other of our future product candidates must undergo rigorous clinical trials before seeking regulatory approvals, and clinical trials may be delayed, suspended or terminated at any time for many reasons, any of which could delay or prevent regulatory approval and, if approval is granted, commercialization of our product candidates.

TOUR006 and any other product candidates we might develop are subject to rigorous and extensive clinical trials before we can seek regulatory approval from the FDA and comparable foreign health authorities such as the European Medicines Authority. Clinical trials may be delayed, altered, suspended or terminated at any time for reasons including but not limited to:

- ongoing discussions with the FDA or comparable foreign health authorities regarding the scope or design of our clinical trials;
- delays in obtaining, or the inability to obtain, required approvals from institutional review boards ("IRBs") and ethics committees or other governing entities at clinical trial sites selected for participation in our clinical trials;
- delays in reaching agreement on acceptable terms with clinical trial sites on clinical budgets and/or clinical trial agreements;
- lack and/or loss of personnel at clinical trial sites to conduct our trials, including patient screening, patient visits and/or assessments, data entry of patient data into the clinical database and/or processing of patient samples;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

- institutional policies related to in-person patient visits resulting in delays to treatments or assessments being conducted, CRO and/or sponsor visits to conduct monitoring visits to verify data and/or site adherence to regulatory requirements;
- delays in patient enrollment and other key trial activities;
- delays in reaching agreement on acceptable terms with prospective CROs;
- the failure of CROs, testing laboratories and other third parties to satisfy their contractual duties to us or meet expected deadlines;
- deviations from the trial protocol by clinical trial sites and investigators, or failures to conduct the trial in accordance with regulatory requirements;
- alterations in the size and scope of the trial;
- lower than anticipated retention rates of participants in clinical trials, including patients dropping out due to protocol non-compliance, side effects or disease progression;
- missing or incomplete data;
- failure of enrolled patients to complete treatment or to return for post-treatment follow-up;
- for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected patients and test any patient samples;
- implementation of new, or changes to, guidance or interpretations from the FDA or comparable foreign health authorities with respect to approval pathways for TOUR006 and any potential future product candidates we are pursuing;
- the need to repeat or conduct additional clinical trials as a result of inconclusive or negative results, poorly executed testing or changes in required endpoints or other changes to the trial or analysis;
- insufficient supply or deficient quality of drug substance, drug product or other clinical trial material necessary to conduct our clinical trials, as well as delays in the testing, validation, manufacturing and delivery to clinical trial sites of such material;
- withdrawal of clinical trial sites or investigators from our clinical trials for any reason, including as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- unfavorable FDA or comparable foreign health authority inspection or review of a clinical trial site or records of any clinical or preclinical investigation;
- drug-related adverse effects or tolerability issues experienced by participants in our clinical trials;
- changes in government regulations or administrative actions;
- lack of adequate funding to continue the clinical trials;
- ability to hire and retain key R&D and other personnel; or
- the placement of a clinical hold on a trial by the FDA or comparable foreign health authorities.

We cannot guarantee that we will be able to successfully obtain FDA or other global health authority clearance to proceed with any planned clinical investigations of TOUR006 or any potential future product candidates or to accomplish required regulatory and/or manufacturing activities or all of the other activities necessary to initiate and complete clinical trials in a timely fashion, if at all. As a result, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approvals or successfully commercialize our products. In addition, we have only limited experience in conducting late-stage clinical trials required to obtain regulatory approval. In any event, we do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects. We or our partners' inability to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenue or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

If clinical trials of TOUR006 or any potential future product candidates fail to timely initiate, enroll, complete, or produce positive results or to demonstrate safety and efficacy to the satisfaction of the FDA or comparable health authorities or sufficient to demonstrate differentiation from other approved therapies or therapies in development, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from health authorities for the sale of TOUR006 or any potential future product candidates, we or our partners must conduct extensive preclinical studies and clinical trials to demonstrate its safety and efficacy in humans. Preclinical studies and clinical trials are expensive, take several years to complete and may not yield results that support further clinical development or product approvals. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. There is a high failure rate for drugs and biologic products proceeding through clinical trials and failure can occur at any stage of testing. Because we have limited experience designing clinical trials, we may be unable to design and execute a clinical trial to support regulatory approval.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

We may also not be successful in generating clinical data sufficient to differentiate TOUR006 from other products in the same therapeutic area. If our competitors' products are, or are perceived to be, more effective, more convenient, less costly or safer than TOUR006, or we are unable to demonstrate differentiation in any of those factors, we may not be able to achieve a competitive position in the market.

In addition, data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In any event, it is impossible to predict when or if any of our product candidates will prove safe and effective in humans or will receive regulatory approval. If we are unable to successfully discover, develop or enable our partners to develop drugs that regulatory authorities deem effective and safe in humans, we will not have a viable business.

We may not be able to file INDs, IND amendments, or clinical trial applications ("CTAs") to commence clinical trials on the timelines we expect, and even if we are able to, the FDA or comparable health authorities may not permit us to proceed.

We may not be able to file INDs or CTAs for TOUR006 or any future product candidates on the timelines we expect, if at all. For example, we may experience, or our partners may experience, manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND or CTA will result in the FDA or comparable health authority allowing initial or later-stage clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or CTA, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND or CTAs. Any failure to file INDs and CTAs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

If we experience delays or difficulties in the enrollment of patients in clinical trials, development of TOUR006, or any potential future product candidates, may be delayed or prevented, which would have a material adverse effect on our business.

We may not be able to initiate or continue clinical trials for our product candidate if we, or a potential future sponsor, are unable to locate and enroll a sufficient number of eligible patients to participate in these continuing trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, at clinical trial sites participating in our clinical trials, or at clinical trial sites not participating in our clinical trials and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment may also be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability of approved therapies, other medicines, surgical procedures, or other therapies or interventions that would lead a patient to opt for that treatment or care approach instead of enrolling in our trial;
- patient eligibility criteria for the trial in question;
- nature of the trial protocol;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- perceived risks and benefits of the product candidate under study;
- the occurrence of adverse events attributable to our lead product candidate;
- efforts to facilitate timely enrollment in clinical trials;
- the number and nature of competing products or product candidates and ongoing clinical trials of competing product candidates for the same indication at clinical trial sites participating in our clinical trials, or at clinical trial sites not participating in our clinical trials;
- patient referral practices of physicians;
- risk that enrolled subjects will drop out or die before completion;
- competition for patients from other clinical trials at clinical trial sites participating in our clinical trials, or at clinical trial sites not participating in our clinical trials;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- continued enrollment of prospective patients by clinical trial sites.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than expected, the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete. Any delays in completing our clinical trials will increase costs, delay or prevent product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any delays in completing our clinical studies for our product candidates may also decrease the period of commercial exclusivity. Any of these occurrences may significantly harm our business, financial condition, results of operations, and prospects.

Success in preclinical studies or earlier-stage clinical trials for TOUR006, or evidence from published observations, clinical studies, or other literature for other anti-IL-6 or anti-IL-6 receptor agents, may not be indicative of such results in future or ongoing clinical trials for TOUR006.

To date, the data supporting our drug discovery and development programs are derived in part from laboratory and preclinical studies and earlier-stage clinical trials conducted by Pfizer. Owing in part to the complexity of biological pathways, when used to treat human patients, as well as differences in the design or conduct of clinical trials, TOUR006 might not demonstrate the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier-stage clinical trials, and it may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. Success in preclinical studies and earlier-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate or positive data to demonstrate the effectiveness and safety of our current and potential future product candidates. In this regard, the data supporting our drug discovery and development programs are derived from laboratory and preclinical studies, and future clinical trials in humans may show that one or more of our product candidates are not safe and effective, in which event we may need to abandon development of such product candidates. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical studies and earlier-stage clinical trials. Similarly, preliminary data and interim results from clinical trials may not be predictive of final results. As a general matter, there is also a substantial risk that Phase 3 trials with larger numbers of patients and/or longer durations of therapy will fail to replicate efficacy and safety results observed in earlier clinical trials. The impact of such differences may lead to a clinical trial(s) of TOUR006 failing to reproduce any positive efficacy, safety, or other findings from laboratory and preclinical studies and earlier-stage clinical trials for TOUR006.

In addition, the rationale supporting our drug discovery and development programs is also based upon published articles describing positive results from clinical trial(s) and/or the clinical experience of physicians using tocilizumab (and other inhibitors of IL-6 or IL-6 receptor) in various diseases. For example, part of the rationale supporting the development and investigation for TOUR006 in TED is from published articles describing the off-label use of tocilizumab in TED, which report observations of positive efficacy and safety results.

Results from our future or ongoing clinical trials of TOUR006 may differ significantly from those from published articles in the literature of other molecules in the anti-IL-6 or anti-IL-6R class. For example, differences in clinical results may arise from differences between drug targets or between molecules that inhibit the same drug target. In addition, there may be substantial differences, even if the same disease or indication, between clinical trial(s) of TOUR006 and published literature (e.g., case series or reports, clinical trials, etc.) for other molecules in the anti-IL-6 or anti-IL-6R class based upon factors such as the clinical use setting, patient population being treated or investigated, assessments (e.g., efficacy, safety, pharmacodynamics, etc.), data collection and handling, analysis, study conduct, or other factors. Bias may have also been introduced in the published clinical reports that led to an incorrect determination or overestimate of the efficacy and safety results for TOUR006 because of the open-label nature and lack of controls or other robustness measures in these case series and uncontrolled clinical studies. There also can be publication bias, if only examples of successful cases of the clinical use of an anti-IL-6 or anti-IL-6R molecule (e.g., tocilizumab, satralizumab, sarilumab, siltuximab, ziltivekimab, etc.) may have been published, while treatment experiences for such molecules that were unsuccessful and/or associated with adverse safety outcomes were not published.

The impact of such differences may lead to a clinical trial(s) of TOUR006 failing to reproduce any positive efficacy, safety, or other findings in relation to inhibition of IL-6 or the IL-6 receptor that were reported in publications of other molecules. If such an event was to occur, there is a risk that the TOUR006 development program in a particular indication(s) or all indications is terminated, longer or more expensive development programs (including larger, longer, and/or costlier clinical trials) may be required to investigate TOUR006, TOUR006 is not approved by the FDA or other regulatory authorities, TOUR006 is not reimbursed by payors or other similar bodies, or there is limited or no success achieved in the commercialization of TOUR006.

Preliminary, initial, or interim results from clinical trials that we announce, present, or publish from time to time may change as more data and information become available (or are updated based upon audit, validation and verification procedures of the data/information commonly performed for clinical trials) that could result in material changes in the final trial results.

From time to time, we may announce, present or publish preliminary, initial, or interim data or other information from our clinical trials. Any such data and other results from our clinical trials may materially change as more patient data and information become available. Such data and information may also undergo significant change following subsequent auditing, validation and/or verification procedures that are commonly conducted in clinical trials. Thus, any preliminary, initial, or interim data or other information may not be predictive of final results from the clinical trial and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or other determinations that may qualify such results, once we have received and fully evaluated the additional data. Differences between preliminary, initial or interim results and final results could lead to significantly different interpretations or conclusions of the trial outcomes.

Further, others, including regulatory authorities and collaboration or regional partners, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of TOUR006, the approvability or commercialization of TOUR006 or any future product candidates, and us in general. In addition, the information we choose to publicly disclose regarding a particular clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the preliminary, initial or interim data that our reports differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, TOUR006 may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

TOUR006 may cause undesirable side effects or adverse events or have other properties or safety risks, which could terminate further development of this product candidate, result in a lack of product approval by the FDA or other regulatory authorities, delay the timing (and/or increase the cost) of a product approval by the FDA or other regulatory authorities, lead to a restrictive product label that significantly limits prescribing of an approved product, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TOUR006.

A concerning safety signal (such as that involving serious adverse events, life-threatening adverse events, or deaths, or a nonserious adverse event that may occur at a high or concerning frequency and/or severity or if rare, leads to a significant safety concern), tolerability concern (e.g., undesirable side effects that cannot be tolerated by patients, require suboptimal dosing alterations require additional monitoring and/or lead to patients missing or delaying doses) or other safety issue caused by TOUR006 may be observed in any future or ongoing clinical trial of TOUR006. For example, dosing in the 200 mg arm of the prior Pfizer Phase 2 trial of TOUR006 in systemic lupus erythematosus was stopped for safety concerns based on an unblinded data review and recommendation from the internal review committee for that study. Prior safety (clinical and nonclinical) data for TOUR006, safety data and observations for other molecules in the anti-IL-6 and anti-IL-6R classes, and published safety data and observations for other molecules in the anti-IL-6 and anti-IL-6R classes used in the same disease or indication as that being investigated in TOUR006 clinical trial(s) may not be indicative of similar safety and tolerability results or profile for TOUR006 in future or ongoing clinical trials. For example, some potential therapeutics developed in the biopharmaceutical industry that initially showed therapeutic promise in early-stage trials have later been found to have a problematic safety or tolerability profile that prevented their further development.

In addition, TOUR006 is a recombinant protein. Recombinant proteins can sometimes induce host immune responses that can cause the production of anti-drug antibodies ("ADAs"). ADAs may neutralize the effectiveness of the product candidate, can require that higher doses be used to obtain a therapeutic effect or can cross react with substances naturally occurring in a subject's body, which can cause unintended effects, including potential impacts on efficacy and adverse events. For example, the ADAs may prevent the drug from offering a therapeutic benefit or lead to a less efficacious effect. ADAs may also cause hypersensitivity reactions (including anaphylaxis) that may require patients to stop taking that drug or can, in some cases, be serious, life-threatening, or fatal. If we determine that ADAs are causing safety or efficacy concerns for TOUR006, we may need to delay, halt, or terminate our clinical trials and the affected product candidates. TOUR006 may never obtain regulatory approval by the FDA or other regulatory authorities. We cannot provide assurance that the detection of ADAs will not occur at a higher rate than what we have observed historically or that ADA will not lead to meaningful impacts upon efficacy or safety, or that the detection of ADAs will not otherwise result in TOUR006 not being approved by the FDA or other regulatory authorities.

If a safety signal, tolerability concern, ADA concern, or other safety issue emerges from any future or ongoing clinical trial for TOUR006, or any other IL-6 inhibitor product candidate, this could result in:

- slowing of patient enrollment in our clinical trials or inability to enroll the trials;
- a meaningful rate of patients dropping out of trials (which could lead to a delay in completing the clinical trial or adversely impact the trial's probability of success in observing a positive efficacy result);
- a meaningful rate of patients missing or postponing their trial procedures (including but not limited to dosing, study visits and efficacy assessments) which in turn could lead to a delay in completing the clinical trial or adversely impact the trial's probability of success in observing a positive efficacy result;
- an inability to use a dose that offers efficacy or necessitating the use of a lower dose that may offer only low or partial efficacy;
- suspension of the clinical trial by us, the FDA or other regulatory authority, or local IRB or ethics committee;
- termination of the clinical trial;
- need for additional and/or larger clinical trial(s) to further evaluate the safety profile of TOUR006;
- abandonment of the development of TOUR006 for that particular indication being evaluated by the clinical trial or for other indications or as a program altogether;
- refusal by the FDA or other regulatory authority to grant product approval;
- restrictions on the product labeling (such as a black boxed warning, warnings and precautions, limitations of use, and/or narrowed and limited indication) that may significantly limit the prescribing and usage of TOUR006;
- requirement to develop a Risk Evaluation and Mitigation Strategy ("REMS") for TOUR006 in the U.S. or a similar strategy as required by a comparable foreign regulatory authority;
- a view by healthcare professionals that TOUR006 presents an unfavorable benefit-risk profile which in turn may significantly limit the prescribing and usage of TOUR006;
- a meaningful rate of patients either choosing to not start TOUR006 treatment or to prematurely discontinue usage of TOUR006;
- use of additional monitoring by healthcare professionals, either on their own or due to the recommendations of expert panels or treatment guidelines, in the use of TOUR006 that in turn may significantly limit the prescribing and usage of TOUR006;
- a view by payors that TOUR006 presents an unfavorable benefit-risk profile which in turn may significantly limit the reimbursement of TOUR006;
- a requirement to conduct additional post-market studies, including clinical trials;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- lawsuit(s) that results in us being held liable for harm caused to trial participants or other patients; and/or
- reputational injury to us.

Any of these occurrences could materially and adversely affect our business, financial condition, results of operations and prospects.

TOUR006 is a product candidate within the IL-6 inhibitor and IL-6R inhibitor class and may be adversely impacted by results for other members in the class, which could delay, terminate or increase the cost of development of TOUR006, delay or prevent approval by the FDA or other regulatory authorities, lead to a restrictive product label that significantly limits prescribing, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TOUR006.

TOUR006 is a member of the IL-6 inhibitor and IL-6R inhibitor class. There are other products and product candidates within this class that are being developed or commercialized by third parties over which we have no control and for which we do not have any information beyond what is publicly available. It is possible that negative data or information may emerge from one or more of these other products or product candidates related to a limitation or failure of efficacy, safety concern, negative publicity or other issue. Such an occurrence may adversely impact TOUR006 or its perceived product profile and could terminate further development of TOUR006, result in a lack of product approval by the FDA or other regulatory authorities, delay the timing (and/or increase the cost) of a product approval, lead to a restrictive product label that significantly limits prescribing, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TOUR006.

We face significant competition from other biotechnology and pharmaceutical companies targeting autoimmune and cardiovascular disease indications. Our operating results will suffer if we fail to compete effectively.

The markets for autoimmune disease therapies are competitive and are characterized by significant technological development and new product introduction. For example, there are several large and small pharmaceutical companies focused on delivering therapeutics for TED or ASCVD. We anticipate that, if we obtain regulatory approval of TOUR006, we will face significant competition from other approved therapies or drugs that become available in the future for the treatment of our target indications. If approved, TOUR006 may also compete with unregulated, unapproved and off-label treatments. TOUR006 may also face biosimilar competition following loss of regulatory exclusivity and/or patent expiry. Even if an approved biosimilar product is less effective than TOUR006, a less effective biosimilar may be more quickly adopted by physicians and patients than our competing product candidate based upon cost. TOUR006 will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our product, if approved, provides an attractive alternative to existing and other new therapies to gain a share of some patients' discretionary budgets and to gain physicians' attention within their clinical practices. Some of the companies that may offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Such competition could lead to reduced market share for our product candidate and contribute to downward pressure on the pricing of our product candidate, which could harm our business, financial condition, results of operations and prospects.

We expect to face competition from agents with different mechanisms of action in both TED and ASCVD. For example, in January 2020, the FDA approved Amgen Inc.'s (formerly Horizon Therapeutics Public Limited Company) TEPEZZA (teprotumumab), an anti-IGF-1R antibody, for the treatment of TED. In addition, there are multiple other agents in various stages of development for the treatment of TED, including Roche's satralizumab, an anti-IL-6R monoclonal antibody. The first line of treatment for patients with TED is generally immunosuppressive therapy, including high doses of corticosteroids. For ASCVD, several classes of therapies are routinely used, including statins, beta-blockers, ACE inhibitors, ARBs, aspirin, and other anti-platelet agents. Additionally, we are aware of two IL-6 blockers currently being developed for the treatment of ASCVD.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the U.S. and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. Competition may reduce the number and types of patients available to us to participate in clinical trials because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

Due to varying regulatory requirements in certain foreign countries, there are many more products and procedures available for use to treat autoimmune diseases in some international markets than are approved for use in the U.S. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market their products.

Our ability to compete successfully will depend largely on our ability to:

- develop and commercialize therapies in our target indications that are competitive with other products in the market;
- demonstrate through our clinical trials that TOUR006 or any potential future product candidates is differentiated from existing and future therapies;
- attract and retain qualified scientific, product development, manufacturing and commercial personnel;
- obtain patent or other proprietary protection for TOUR006 and any potential future product candidates;
- obtain required regulatory approvals, including approvals to market TOUR006 or any potential future product candidates we develop;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

- have commercial quantities of any approved product manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;
- successfully commercialize TOUR006 or any potential future product candidates, if approved;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- avoid regulatory exclusivities or patents held by competitors that may inhibit our products' entry to the market.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we develop. The inability to compete with existing or subsequently introduced treatments would have an adverse impact on our business, financial condition, results of operations and prospects.

If the market opportunities for TOUR006 and any potential future product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, then our revenue potential and ability to achieve profitability will be adversely affected.

The total addressable market opportunity for TOUR006 and any other potential future product candidates we may develop will ultimately depend upon, among other things, the proportion of patients identified as sensitive to our treatments, acceptance by the medical community, patient access, drug and any related companion diagnostic pricing and their reimbursement.

We intend to initially seek regulatory approval of TOUR006 as therapies for patients with TED and ASCVD. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. In addition, we may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, which may prove to be the wrong choice and may adversely affect our business, financial condition, results of operations and prospects.

We may not successfully identify new product candidates to expand our development pipeline.

The success of our business over the longer term depends upon our ability to identify and validate new potential therapeutics. Efforts to identify new product candidates require substantial technical, financial and human resources, and our methodology may not successfully identify medically relevant potential therapeutics to be developed as product candidates. Moreover, our research and business development efforts may identify molecules that initially show promise yet fail to yield product candidates for clinical development for multiple reasons. For example, potential product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal drug profiles, suboptimal manufacturability or stability, or other characteristics suggesting that they are unlikely to be commercially viable products. Our inability to successfully identify additional new product candidates to advance into clinical trials could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to the Marketing and Commercialization of Our Product Candidates

Even if any of our current or future product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If TOUR006 or any of our potential future product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our current or potential future candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments, including pharmaceutical and nonpharmaceutical interventions;
- the acceptance of our product candidates as front-line treatments for various indications;
- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the size of the target patient population;
- the willingness and ability of the target patient population to try new therapies and adhere or comply with taking such therapy as prescribed and of physicians to prescribe these therapies;
- our ability to offer our products for sale at competitive prices;
- our ability to protect our approved products from generic or biosimilar competition through the use of regulatory exclusivity or patents;
- the convenience and ease of administration compared to alternative treatments;
- the amount of clinical burden upon healthcare professionals or patients related to any additional monitoring or other measures needed in order for patients to initiate and/or continue receiving such products;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

- the strength of marketing, sales and distribution support;
- publicity for our product candidates and competing products and treatments;
- the availability of third-party payor coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups; and
- any restrictions on the use of our products together with other medications.

Even if we obtain approval to market TOUR006 or other potential future product candidates, these products may become subject to unfavorable pricing regulations, reimbursement practices from third-party payors or healthcare reform initiatives in the U.S. and abroad, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. In many regions, including the European Union ("EU"), Japan and Canada, the pricing of prescription drugs is controlled by the government and some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after regulatory approval for the product is granted. Regulatory agencies in those countries could determine that the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit its commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, private health insurers, health maintenance organizations and other organizations, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. In the U.S. and markets in other countries, governments and private insurers closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drug products. We cannot be sure that coverage and reimbursement will be available for any product that we or our partners commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our partners obtain regulatory approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our partners may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign health authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including costs of research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize products and overall financial condition.

Even if we are able to obtain regulatory approval for TOUR006 or any of our future product candidates, we may receive an undesirable label, including, but not limited to, a black boxed warning, which could impede our ability to successfully commercialize TOUR006 or any of our future product candidates or compete successfully.

Even if we receive regulatory approval for any of our product candidates, the FDA may determine that labels for our product candidates may require safety restrictions such as a black boxed warning, warnings and precautions, limitations of use, and/or narrowed and limited indication that may significantly limit the prescribing and usage of TOUR006. Safety restrictions such as a black boxed warning may impede our ability to successfully market and commercialize our product candidates and our ability to compete successfully against our competitors.

Two approved therapies in the IL-6 class, tocilizumab (Actemra®) and sarilumab (Kevzara®) have received black boxed warning for risks of serious infections. Two approved therapies in the IL-6 class, satralizumab (Enspryng®) and siltuximab (Sylvant®) have not. We cannot guarantee or ensure that TOUR006 will not get a black boxed warning or significant safety restrictions on its product labels, if approved.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, the ability to gain market share and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as our estimates, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit development and commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we or our partner commercializes any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for TOUR006 or any potential future product candidates, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician endorsement of our products or expand our business.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and comparable foreign health authorities are lengthy and inherently unpredictable. Our inability to obtain regulatory approval for TOUR006 would substantially harm our business.

Currently, we have no product candidate that has received regulatory approval and TOUR006 or any potential future product candidates is not expected to be commercially available for several years, if at all. The time required to obtain approval from the FDA and comparable foreign health authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the health authorities. In addition, approval policies, regulations or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. It is possible that none of our existing or future product candidates will ever obtain regulatory approval.

TOUR006 or any of our future product candidates could fail to receive regulatory approval from the FDA or a comparable foreign health authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of results of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials to support the submission and filing of a Biologics License Application ("BLA") or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies;
- unfavorable quality review or audit/inspection findings; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign health authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and commercialization, or we may decide to abandon the development program for other reasons. If we obtain approval, regulatory authorities may approve TOUR006 or any potential future product candidates for fewer or more limited indications than we request, may grant accelerated approval or conditional marketing authorization based on a surrogate endpoint and contingent on the successful outcome of costly and time-consuming post-marketing confirmatory clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

We may seek fast track and/or breakthrough therapy designations or priority review for one or more of our product candidates, but we might not receive such designation or priority review, and even if we do, such designation or priority review may not lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates. Even if a product qualifies for such designation or priority review, the FDA may later decide that the product no longer meets the conditions for qualification or may decide that the time period for FDA review or approval will not be shortened.

We may seek fast track and/or breakthrough therapy designations for one or more of our product candidates.

The FDA may issue a fast track designation to a product candidate if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the

FDA designate the biologic as a fast track product at any time during the clinical development of the product. For fast track products, sponsors may have greater interactions with the FDA during product development. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. However, the FDA's PDUFA goal for reviewing a BLA fast track application under the Prescription Drug User Fee Act ("PDUFA") does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Fast track designation and breakthrough therapy designation are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for any such designation, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of such designation may expedite the development or approval process, but does not change the standards for approval. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the BLA is eligible only for standard review.

In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines ("PRIME"), scheme, which provides incentives similar to the breakthrough therapy designation in the U.S.

Sponsors that benefit from PRIME designation are potentially eligible for accelerated assessment of their marketing authorization applications, although this is not guaranteed. If a product for which PRIME designation was granted is the subject of an accelerated assessment, the product may be placed on the market in the EU before our product candidate with a similar therapeutic indication.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operation.

Our failure to obtain health authority approval in foreign jurisdictions would prevent us from marketing TOUR006 or any potential future product candidates outside the U.S.

If we or our partners succeed in developing any products, we intend to market them in the EU and other foreign jurisdictions in addition to the U.S. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., we must secure product pricing and reimbursement approvals before health authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by health authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we fail to obtain approval of TOUR006 or any potential future product candidates by health authorities in another country, we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline. In addition, failure to obtain regulatory approval in one country or region could adversely affect future regulatory approvals in other countries.

Even if TOUR006 and any potential future product candidates receive regulatory approval, they will still face extensive ongoing regulatory requirements, which may result in significant expenses, and may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign health authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. We will be subject to ongoing requirements, including submissions of safety and other post-marketing information, reports, establishment registration and product listing requirements, requirements relating to current cGMP, applicable product tracking and tracing requirements, quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. We will also need to ensure continued compliance by it and/or any future contract manufacturing organizations and CROs for any post-approval clinical trials that we conduct. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Additionally, under the Food and Drug Omnibus Reform Act of 2022, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

Even after approval, the FDA and comparable foreign health authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign health authorities become aware of new safety information after approval of TOUR006 and any potential future product candidates, they may require labeling changes or establishment of a REMS, or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Failure to comply with any related obligations may result in the suspension or withdrawal of an obtained approval and in civil and/or criminal penalties. Receipt of approval for narrower indications than sought, restrictions on marketing through a REMS or similar strategy imposed by the FDA or in an EU member state or other foreign country, or significant labeling restrictions or requirements in an approved label such as a black boxed warning could have a negative impact on our ability to recoup our R&D costs and to successfully commercialize that product, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects. In any event, if we are unable to comply with our post-marketing obligations imposed as part of the marketing approvals in the U.S., the EU, or other countries, our approval may be varied, suspended or revoked, product supply may be delayed and our sales of our products could be materially adversely affected.

In addition, manufacturers of drug substance and drug product and their facilities are subject to continual review and periodic inspections by the FDA and comparable foreign health authorities for compliance with cGMP regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S. If we or the manufacturing facilities for TOUR006 or any potential future product candidates fail to comply with applicable regulatory requirements, or if TOUR006 or any potential future product candidates are found to cause undesirable or unacceptable side effects, a regulatory agency may:

- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labelling or marketing of such products;
- require that we conduct and complete post-marketing studies;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- suspend marketing of, withdraw or modify regulatory approval of or initiate a recall of such product;
- suspend or modify any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or refuse to permit the import or export of products.

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

Advertising and promotion of any product candidate that obtains approval in the U.S. will be heavily scrutinized by the FDA, DOJ, HHS, OIG, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations and civil and criminal sanctions by the government. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties. Additionally, comparable foreign health authorities, public prosecutors, industry associations, healthcare professionals and other members of the public will heavily scrutinize advertising and promotion of any product candidate outside of the U.S.

In the U.S., engaging in the impermissible promotion of our products for off-label uses can subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal FCA, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these FCA lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines in excess of $1 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of TOUR006 or any potential future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU member state laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), as approved by the competent authorities in connection with a marketing authorization. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

Failure to comply with EU, EU member state, and other country laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of a marketing authorization, or with other applicable regulatory requirements, may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties. In addition, directives adopted at the EU level may be implemented differently by individual member states. These directives, and their differing implementations in member states, increase our legal and financial compliance costs and may make some activities more time-consuming and expensive.

Healthcare reform may negatively impact our ability to profitably sell TOUR006 and any potential future product candidates, if approved.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of TOUR006 or any potential future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

For example, on July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede generic drug and biosimilar competition.

Additionally, on August 16, 2022, President Biden signed the IRA, into law, which among other things, (1) directs the HHS, to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA includes certain exemptions to the price negotiation program, including a limited exemption for products with orphan drug designation. This exemption applies only to products with one orphan drug designation that is (i) for a rare disease or condition and (ii) is approved for indication(s) for such rare disease or condition. By limiting price negotiation exemption to products with only one orphan drug designation, the IRA may decrease our interest in pursuing orphan drug designation for our product candidates in multiple indications. The IRA also, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations,

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

although the Medicare drug pricing negotiation program is currently subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive legislation repealing the ACA, such legislation may be reintroduced. Members of Congress have introduced legislation to modify or replace certain provisions of the ACA. It is unclear how these efforts to repeal and/or replace the ACA will impact the ACA and our business. For example, the Tax Cuts and Jobs Act (the "2017 Tax Act"), repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA and IRA may be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures may impact the ACA or IRA, increase the pressure on drug pricing or limit the availability of coverage and adequate reimbursement for TOUR006 and any potential future product candidates, which would adversely affect our business.

There has also been increasing executive, legislative and enforcement interest in the U.S. with respect to drug pricing practices. There have been U.S. congressional inquiries, presidential executive orders and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, in an executive order, the administration of President Biden expressed its intent to pursue certain policy initiatives to reduce drug prices and, in response, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to lower drug prices. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS, Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve the quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product and could seriously harm its future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.
There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenue from TOUR006 and any potential future product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

In many countries outside the U.S., government-sponsored healthcare systems are the primary payors for drugs. With increasing budgetary constraints and/or difficulty in understanding the value of medicines, governments and payors in many countries are applying a variety of measures to exert downward price pressure and we expect that legislators, policy makers and healthcare insurance funds in the EU Member States will continue to propose and implement cost cutting measures. These measures include mandatory price controls, price referencing, therapeutic-reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage, government-mandated price cuts, limitations on coverage of target population and introduction of volume caps.

Many countries implement health technology assessment ("HTA"), procedures that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies. These assessments are increasingly implemented in established and emerging markets. In the EU, Regulation (EU) 2021/2282 on Health Technology Assessment, which will become effective on January 12, 2025, will allow EU member states to use common HTA tools, methodologies and procedures to conduct joint clinical assessments and joint scientific consultations whereby HTA authorities may provide advice to health technology developers. Each EU member state will, however, remain exclusively competent for assessing the relative effectiveness of health technologies and making pricing and reimbursement decisions. Given that the extent to which pricing and reimbursement decisions are influenced by the HTA process currently varies between EU member states, it is possible that our products may be subject to favorable pricing and reimbursement status only in certain EU countries. If we are unable to maintain favorable pricing and reimbursement status in EU member states that represent significant markets, including following periodic review, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. Moreover, in order to obtain reimbursement for our products in some EU member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Efforts to generate additional data for the HTA process will involve additional expenses which may substantially increase the cost of commercializing and marketing our products in certain EU member states.

We cannot predict the likelihood, nature or extent of healthcare reform initiatives that may arise from future legislation or administrative action. However, it is possible that countries will continue taking aggressive actions to seek to reduce expenditures on drugs. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

profitability.

Our relationships with healthcare providers, customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors, will play a primary role in the recommendation and prescription of any product candidates for which we or our partner obtains marketing approval. Our existing and future arrangements with healthcare providers, and any arrangements we enter into with third-party payors and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we currently research, and in the future, market, sell and distribute products for which we or our partner obtain marketing approval. Restrictions under federal and state healthcare laws and regulations that are or may be applicable to us, include the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal FCA or federal civil monetary penalties;

- the FCA imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses, and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, processing, and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal Sunshine Act, as amended, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the HHS information related to “payments or other transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and local laws requiring the registration of pharmaceutical sales representatives; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing; federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and state and foreign laws that govern the privacy and security and other processing of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, disgorgement, additional regulatory oversight, litigation, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Outside the U.S., interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of EU member states, national sunshine rules, regulations, industry self-regulation codes of conduct, and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Changes in tax laws or regulations could adversely affect our business and financial condition.

New tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. For instance, the IRA imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect. In particular, changes in corporate tax rates, the realization of our net deferred tax assets, the taxation of foreign earnings, and the deductibility of expenses under the 2017 Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act or any future tax reform legislation, could have a material impact on the value of our deferred tax assets, result in significant one-time charges, and increase our future tax expenses.

Our ability to use our U.S. net operating loss carryforwards and certain other U.S. tax attributes may be limited.

As of December 31, 2023, we had U.S. federal net operating loss carryforwards of approximately $16.7 million. Under current law, U.S. federal net operating loss carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such net operating loss carryforwards is limited to 80% of taxable income. In addition, our U.S. federal net operating loss carryforwards and tax credits may be subject to limitations under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if we have undergone or undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period. We may have experienced such ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Our net operating loss carryforwards and tax credits may also be impaired or restricted under state law. If we earn taxable income, such limitations could result in increased future income tax liability and our future cash flows could be adversely affected. We have recorded a valuation allowance related to our net operating loss carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the U.S. are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred frequently in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, could have a material adverse effect on our business and share price.

Our management is required to establish and maintain an adequate internal control structure and procedures for financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins our reporting on internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements would not be prevented or detected on a timely basis.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner commensurate with the financial reporting requirements of an SEC registrant. Prior to the completion of the Merger, we were a private company and therefore had not designed or maintained internal controls over financial reporting commensurate with the financial reporting requirements of an SEC registrant.

Our management identified material weaknesses in our internal control over financial reporting primarily related to limited staffing levels within the finance and accounting departments that were not commensurate with our financial accounting and reporting requirements. We had to rely increasingly on outsourced service providers and specialists, without adequate resources to monitor such work and did not maintain appropriate segregation of duties. Based on this, we did not fully implement components of the COSO framework, resulting in material weaknesses either individually, or in the aggregate, in the control environment, risk assessment, control activities, information and communication, and monitoring components.

There have been no historical financial statement adjustments resulting from the above material weaknesses. However, the material weaknesses described above could result in a future misstatement of one or more account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

We are in the process of implementing measures designed to improve our internal control over financial reporting and remediate these material weaknesses. Such measures include, but are not limited to: hiring additional accounting personnel with expertise commensurate with our financial accounting and reporting requirements and that have the requisite experience to oversee outsourced service providers and specialists, upgrading our financial systems and implementing information technology general controls, establishing controls to identify, assess, and respond to the risks of material misstatement, and establishing controls to identify and account for certain non-routine, unusual or complex transactions in a timely fashion. While we are currently in the process of remediating the material weaknesses outlined above, we cannot assure you that these efforts will remediate the material weaknesses in a timely manner, or at all.

We expect to expand our clinical development, manufacturing and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, including significant growth in the number of our employees, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of March 15, 2024, we had 44 full-time employees, including 31 who are engaged in research and development activities, and no part-time employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical product development, business development, regulatory affairs and, if TOUR006 or any potential future product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our choice to focus on multiple therapeutic areas may negatively affect our ability to develop adequately the specialized capability and expertise necessary for operations. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current management team or to continue to attract and retain qualified scientific, technical and business personnel, our business may suffer.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. An important element of our strategy is to take advantage of the R&D and other expertise of our current management. The loss of any one of our executive officers, other senior members of the leadership team, or other key personnel could result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and further commercialization of TOUR006 and any potential future product candidates.

There is intense competition for qualified personnel, including management, in the technical fields in which we operate and we may not be able to attract and retain qualified personnel necessary for the successful research, development and future commercialization, if any, of TOUR006 and any potential future product candidates.

Our Executive Severance and Change in Control Plan with certain of our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us or otherwise, which could harm our financial condition or results.

Certain of our executive officers are parties to our Executive Severance and Change in Control Plan that contains change in control and severance provisions providing for aggregate cash payments for (i) severance and other benefits and (ii) acceleration of vesting of stock options, in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the U.S.

Our business is subject to risks associated with conducting business internationally. Some of our manufacturing and clinical trial sites are located outside of the U.S. Furthermore, if we or any future partner succeeds in developing TOUR006 or any of our potential future product candidates, we intend to market them in the EU and other jurisdictions in addition to the U.S. If approved, we or any future partner may hire sales representatives and conduct physician and patient association outreach activities outside of the U.S. Doing business internationally involves a number of challenges and risks, including but not limited to:

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- multiple, conflicting and changing laws and regulations, such as privacy and data protection regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- delays or interruptions in the supply of clinical trial material resulting from any events affecting raw material or component supply or manufacturing capabilities abroad;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits on our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of inflation and local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political, global geopolitical and economic instability, including geopolitical conflicts such as the ongoing war in Ukraine and hostilities in the Middle East, terrorism and political unrest, disease outbreaks, epidemics and pandemics;
- export control and economic sanctions restrictions, which may restrict or prohibit altogether the sale or supply of certain of our product candidates to certain governments, persons, entities, countries and territories, including those that are the target of comprehensive sanctions, unless there are license exceptions that apply or specific licenses are obtained; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics, and pandemics.

Disease outbreaks, epidemics and pandemics in regions where we may have clinical trial sites or other business operations could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of third-party manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics have negative impacts on our ability to initiate new clinical trial sites, to enroll new patients and to maintain existing patients who are participating in our clinical trials, which may include increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of TOUR006 and any potential future product candidates, if at all. Disease outbreaks, epidemics and pandemics also could adversely impact clinical trial results for TOUR006 or other future potential product candidates, such as by diminishing or eliminating their efficacy or by producing a safety concern, either through direct biological effects or through confounding of the data collection and analysis. This adverse impact could terminate further development of TOUR006, result in a lack of product approval by the FDA or other regulatory authorities, delay the timing (and/or increase the cost) of a product approval by the FDA or other regulatory authorities, lead to a restrictive product label that significantly limits prescribing of an approved product, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TOUR006.

General supply chain issues may be exacerbated during disease outbreaks, epidemics and pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. If our CDMOs are required to obtain an alternative source of certain raw materials and components, for example, additional testing, validation activities and regulatory approvals may be required which can also have a negative impact on timelines. Any associated delays in the manufacturing and supply of drug substance and drug product for our clinical trials could adversely affect our ability to conduct ongoing and future clinical trials of TOUR006 on our anticipated development timelines. Likewise, the operations of our third-party manufacturers may be requisitioned, diverted or allocated by U.S. or foreign government orders. If any of our CDMOs or raw materials or components suppliers become subject to acts or orders of U.S. or foreign government entities to allocate or prioritize manufacturing capacity, raw materials or components to the manufacture or distribution of vaccines or medical supplies needed to test or treat patients in a disease outbreak, epidemic or pandemic, this could delay our clinical trials, perhaps substantially, which could materially and adversely affect our business.

Unfavorable domestic or global economic conditions could adversely affect our business, financial condition, results of operations, or cash flows.

Our results of operations could be adversely affected by general conditions in the domestic or global economy and in the domestic or global financial markets. Political developments impacting government spending and international trade,

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

including current or potential government-imposed sanctions, potential government shutdowns and trade disputes and tariffs, may negatively impact markets and cause weaker macro-economic conditions. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our current and future potential product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, terrorist activity and other events beyond our control, which could harm our business.

Our facilities may experience electrical blackouts as a result of a shortage of available electrical power. Future blackouts, which may be implemented by the local electricity provider in the face of high winds and dry conditions, could disrupt our operations. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disasters and do not have a comprehensive recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business.

We and the third parties with whom we contract use and generate materials that may expose us to material liability.

Our clinical development activities require the use of hazardous materials, chemicals, and radioactive and biological materials. We contract with CDMOs, laboratories and other vendors that are subject to foreign, federal, state and local environmental and health and safety laws and regulations related to such hazardous materials and byproducts. We cannot completely eliminate the risks associated with the use, manufacture, handling, storage and disposal of hazardous materials and waste products, which could cause personal injuries or illnesses, accidental contamination of our raw materials, drug substance, and/or drug product, interruption of our development or manufacturing efforts, environmental damage resulting in costly cleanup, or liabilities under domestic or foreign laws and regulations. Also, we may incur significant costs to ensure our CDMOs, laboratories and other vendors comply with these current or future environmental and health and safety laws and regulations. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our applicable insurance, and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

We may be exposed to litigation, including stockholder litigation, which could have an adverse effect on our business and operations.

We may be exposed to litigation from stockholders, suppliers and other third parties from time to time. Such litigation may have an adverse impact on our business and results of operations or may cause disruptions to our operations. In addition, in the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in the market prices of these companies' common stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty and breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Risks Related to Our Intellectual Property

Our success depends in significant part upon our ability to obtain and maintain intellectual property protection for our products and technologies.

Our success depends in significant part on our ability and the ability of our current or future licensors, licensees, partners and collaborators to establish and maintain adequate intellectual property rights covering the product candidates, products and technologies that we plan to develop. In addition to taking other steps designed to protect our intellectual property, we have applied for, and intend to continue applying for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. However, the patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees, partners or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees, partners or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Pending and future patent applications filed by us or our current or future licensors', licensees', partners' or collaborators' may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products.

We have filed five provisional patent applications in the U.S. to obtain patent rights to our inventions, with claims directed to methods of use, combination therapy and other technologies relating to our product candidates. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, whether the claims of the patents will exclude others from making, using or selling our product or product candidates, or products or product candidates that are substantially similar to us for the same or similar uses. In countries where we have not and do not seek patent protection, third parties may be able to manufacture and sell products that are substantially similar or identical to our products or product candidates without our permission, and we may not be able to stop them from doing so.

Similar to other biotechnology companies, our patent position is highly uncertain and involves complex legal and factual questions. In this regard, we cannot be certain that we or our current or future licensors, licensees, partners or collaborators were the first to make an invention, or the first inventors to file a patent application claiming an invention in our

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

owned or licensed patents or pending patent applications. In addition, even if patents are issued, given the amount of time required for the development, testing and regulatory review of our product candidates, any patents protecting such candidates might expire before or shortly after the resulting products are commercialized. Moreover, the laws and regulations governing patents could change in unpredictable ways that could weaken the ability of us and our current or future licensors, licensees, partners or collaborators to obtain new patents or to enforce existing patents and patents we may obtain in the future. In any event, our patent rights and those of our current or future licensors, licensees, partners or collaborators may not effectively prevent others from commercializing competitive technologies and products.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees, partners or collaborators to perform these activities, which means that these patent applications may not be prosecuted or maintained, and these patents may not be enforced, in a manner consistent with the best interests of our business. If our current or future licensors, licensees, partners or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees, partners or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the U.S. may not be as broad or effective as that in the U.S. and we may be unable to acquire and enforce intellectual property rights outside the U.S. to the same extent as in the U.S., if at all. Accordingly, our efforts, and those of our licensors, licensees, partners and collaborators, to enforce intellectual property rights around the world may be inadequate to obtain a commercial advantage from the intellectual property that we own or license.

We do not currently own or have a license to any issued patents that cover TOUR006, although this product candidate is disclosed and its use claimed in our pending U.S. non-provisional applications. The patent landscape surrounding TOUR006 is crowded, and there can be no assurance that we will be able to secure patent protection that would adequately cover the use of such product candidate, that we will obtain sufficiently broad claims to be able to prevent others from selling competing products for the same or similar uses, or that we will be able to protect and maintain any patent protection that we initially secure.

Any changes we make to TOUR006 to cause it to have what we view as more advantageous properties may not be covered by its existing patent applications, and we may be required to file new patent applications and/or seek other forms of protection for any such altered product candidate.

We are dependent on patents, know-how and technology, both our own and licensed from others. In particular, we are dependent on our license agreements with Pfizer and Lonza. Any termination, or reduction or narrowing, of these licenses could result in the loss of significant rights and could harm our ability to commercialize TOUR006 and any potential future product candidates.

Disputes may also arise between us and our current licensor and future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our product candidates and technologies infringe intellectual property rights of the licensor that are not subject to the licensing agreement;
- our right to sublicense patent rights and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of TOUR006 and any potential future product candidates, and the activities that are deemed to satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- our payment obligations with respect to licensed intellectual property.

Additionally, with regard to the Pfizer License Agreement, if we fail to cure a material breach, Pfizer has customary rights to terminate the Pfizer License Agreement. With regard to the Lonza License Agreement, Lonza has the right to terminate the Lonza License Agreement in the event of a change of control or if we contest the secret or substantial nature of the licensed know-how.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current or future licensing arrangements on acceptable terms, or if Pfizer or Lonza terminates their respective license agreement, we may be unable to successfully develop and commercialize the affected product candidates and technologies.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as it is for intellectual property that we own, which are described herein. If we, Pfizer, Lonza or any other current or future licensors fail to adequately protect any licensed intellectual property, our ability to commercialize products could suffer.

We may be unable to obtain intellectual property rights or technologies necessary to develop and commercialize TOUR006 or any potential future product candidates.

Several third parties are actively researching and seeking and obtaining patent protection in the fields of TED and Cardiovascular Disease, and there are issued third-party patents and published third-party patent applications in these fields. The patent landscape around our product candidate is complex, and we are aware of several third-party patents and patent applications containing claims directed to compositions-of-matter, methods of use and related subject matter, some of which pertain, at least in part, to subject matter that might be relevant to our product candidate. However, we may not be aware of all third-party intellectual property rights potentially relating to our product candidate and technologies, since patent applications are not published until eighteen months after their initial filing date. Therefore, we cannot know whether certain unpublished patent applications, if ultimately issued, may recover relevant uses of TOUR006 or other products of ours.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Depending on what patent claims ultimately issue and how courts construe the issued patent claims, as well as the ultimate formulation and methods of use of our product candidate, we may need to obtain a license to practice the technology claimed in such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing rights to third-party intellectual property rights we have, we might be unable to develop and commercialize TOUR006 or any potential future product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We could lose the ability to continue the development, manufacture, and commercialization of TOUR006 or any potential future product candidates if we breach any license agreement with service providers and vendors related to those product candidates.

Our commercial success depends upon our ability, and the ability of our current and future licensors, licensees, partners and collaborators, to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. A third-party may hold intellectual property rights, including patent rights, that are important or necessary to the development of our product candidates and products. As a result, we are a party to a number of technology and patent licenses that are important to our business, and we expect to enter into additional licenses in the future. If we fail to comply with the obligations under these agreements, including payment and diligence obligations, our licensors may have the right to terminate these agreements. In the event of a termination of these agreements, we may not be able to develop, manufacture, market or sell any product that is covered by the intellectual property rights that are the subject of these agreements or to engage in any other activities necessary to our business that require the freedom-to-operate afforded by the agreements, or we may face other penalties under the agreements. For example, in addition to the license agreements with Pfizer and Lonza described above we are party to license agreements with multiple vendors, under which we license technology used to produce TOUR006. We are required to obtain prior consent from some of these vendors to grant sub-licenses under these agreements. Therefore, these vendors may prevent us from granting sub-licenses to third parties, which could affect our ability to use certain desired manufacturers in order to manufacture our current and future product candidates. In the event of a termination of any of our license agreements, our ability to manufacture or develop any product candidates covered by these agreements may be limited or halted unless we can develop or obtain the rights to technology necessary to produce these product candidates.

Any of the foregoing could materially adversely affect the value of the product or product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in having to negotiate new or amended agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful, and have a material adverse effect on the success of our business.

Third parties may infringe patents or misappropriate or otherwise violate intellectual property rights owned or controlled by us or our current or future licensors, licensees, partners or collaborators. In the future, it may be necessary to initiate legal proceedings to enforce or defend these intellectual property rights, to protect trade secrets or to determine the validity or scope of intellectual property rights that are owned or controlled by us or our current or future licensors, licensees, partners or collaborators. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results.

If we or our current or future licensors, licensees, partners or collaborators initiate legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us or our current or future licensors, licensees, partners or collaborators is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent does not cover the technology in question. An adverse result in any litigation proceeding could put one or more of the patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third parties may initiate legal proceedings against us or our current or future licensors, licensees, partners or collaborators to challenge the validity or scope of intellectual property rights we own or control. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of patents owned or controlled by us or our current or future licensors, licensees, partners or collaborators. These proceedings can be expensive and time-consuming, and many of our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us. Accordingly, despite our efforts, we or our current or future licensors, licensees, partners or collaborators may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have rights to, particularly in countries where the laws may not protect those rights as fully as in the U.S.

There is a risk that some of our confidential information could be compromised by disclosure during litigation because of the substantial amount of discovery required. Additionally, many foreign jurisdictions have rules of discovery that are different than those in the U.S. and that may make defending or enforcing our patents extremely difficult. There also could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

Third-party pre-issuance submission of prior art to the USPTO, opposition, derivation, revocation, reexamination, inter partes review or interference proceedings, or other pre-issuance or post-grant proceedings, as well as other patent office proceedings or litigation in the U.S. or other jurisdictions brought by third parties against patents or patent applications owned or controlled by us or our current or future licensors, licensees, partners or collaborators, may affect the inventorship, priority, patentability or validity of these patents or patent applications. An unfavorable outcome could leave our technology or current and future product candidates without patent protection and allow third parties to commercialize its technology or product candidates without payment to us. Additionally, potential licensees, partners or collaborators could be dissuaded from collaborating with us to license, develop or commercialize current or future product candidates if the breadth or strength of protection provided by our patents and patent applications is threatened. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and we may distract our management and other employees.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of the third-party intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Third parties may initiate legal proceedings against us or our current or future licensors, licensees, partners or collaborators alleging that we infringe their intellectual property rights. Alternatively, we may initiate legal proceedings to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences,

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

revocations, reexaminations, inter partes review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. In this regard, we are aware of several third-party patents and patent applications containing claims directed to compositions-of-matter, methods of use and related subject matter, some of which pertain, at least in part, to subject matter that might be relevant to TOUR006. These proceedings can be expensive and time-consuming, and many of our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us.

In addition, we may be subject to claims that we or our employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Likewise, we and our current and future licensors, licensees, partners and collaborators may be subject to claims that former employees, partners, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor or an owner of rights via assignment from such an inventor or co-inventor. Litigation may be necessary to defend against these claims.

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity in favor of the granted third-

party patent. This is a high burden, requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim.

An unfavorable outcome in any such proceeding could require us and our current or future licensors, licensees, partners or collaborators to cease using the related intellectual property or developing or commercializing the product or product candidate, or to attempt to license rights to us from the prevailing party, which may not be available on commercially reasonable terms, or at all. Additionally, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing TOUR006 or any potential future product candidates or force us to cease some of our business operations, which could materially harm our business.

Reliance on third parties requires us to share our proprietary information, which increases the possibility that such information will be misappropriated or disclosed.

Because we rely on third parties for aspects of development, manufacture, or commercialization of TOUR006 and our technologies, or if we collaborate with third parties for the development or commercialization of our future product candidates and technologies, we must, at times, share proprietary information with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share confidential information increases the risk that such information become known by our competitors, is inadvertently incorporated into the technology of others, or is disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how, a competitor's discovery of our know-how or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors, and consultants to publish data potentially relating to our know-how. Despite our efforts to protect our know-how, we may not be able to prevent the unauthorized disclosure or use of our technical know-how by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. 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 collaborators, scientific advisors, employees, contractors, and consultants who are 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. Moreover, if confidential information that is 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 third-party illegally obtained and is using our proprietary information, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect proprietary information.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S., even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing its or its licensors' inventions in all countries outside the U.S., even in jurisdictions where we or our licensors pursue patent protection. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop its own competing products and, further, may export otherwise infringing products to territories where it has patent protection, but enforcement is not as strong as that in the U.S.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

In Europe, starting from June 1, 2023, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the Unified Patent Court (the "UPC"). This is a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

of any litigation. It is our initial belief that the UPC, while offering a cheaper streamlined process, has potential disadvantages to patent holders, such as making a single European patent vulnerable in all jurisdictions when challenged in a single jurisdiction.

We, our CROs, our CDMOs, service providers, our current and potential future partners or other third parties upon which we rely, could experience a security incident, system disruption or failure, data loss, cyberattack, or similar event that could compromise our systems and data (or those of the third parties upon whom we rely), result in material disruptions to our business operations, lead to regulatory investigations or actions, litigation, fines and penalties, affect our reputation, revenue or profits, or otherwise harm our business.

We collect, store, receive, transmit, generate, use, transfer, disclose, make accessible, protect, secure, dispose, share and otherwise process (collectively, process) proprietary, confidential and otherwise sensitive information, including personal information (such as health-related data of clinical trial participants and employee information), in the course of our business. Our technology systems and the information and data processed and stored by us or by third parties upon whom we rely (e.g., research collaborators, partners, CROs, CDMOs, contractors, consultants and other third parties), are vulnerable to a variety of evolving online and offline threats that could result in security incidents, including unauthorized, unlawful, or accidental loss, damage, corruption, access, use, encryption, acquisition, disclosure, misappropriation, or other compromise of such systems or data. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to operate our business and may have other adverse effects.

We and third parties on which we rely face threats that are constantly evolving and growing in frequency, sophistication, and intensity. For example, these threats may include (without limitation) malware (including as a result of advanced persistent threat intrusions), viruses, worms, software vulnerabilities and bugs, software or hardware failures, hacking, denial of service attacks, social engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing), credential harvesting, ransomware, personnel misconduct or errors, credential stuffing, telecommunications failures, loss or theft of devices, data or other information technology assets, attacks enhanced or facilitated by AI, earthquakes, fires, floods and other similar threats. Threats such as ransomware attacks, for example, are becoming increasingly prevalent and severe, and attackers are increasingly leveraging multiple attack methods to extort payment from victims, such as data theft and disabling systems. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Security incidents may result from the actions of a wide variety of actors with a wide range of motives and expertise, including traditional hackers, hacktivists, our personnel, or the personnel of the third parties we work with, sophisticated nation-states, nation-state-supported actors, and organized criminal threat actors. During times of war and other major conflicts, we, the third party upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

Certain functional areas of our workforce work remotely on a full- or part-time basis outside of our corporate network security protection boundaries or otherwise utilize network connections, computers and devices outside of our premises or network, which imposes additional risks to our business, including increased risk of industrial espionage, phishing, and other cybersecurity attacks, and unauthorized dissemination of proprietary or confidential information, including personal information, any of which could have a material adverse effect on our business. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

In addition, we rely on third parties to operate critical business systems and process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions. We also rely on third parties, including CROs, clinical trial sites and clinical trial vendors, to process sensitive data as part of our research activities. Our ability to monitor these third parties is limited, and these third parties may not have adequate information security measures in place and may expose us to cyberattacks and other security incidents. Supply-chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. If

our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

We may be required to, or we may choose to, expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect our information systems and data (including against security incidents), particularly where required by applicable data privacy and security laws or regulations or industry standards. While we have implemented security measures and processes designed to protect against security incidents, we cannot assure you that these security measures that we or our service providers implement will be effective in preventing security incidents, disruptions, cyberattacks, or other similar events. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, detect and remediate, all such vulnerabilities including on a timely and effective basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident. A security incident could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data. If our information systems or data, or that of the third parties on which we rely, are compromised or were perceived to be compromised, it could interrupt our operations, disrupt our development programs and have a material adverse effect on our business, financial condition and results of operations. For example, the loss or corruption of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of TOUR006, to analyze clinical trial samples and to conduct clinical trials, and security incidents experienced by these third parties could have a material adverse effect on our business. Actual or perceived security incidents affecting us or the third parties we rely on or partner with could result in substantial remediation costs and expose us to litigation (including class claims), regulatory enforcement action (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and/or oversight, fines, penalties, indemnification obligations, negative publicity, reputational harm, monetary fund diversions, diversion of management attention, interruptions in our operations (including availability of data), financial loss and other liabilities, and harms. Additionally, such incidents may trigger data privacy and security obligations requiring us to notify relevant stakeholders, such as individuals, regulators, and others, or take other remedial or corrective actions, and may subject us to liability. Such disclosures and remediation efforts may be costly, and related requirements or the failure to comply with them could lead to adverse consequences.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from claims related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could adversely affect our reputation, business, financial condition and results of operations.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our personnel's, or vendors' use of generative AI technologies.

We are subject to rapidly changing and increasingly stringent foreign and domestic laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations relating to privacy, data protection and information security. The restrictions imposed by these requirements or our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation (including class claims) and mass arbitration demands, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits , loss of customers or sales, and other adverse business consequences .

We may process proprietary, confidential and sensitive information, including personal information (including health-related data), which subjects us to numerous evolving and complex data privacy and security obligations, including various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and other obligations that govern the processing of such information in connection with our business.

Outside the U.S., an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation, ("EU GDPR") and the United Kingdom's GDPR, ("UK GDPR") and the Swiss Federal Data Protection Act, ("Swiss FADP") impose strict requirements for processing personal information, and may apply to our processing of personal information from clinical trial participants and other individuals located in the European Economic Area ("EEA"), the UK, or Switzerland and, if TOUR006 or any potential future product candidates are approved, our possible commercialization of those products in the EEA, the UK, or Switzerland (as applicable). Companies that violate the GDPR can face private litigation, regulatory investigations and enforcement actions, prohibitions on data processing, other administrative measures, reputational damage and fines of up to the greater of 20 million Euros under the EU GDPR/17.5 million pounds sterling under the UK GDPR, or 4% of their worldwide annual revenue, in either case, whichever is greater. The EU and UK GDPR require us to, among other things: give detailed disclosures about how we collect, use and share personal information; contractually commit to data protection measures in our contracts with vendors; maintain appropriate data security measures; notify regulators and affected individuals of certain personal data breaches; meet privacy governance and documentation requirements; and honor individuals' data protection rights, including their rights to access, correct and delete their personal information.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the U.S or other countries. Certain jurisdictions have enacted data localization restrictions or laws and regulations restricting cross-border transfers of personal information. In particular, regulators and courts in the EEA, the UK, and Switzerland have significantly restricted the transfer of personal information to the U.S. and other countries that have not been declared "adequate" for data protection purposes by a relevant governmental authority. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently mechanisms that may be used to transfer personal information from the EEA, the UK, or Switzerland to the U.S. in compliance with European data protection laws, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement/Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the EU-U.S. Data Privacy Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to transfer personal data to the U.S.

If we are unable to implement a valid compliance mechanism for cross-border transfers of personal information, or if the requirements for a legally-compliant transfer are too onerous, we will face increased exposure to significant adverse consequences, including substantial fines, regulatory actions, as well as injunctions against the export and processing of personal information from the EEA, UK, Switzerland, or other countries that implement cross-border data transfer restrictions. Our inability to import personal information from the EEA, UK or Switzerland or other countries may also restrict or prohibit our clinical trial activities in those countries; limit our ability to collaborate with CROs, service providers, contractors and other companies subject to laws restricting cross-border data transfers; require us to increase our data processing capabilities in other countries at significant expense and may otherwise negatively impact our business operations. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the U.S, are subject to increased scrutiny from regulators, individual litigants, and activist groups. We may also become subject to new laws in the EEA and other jurisdictions that regulate cybersecurity and non-personal data, such as data collected through the internet of things. Depending on how these laws are interpreted, we may have to make changes to our business practices and products to comply with such obligations.

Additionally, other countries have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

Privacy and data security laws in the U.S. at the federal, state and local level are increasingly complex and changing rapidly. For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, at the state level, the privacy and data protection landscape is changing rapidly. Many states have enacted comprehensive privacy laws —including California, Virginia, Colorado, Connecticut, and Utah — that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. If these laws apply or were to apply to us, the exercise of these rights may impact our business. Certain state laws also impose stricter requirements for processing sensitive personal information such as obligating covered businesses to conduct data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA"), applies to personal data of consumers, business representatives, and employees who are California residents, and requires certain businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines for noncompliance of up to $7,500 per intentional violation, and a limited private right of action in connection with certain data breaches. While the CCPA and other comprehensive state privacy laws contain exemptions for certain personal information processed in connection with clinical trials, we may process other personal information that is or may become subject to these laws. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. The evolving patchwork of differing state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including from third-party litigation and regulatory investigations, enforcement, fines, and penalties.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

We publish privacy policies and provide notices regarding data privacy and security. If these policies or notices are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security (and individuals' data privacy expectations) are quickly changing in an increasingly stringent fashion and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Monitoring, preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems and practices and to those of any third parties that process personal information on our behalf. In addition, these obligations may require us to change aspects of our business model (such as where we conduct clinical trials). Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations.

If we (or third parties upon which we rely) fail, or are perceived to have failed, to address or comply with data privacy, protection and security obligations, we could face significant consequences, including (without limitation): government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-related claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and/or imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

Risks Related to Our Common Stock

The market price of our common stock is expected to be volatile, and the market price of the common stock may drop.

The market price of our common stock could be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials and preclinical studies of our current and future potential product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- failure of us to achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our current and future potential product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if we issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our current and future potential product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to IL-6 inhibitor and IL-6R inhibitor product candidates, including with respect to other such products on the market;
- the introduction of technological innovations or new therapies that compete with the products and services of ours; and
- period-to-period fluctuations in our financial results.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event resulting from rising interest rates, inflation, global geopolitical conflict, or other macroeconomic conditions could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

Provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may discourage any takeover attempts stockholders may consider favorable, and may lead to entrenchment of management.

Provisions of our amended and restated certificate of incorporation, as amended, and amended and restated bylaws could delay or prevent changes in control or changes in management without the consent of the board of directors. These provisions will include the following:

- 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 board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board;
- a requirement that no member of our board 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 charter; 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, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We will also be subject to the anti-takeover provisions contained in Section 203 of the DGCL. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to any provisions of the DGCL, our certificate of incorporation or bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The exclusive forum provision does not apply to actions arising under the Exchange Act. The amended and restated bylaws will also provide that the federal district courts of the U.S will be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. The provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in the certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our data, including intellectual property, confidential information that is proprietary, strategic, or competitive in nature, data related to our manufacturing, clinical development and clinical trials, and personal data (collectively, "Information Systems and Data").

The cybersecurity function within the Company, which comprises, in part, our internal information technology ("IT") and legal personnel who work with external service providers (including an external chief information security officer ("CISO") and certain information security vendors) helps identify, assess and manage the Company's cybersecurity threats and risks. Together with, and under the direction of, our Head of IT, our cybersecurity function identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods. These methods include, for example, manual and automated tools, subscriptions to services that identify cybersecurity threats and actors, evaluations of our and our industry's risk profile, evaluations of threats reported against us, work with third parties who conduct threat assessments, and conducting vulnerability assessments.

Depending on the environment and data, we implement and maintain various technical, physical, and organizational measures, processes, standards, and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: strategies related to incident detection, incident response, disaster recovery and business continuity; assessing security risk and the results of gap assessments conducted by third parties of certain Company systems; encrypting certain data; maintaining certain access and physical security controls; engaging in asset, system, and vendor management; conducting personnel training on cybersecurity risks; and maintaining cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, (1) our Head of IT works with the Chief Business Officer and General Counsel, and other Company management as appropriate to prioritize our risk management processes and mitigate cybersecurity threats that may be more likely to lead to a material impact to our business; and (2) our executive leadership team evaluates material risks from cybersecurity threats against our overall business objectives and reports to the Audit Committee of the Tourmaline Board of Directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example, our external CISO, professional services firms (including legal counsel), threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, and managed cybersecurity service providers.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, contract development and manufacturing organizations, supply chain resources, laboratories, and clinical database and data management providers and consultants. We have vendor security assessment processes such as assessing cybersecurity risks associated with our use of certain vendors for our clinical trials, manufacturing, and related operations. Our vendor risk management processes, depending upon the type of vendor, include conducting vendor risk assessments, submitting security questionnaires, conducting audits, and imposing contractual obligations related to information security and data protection. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management processes may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including ***Risks Related to Government Regulation,Risks Related to Intellectual Property,*** *and risk factors entitled* ***"We, our CROs, our CDMOs, service providers, our current and potential future partners or other third parties upon which we rely, could experience a security incident, system disruption or failure, data loss, cyberattack, or similar event that could compromise our systems and data (or those of the third parties upon whom we rely), result in material disruptions to our business operations, lead to regulatory investigations or actions, litigation, fines and penalties, affect our reputation, revenue or profits, or otherwise harm our business"*** *and* ***"We are subject to rapidly changing and increasingly stringent foreign and domestic laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations relating to privacy, data protection and information security. The restrictions imposed by these requirements or our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation (including class claims) and mass arbitration demands, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, loss of customers or sales, and other adverse business consequences***."

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The Audit Committee of the Tourmaline Board of Directors is responsible for overseeing the Company's cybersecurity risk management processes, including oversight of mitigating risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our: (1) Chief Business Officer and General Counsel, who reports to the Chief Executive Officer; (2) Head of IT, who reports to the Chief Business Officer and General Counsel; and (3) Assistant General Counsel, who also reports to the Chief Business Officer and General Counsel.

Our Head of IT is responsible for engaging and managing external consultants and vendors related to cybersecurity, hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, developing an information and cybersecurity strategy roadmap, and communicating key priorities to relevant personnel. Our Head of IT works with our Chief Business Officer and General Counsel, along with our Chief Financial Officer and Assistant General Counsel, to prepare appropriate budgets, prepare for cybersecurity incidents, review and approve cybersecurity processes, and review security assessments and other security-related reports. Our

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Head of IT has 18 years of experience in IT and information security functions. Our external CISO has 25 years of experience in IT and information security functions, as well as advanced degrees and certain certificates pertaining to information security.

Our cybersecurity incident response strategy is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including Head of IT and/or Chief Business Officer and General Counsel. Our Head of IT works with our external CISO, managed risk detection and response vendors, the Company's legal team and external counsel, and other third-party consultants and vendors to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response strategy includes reporting to the Audit Committee of the Board of Directors for certain cybersecurity incidents.

The Audit Committee receives reports from, as appropriate depending upon given circumstances, the Head of IT, the Chief Business Officer and General Counsel, or their designees concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The Audit Committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

We lease approximately 3,274 square feet of office space at 27 West 24th Street, Suite 702, New York, New York, 10010, which serves as our corporate headquarters. The lease expires on February 28, 2026. We believe that our current facilities are adequate to meet our ongoing needs, and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. For additional information regarding legal proceedings, see Note 13 "Commitments and Contingencies—Litigation" to our audited financial statements included elsewhere in this Report. We believe there are currently no pending legal proceedings to which we or our property are subject that could have a material adverse effect on our financial position, results of operations or cash flows.

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.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. Our future ability to pay cash dividends on our capital stock may also be limited by the terms of any future debt or preferred securities or future credit facility.

Stockholders

Our common stock is listed on The Nasdaq Global Select Market under the symbol "TRML". As of March 15, 2024, there were 44 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Recent Sales of Unregistered Securities

Not applicable.

Purchases of Equity Securities by the Issuer and Affiliated Parties

None.

Item 6. Reserved.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

In this section, we discuss our financial condition, changes in financial condition and results of our operations for the year ended December 31, 2023 compared to the year ended December 31, 2022. For a discussion and analysis comparing our results for the year ended December 31, 2022 to the period from September 17, 2021 (inception) to December

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

31, 2021, see Exhibit 99.2 to our Current Report on Form 8-K filed with the SEC on January 24, 2024. References to "we", "our" and "the Company" refers to Legacy Tourmaline for periods prior to the closing of the Merger, and to Tourmaline Bio, Inc. (formerly Talaris Therapeutics, Inc.) for all other periods, as the context requires.

Overview

We are a late-stage clinical biotechnology company focused on developing transformative medicines that dramatically improve the lives of patients with life-altering immune and inflammatory diseases. In doing so, we seek to identify and develop medicines that have the potential to establish new standards-of-care in areas of high unmet medical need.

Our initial product candidate is TOUR006, a fully human monoclonal antibody that selectively binds to interleukin-6 ("IL-6"), a key proinflammatory cytokine involved in the pathogenesis of many autoimmune and inflammatory disorders.

The anti-IL-6 and anti-IL-6 receptor ("IL-6R") antibody class ("IL-6 class") has over two decades of clinical and commercial experience treating over a million patients with a variety of autoimmune and inflammatory diseases. To date, four anti-IL-6 or anti-IL-6R antibodies have been approved in the United States ("U.S."). These four anti-IL-6 or anti-IL-6R antibodies together generated more than $3.5 billion in global sales in 2023.

TOUR006 is a long-acting anti-IL-6 antibody which we believe has best-in-class properties including a high binding affinity to IL-6, long half-life, and low observed immunogenicity. These characteristics may allow TOUR006 to achieve substantial IL-6 pathway suppression with relatively low amounts of drug exposure, potentially enabling delivery in a convenient, low volume, infrequently administered, subcutaneous injection.

We are pursuing two strategic paths for TOUR006, the first of which we refer to as "FcRn+". Neonatal Fc receptor ("FcRn") inhibitors have emerged as a novel therapeutic class to treat autoantibody-driven diseases. However, FcRn inhibitors have significant limitations including suboptimal efficacy, lack of durable efficacy, high burden dosing profile, and an unknown long-term safety profile. We believe TOUR006 has the potential to be a superior therapy for a wide range of autoantibody-driven diseases, compared to FcRn inhibitors. We have identified thyroid eye disease ("TED") as our beachhead indication for our FcRn+ strategy. TED is an autoimmune disease characterized by autoantibody-mediated activation of the tissues surrounding the eye, causing inflammation and disfigurement which can be sight-threatening in severe cases. We have identified a substantial body of published clinical observations characterizing the beneficial off-label use of currently marketed IL-6 pathway inhibitors, namely Actemra® (tocilizumab), an anti-IL-6R monoclonal antibody, in reducing inflammation, eye-bulging, and levels of autoantibodies in patients with TED. However, no formal, industry-sponsored development effort studying the IL-6 class for the treatment of TED has been completed to date.

We are currently evaluating TOUR006 in a pivotal Phase 2b trial in first-line TED, which we refer to as the spiriTED trial. We initiated the spiriTED trial in September 2023 and expect to report topline data in the first half of 2025. Further, we expect to commence a pivotal Phase 3 trial of TOUR006 in first-line TED in 2024, with topline data expected to be reported in 2026.

Our second strategic path is cardiovascular inflammation. We believe TOUR006 has the potential to transform the care of high-risk cardiovascular patients by targeting key inflammatory pathways driving cardiovascular disease. Atherosclerotic cardiovascular disease ("ASCVD") is a leading cause of death globally. Preventing major adverse cardiovascular events ("MACE"), such as death, nonfatal myocardial infarction or nonfatal stroke, has the potential to significantly reduce global cardiovascular disease burden. IL-6 has been identified as a promising drug target for addressing the risk of MACE in ASCVD, and multiple external Phase 3 cardiovascular outcome trials investigating IL-6 blockade are ongoing. We believe that TOUR006 potentially offers a meaningfully enhanced product profile to these competitor programs with a potential for subcutaneous dosing once every three months. As previously announced in January 2024, we have reached alignment with the U.S. Food and Drug Administration ("FDA") on the ASCVD clinical development program, including a Phase 2 trial evaluating the reduction of C-reactive protein ("CRP"), a validated biomarker for inflammation, with quarterly and monthly dosing of TOUR006 in patients with elevated cardiovascular risk. In March 2024, the FDA cleared our Investigational New Drug application ("IND") related to our ASCVD clinical development program. The Phase 2 trial is targeted to commence in the first half of 2024, and we expect to report topline data in the first half of 2025. Pending successful initiation and completion, positive results from the Phase 2 trial are expected to position us to be ready in 2025 to commence a pivotal Phase 3 trial for TOUR006 in cardiovascular disease.

We also plan to identify additional indication opportunities for TOUR006. In addition, we continue to evaluate new in-licensing and acquisition opportunities for assets that we believe have standard-of-care changing potential for patients with immune and inflammatory diseases.

Since our inception, we have funded our operations primarily through the sale of convertible preferred stock, the Merger and Pre-Merger Financing Transaction, each as defined and outlined further below, and the January 2024 Offering as defined and described below. As of December 31, 2023, we had total cash, cash equivalents and investments of $203.0 million, which excludes subsequent proceeds received from the January 2024 Offering.

Due to our significant research and development expenditures, we have accumulated substantial losses since our inception, including net losses of $42.1 million and $19.7 million for the years ended December 31, 2023 and 2022, respectively. In addition, we had an accumulated deficit of $62.1 million as of December 31, 2023. We expect to incur additional losses in the future as we expand our research and development activities.

Recent Developments

January 2024 Public Offering

On January 25, 2024, we entered into an underwriting agreement with Jefferies LLC, Piper Sandler & Co., Guggenheim Securities, LLC and Truist Securities, Inc. (collectively, the "Underwriters") relating to the public offering of 4,615,384 shares of our common stock at a public offering price of $32.50 per share (the "January 2024 Offering"). We granted the

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Underwriters a 30-day option to purchase up to 692,307 shares of common stock at the public offering price, less underwriting discounts and commissions, which was exercised by the Underwriters in full on January 25, 2024. The January 2024 Offering closed on January 29, 2024, and we issued and sold a total of 5,307,691 shares of common stock to the Underwriters for net proceeds of $161.3 million after deducting underwriting discounts and offering costs.

Merger with Talaris and Pre-Merger Financing Transaction

On June 22, 2023, Legacy Tourmaline entered into an Agreement and Plan of Merger (the "Merger Agreement") with Talaris Therapeutics, Inc. ("Talaris") and Terrain Merger Sub, Inc., a direct, wholly owned subsidiary of Talaris ("Merger Sub"). On October 19, 2023, we completed the merger with Talaris in accordance with the terms of the Merger Agreement, pursuant to which, among other matters, Merger Sub merged with and into Legacy Tourmaline, with Legacy Tourmaline surviving as a wholly owned subsidiary of Talaris (such transaction, the "Merger"). The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Immediately prior to the effective time of the Merger, Talaris effected a 1-for-10 reverse stock split of its common stock (the "Reverse Stock Split").

Pursuant to the terms of the Merger Agreement, immediately prior to the effective time of the Merger, each share of Legacy Tourmaline's Series A convertible preferred stock was converted into a share of Legacy Tourmaline common stock. At the effective time of the Merger, Talaris issued an aggregate of approximately 15,877,090 shares of common stock to Legacy Tourmaline's stockholders, based on an exchange ratio of 0.07977 shares of common stock for each share of Legacy Tourmaline's capital stock, including those shares of Legacy Tourmaline's common stock issued upon the conversion of the Series A convertible preferred stock and those shares of Legacy Tourmaline's common stock issued in the Pre-Merger Financing Transaction (as described below), resulting in approximately 20,336,741 shares of common stock of the combined company being issued and outstanding immediately following the effective time of the Merger. In connection with the Merger, the Amended and Restated Investor Rights Agreement, dated May 2, 2023, between Tourmaline and certain of its stockholders (the "Tourmaline IRA") and the Amended and Restated Investors' Rights Agreement, dated September 22, 2020, between Talaris and certain of its stockholders (the "Talaris IRA"), were terminated.

Immediately prior to the completion of the Merger, pursuant to a securities purchase agreement, Legacy Tourmaline issued 4,092,035 shares (as effected by the exchange ratio described above) of Legacy Tourmaline's common stock in a private placement for gross proceeds of $75.0 million (the "Pre-Merger Financing Transaction").

In connection with the completion of the Merger, Talaris changed its name from "Talaris Therapeutics, Inc." to "Tourmaline Bio, Inc.," Legacy Tourmaline changed its name to "Tourmaline Sub, Inc.," and we began conducting the business conducted by Legacy Tourmaline.

Series A Convertible Preferred Stock Financing Extension

On May 2, 2023, we entered into a Series A Preferred Stock Purchase Agreement (the "Series A Extension") with various entities and individuals for the purchase of additional shares of Series A convertible preferred stock. On May 2, 2023, we authorized the issuance and sale of 92,200,000 shares of our Series A convertible preferred stock at a price of $1.00 per share for total gross proceeds of $92.2 million. In addition, we issued 8,823,529 additional shares of our Series A convertible preferred stock to Pfizer Inc. ("Pfizer") pursuant to an anti-dilution provision within the Pfizer License Agreement. See "License Agreements—Pfizer License Agreement" included below for further details on this arrangement.

License Agreements

Pfizer License Agreement

On May 3, 2022, we entered into the Pfizer License Agreement with Pfizer, pursuant to which we obtained an exclusive, sublicensable, royalty-bearing, worldwide right to use and license under certain know-how for the development, commercialization and manufacture of PF-04236921 (now known as TOUR006) and any pharmaceutical or biopharmaceutical product incorporating such compound for the treatment, diagnosis, or prevention of any and all diseases, disorders, illnesses and conditions in humans and animals. In consideration for the license and other rights we received under the Pfizer License Agreement, we paid Pfizer an upfront payment of $5.0 million of cash and granted Pfizer 7,125,000 Series A preferred units of Tourmaline Bio, LLC, the predecessor of Legacy Tourmaline (which subsequently converted to 7,125,000 shares of our Series A preferred stock) at $1.00 per share for aggregate consideration of approximately $7.1 million to us, with such shares representing 15% of all of our capital stock on a fully-diluted basis at the time of issuance.

As additional consideration for the license, we are obligated to pay Pfizer up to $128.0 million upon the achievement of specific development and regulatory milestones. We are also obligated to pay Pfizer up to $525.0 million upon the first achievement of specific sales milestones. We are obligated to pay Pfizer a marginal royalty rate in the low double digits (less than 15%), subject to specified royalty reductions. The royalty term, on a Product-by-Product and country-by-country basis, begins on the first commercial sale of such Product and expires upon the later of twelve years following the date of the first commercial sale or the expiration of regulatory exclusivity protecting such Product. In the event we complete a Significant Transaction (as defined in the Pfizer License Agreement), we will be obligated to pay Pfizer a one-time payment in the low-eight digits (up to $20.0 million); the amount of such payment is based on the timing of the transaction.

The Pfizer License Agreement originally contained an anti-dilution provision that allowed Pfizer to maintain a 15% interest in us on a fully-diluted basis unless and until certain thresholds are met, whereupon the anti-dilution provision would no longer apply. Upon consummation of the Series A Extension on May 4, 2023, we issued 8,823,529 shares of our Series A convertible preferred stock to Pfizer pursuant to this anti-dilution provision. Subsequent to the issuance of these additional shares of Series A convertible preferred stock, the anti-dilution provision is no longer in force and effect. Such shares of Series A convertible preferred stock were converted into 1,272,214 aggregate shares of our common stock upon consummation of the Merger outlined above.

The Pfizer License Agreement expires, unless earlier terminated, upon the last to expire royalty term, and at such time our license will become fully paid-up, irrevocable and perpetual. Each party has the right to terminate the Pfizer License Agreement in its entirety in the event of a material breach if the breaching party fails to cure such breach within a specified cure period after written notice. Pfizer may terminate the Pfizer License Agreement on a Product-by-Product and country-by-country basis if we have materially breached

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

our diligence obligations. Each party has the right to terminate the Pfizer License Agreement in the event of a bankruptcy event. We have the right to terminate the Pfizer License Agreement at our convenience in its entirety or on a country-by-country basis (except with respect to the major market countries identified therein) upon a specified notice period based on the time of the termination.

As of December 31, 2023, we do not owe any amounts under the Pfizer License Agreement and no royalties or milestone payments have been paid to date under the Pfizer License Agreement.

Lonza License Agreement

In May 2022, we entered into the Lonza License Agreement with Lonza Sales AG ("Lonza"), pursuant to which we obtained a worldwide, non-exclusive, sublicensable (subject to certain conditions) license under certain know-how to market, sell, offer for sale, distribute, import and export products containing TOUR006 ("Product"). We also obtained a non-exclusive, sublicensable (subject to certain conditions) license under certain licensed know-how to use, develop, and manufacture (including have manufactured in accordance with the terms of the Lonza License Agreement) the Product at premises approved by Lonza.

In consideration for the licenses and other rights we received under the Lonza License Agreement, we are obligated to pay Lonza a royalty in the low-single digits on the Net Sales (as defined in the Lonza License Agreement) of Product, and the royalty rate shall be based on the entity manufacturing the drug substance contained in the Product. Royalties are payable on a Product-by-Product basis and a country-by-country basis for ten years following the first commercial sale of a Product

in a certain country. In addition, we may owe Lonza a low six figure annual fee following the occurrence of a specified event depending on which entity manufactures the drug substance, all as specified in the Lonza License Agreement.

The Lonza License Agreement shall continue in full force and effect unless terminated in accordance with the terms of the Lonza License Agreement. Each party shall have the right to terminate the Lonza License Agreement in its entirety in the event of a breach by the other party if the breach is irremediable or the breaching party fails to cure such breach within a specified cure period after written notice. Each party shall have the right to terminate the Lonza License Agreement in the event of a bankruptcy event of the other party. We shall have the right to terminate the Lonza License Agreement at its convenience upon a specified notice period. Lonza shall have the right to terminate the Lonza License Agreement in the event of a change of control of our company or we contest the secret or substantial nature of the licensed know-how.

As of December 31, 2023, no royalty payments or other fees have been paid under the Lonza License Agreement.

Macroeconomic Considerations

Worldwide economic conditions remain uncertain and we continue to monitor the impact of macroeconomic conditions, including those related to COVID-19, global geopolitical conflicts such as the war in Ukraine and hostilities in the Middle East and rising inflation rates. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed.

Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience increases in the near future on our operating costs, including our labor costs and research and development costs, due to supply chain constraints, consequences associated with COVID-19, global geopolitical conflicts, and employee availability and wage increases, which may result in additional stress on our working capital resources.

Financial Operations Overview

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts are successful and result in commercialization of TOUR006 or any future product candidates or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, payments from such collaboration or license agreements or a combination thereof.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of consulting fees for medical and manufacturing advisory services related to our clinical trials, costs related to manufacturing material for preclinical studies and other costs incurred for the development of our product candidates. Research and development expenses include:

- personnel-related costs, including salaries, bonuses, benefits and stock-based compensation expenses for employees engaged in research and development functions;
- payments to third parties in connection with the research and development of TOUR006 and any future product candidates, including agreements with third parties such as contract research organizations ("CROs"), clinical trial sites and consultants;
- the cost of manufacturing products for use in our clinical and preclinical studies, including payments to contract development and manufacturing organizations ("CDMOs") and consultants; and
- payments to third parties in connection with the preclinical development of TOUR006 and any future product candidates, including for outsourced professional scientific development services, consulting research and collaborative research.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Research and development expenses also include the cost of in-process research and development ("IPR&D") assets purchased in asset acquisition transactions. IPR&D assets are expensed as incurred if the asset has not yet received regulatory approval and does not have an alternative future use. Acquired IPR&D payments are immediately expensed in the period in which they are incurred and have historically included upfront payments as well as shares of our capital stock. Research and development costs incurred after the acquisition of IPR&D assets are expensed as incurred.

We recognize research and development expenses in the periods in which they are incurred. Our internal resources, employees and infrastructure are not directly tied to any one research or drug discovery program and are typically deployed across multiple programs. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We utilize CROs for research and development activities and CDMOs for manufacturing activities and we do not have our own laboratory or manufacturing facilities. Therefore, we have no material facilities expenses attributed to research and development.

Product candidates in later stages of development generally have higher development costs than those in earlier stages. As a result, management expects that our research and development expenses will increase substantially over the next several years as we advance our product candidate and any future product candidates into larger and later-stage clinical trials, works to discover and develop additional product candidates, seeks to expand, maintain, protect and enforce our intellectual property portfolio, and hires additional research and development personnel.

The successful development of TOUR006 and any future product candidates is highly uncertain, and management does not believe it is possible at this time to accurately project the nature, timing and estimated costs of the efforts necessary to complete the development of, and obtain regulatory approval for, TOUR006 and any future product candidates. To the extent TOUR006 and any future product candidates continue to advance into larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. The duration, costs and timing of development of TOUR006 and any future product candidates are subject to numerous uncertainties and will depend on a variety of factors, including:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to activate clinical sites and recruit, screen, and enroll eligible patients;
- the number of patients that participate in the trials;
- the length of hospitalization of patients in clinical trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing TOUR006 and any future product candidates;
- the phase of development of TOUR006 and any future product candidates;
- the efficacy and safety profile of TOUR006 and any future product candidates;
- the timing and progress of nonclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;

- raising necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development program and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance and drug product for use in production of TOUR006 and any future product candidates;
- the development of commercial scale manufacturing and distribution processes for TOUR006 and any future product candidates;
- establishing and maintaining agreements with third-party manufacturers for commercial manufacturing, if we pursue a third party manufacturing strategy outside of the U.S, and if TOUR006 and any future product candidates are approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the U.S and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- our ability to successfully recruit and retain employees;
- the commercialization of TOUR006 and any future product candidates, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of TOUR006 and any future product candidates, if approved, by patients, the medical community and third-party payors;
- evolving standards of care in target indications;
- competition with other marketed or development-stage products; and
- a continued acceptable safety profile of our therapies following approval, if and when approved.

A change in the outcome of any of these variables with respect to the development of TOUR006 or any future product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for our product candidate or any future product candidates.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries, bonuses, benefits, and stock-based compensation expense for personnel in executive, finance, and administrative functions; professional fees for legal, consulting, accounting, and audit services; recruiting costs; travel expenses; technology costs; and other allocated expenses. General and administrative expenses also include corporate facility costs, including rent, utilities, depreciation, and maintenance. We recognize general and administrative expenses in the periods in which they are incurred.

We expect that our general and administrative expenses will increase in the future to support our continued research and development activities, pre-commercial preparation activities for our product candidate and any future product candidates and, if any product candidate receives marketing approval, commercialization activities. Going forward, we expect that we will incur additional expenses associated with being a public company, including expenses related to accounting, audit, legal, regulatory, public company reporting and compliance, director and officer insurance, investor and public relations, and other administrative and professional services.

Other Income, Net

Other income, net is primarily comprised of interest and investment income on our cash equivalents and short-term investments.

Results of Operations

Comparison of Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for years ended December 31, 2023 and 2022:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**$ Change**
Operating expenses:			
Research and development	$ 32,368	$ 17,526	$ 14,842
General and administrative	13,041	2,175	10,866
Total operating expenses	45,409	19,701	25,708
Loss from operations	(45,409)	(19,701)	(25,708)
Other income, net	3,285	—	3,285
Net loss	$ (42,124)	$ (19,701)	$ (22,423)

Research and Development Expenses

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Research and development expenses increased by $14.8 million from $17.5 million for the year ended December 31, 2022 to $32.4 million for the year ended December 31, 2023. The increase in research and development expenses was primarily attributable to the following:

- $7.1 million of increased employee compensation costs, including $2.3 million of increased stock-based compensation expense, attributable to an increase in headcount as well as stock-based compensation expense associated with the Merger;
- $7.9 million of increased chemistry, manufacturing, and controls expenses associated with the production of drug substance and drug product for use in our clinical trials; and
- $1.8 million of increased clinical trial expenses related to our spiriTED trial.

These increases were partially offset by a decrease of $3.3 million in costs incurred related to the Pfizer License Agreement. We recognized $8.8 million of research and development expense during the year ended December 31, 2023 related to the issuance of additional shares to Pfizer under the anti-dilution provision outlined above and $12.1 million of expense during the year ended December 31, 2022 related to the acquisition of IPR&D under the Pfizer License Agreement.

General and Administrative Expenses

General and administrative expenses increased by $10.9 million from $2.2 million for the year ended December 31, 2022 to $13.0 million for the year ended December 31, 2023. The increase in general and administrative expenses was primarily attributable to the following:

- $5.8 million of increased employee compensation costs, including $3.3 million of increased stock-based compensation expense, attributable to an increase in headcount as well as stock-based compensation expense associated with the Merger;
- $2.3 million of increased consulting expenses, including recruiting, commercial planning and other services;
- $1.0 million of increased legal expenses; and
- $0.8 million of increased accounting, audit and tax fees.

Other Income, Net

Other income, net during the year ended December 31, 2023 was primarily comprised of interest and investment income on our cash equivalents and short-term investments. No such interest and investment income was recognized during the year ended December 31, 2022 as we did not yet have cash equivalents or investments.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidate and any future product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and potentially manufacturing for our product candidate and any future product candidates to support commercialization and providing general and administrative support for our operations, including the cost associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

Since our inception, we have funded our operations primarily with outside capital, including proceeds from the sale of Series A convertible preferred stock, the Pre-Merger Financing Transaction and the January 2024 Offering, having raised aggregate gross proceeds of approximately $359.7 million as of the date hereof. However, we have incurred significant recurring losses, including net losses of $42.1 million and $19.7 million for the years ended December 31, 2023 and 2022, respectively. In addition, we have an accumulated deficit of $62.1 million as of December 31, 2023.

As of December 31, 2023, we had $203.0 million in cash, cash equivalents and investments. Based upon our current operating plan, we believe that our working capital will be sufficient to fund our operating expenses and capital expenditure requirements into 2027. We have based this estimate on assumptions that may prove to be wrong, incorrect, and we could exhaust may use all of our available capital resources sooner than we expect. In addition,

Future Capital Requirements

Since inception, we have not generated any revenue from product sales. Management does not expect to generate any meaningful product revenue unless and until we obtain regulatory approval of and commercializes our resource requirements could materially change depending on product candidate and any future product candidates, and management does not know when, or if, that will occur. Until we can generate significant revenue from product sales, if ever, we will continue to require substantial additional capital to develop our product candidate and any future product candidates and fund operations for the outcome of foreseeable future. Management expects our expenses to increase in connection with our ongoing strategic review process, including activities as described in greater detail below. We are subject to all the extent we identify and enter into any potential strategic transaction. Because our resource requirements could materially change depending on risks incident in the outcome development of our ongoing strategic alternative review process, we are unable to estimate the exact amount of our working capital requirements.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Developing pharmaceutical new biopharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may harm our business.

In order to complete the necessary data or results required to obtain marketing approval for development of TOUR006 and any future product candidates or generate revenue from and to build the sale of any product candidate for which we may obtain sales, marketing approval. In addition, our and distribution infrastructure that management believes will be necessary to commercialize product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain require substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. Until capital. Accordingly, until such time if ever, as that we can generate substantial a sufficient amount of revenue from product revenue, we expect sales or other sources, if ever, management expects to finance our cash needs seek to raise any necessary additional capital through a combination of private or public equity offerings, royalty-based financings, or debt financings, loans or other capital sources, which could include income from collaborations, strategic alliances, and partnerships or other marketing, distribution, licensing or licensing other strategic arrangements with third parties. parties, or from grants. To the extent that we raise additional capital through the sale of equity financings or convertible debt securities, the ownership interest may of our stockholders will be materially or could be diluted, and the terms of such these securities could may include liquidation or other preferences that adversely affect your the rights as a of our common stockholder. stockholders. Debt financing royalty-based financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit limiting or restricting our ability to take specified specific actions, such as incurring including restricting our operations and limiting our ability to incur liens, issue additional debt, making capital expenditures pay dividends, repurchase our own common stock, make certain investments or declaring dividends. engage in merger, consolidation, licensing, or asset sale transactions. If we raise funds capital through royalty-based financings, collaborations, strategic alliances or marketing, distribution or licensing partnerships, and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may

not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. themselves. We may be unable to raise additional capital from these sources on favorable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S and worldwide resulting from recent bank failures, other general macroeconomic conditions (including the ongoing impacts of COVID-19) and otherwise. The failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research, product development or future commercialization efforts. We may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Management cannot provide assurance that we will ever generate positive cash flow from operating activities.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, timing, progress, results, and costs of researching and developing TOUR006, and conducting larger and later-stage clinical trials;
- the scope, timing, progress, results, and costs of researching and developing other product candidates that we may pursue;
- the costs, timing, and outcome of regulatory review of TOUR006 and any future product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for TOUR006 and any future product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of our product candidate and any future product candidates receive marketing approval;
- the cost and timing of attracting, hiring, and retaining skilled personnel to support our operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish, maintain, and derive value from collaborations, partnerships or other marketing, distribution, licensing, or other strategic arrangements with third parties on favorable terms, if at all;
- the extent to which the profile of marketed or development stage competing products affects the clinical and commercial potential of our products;
- the extent to which we acquire or in-licenses other product candidates and technologies, if any; and
- the costs associated with operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of TOUR006 and any of our future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional capital to meet the

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

capital requirements associated with such operating plans.

As described above, if we progress TOUR006 through clinical development and, if approved, commercialize it, we may be required to pay Pfizer up to $128.0 million upon the achievement of specific development and regulatory milestones and up to $525.0 million upon the first achievement of specific sales milestones. Upon commercialization, we would also be obligated to pay Pfizer and Lonza royalties on product sales, as outlined in more detail above.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
(in thousands)	**2023**	**2022**
Net cash (used in) provided by:		
Operating activities	$ (28,081)	$ (6,458)
Investing activities	3,840	(5,068)
Financing activities	156,720	19,850
Net increase in cash, cash equivalents and restricted cash	$ 132,479	$ 8,324

Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was $28.1 million, compared to net cash used in operating activities of $6.5 million for the year ended December 31, 2022. Net cash used in operating activities increased by $21.6 million primarily due to the overall growth in our operations, including headcount.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the year ended December 31, 2023 was $3.8 million, compared to net cash used in investing activities of $5.1 million for the year ended December 31, 2022. This net change of $8.9 million was primarily due to maturities of short-term investments during the year ended December 31, 2023 as compared to a $5.0 million upfront payment made to Pfizer during the year ended December 31, 2022 related to the Pfizer License Agreement.

Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was $156.7 million, compared to net cash provided by financing activities of $19.9 million for the year ended December 31, 2022. Net cash provided by financing activities increased by $136.9 million primarily due to $91.8 million of net cash proceeds received from the Series A Extension as well as $70.5 million of net cash proceeds received from the Pre-Merger Financing Transaction during the year ended December 31, 2023. During the year ended December 31, 2022 net cash provided by financing activities was primarily attributable to $20.0 million of net cash proceeds received from an earlier sale of Series A convertible preferred stock.

Contractual Obligations and Commitments

Research and Development and Manufacturing Agreements

We enter into agreements with certain vendors for the provision of goods and services, which includes manufacturing services with CDMOs and development and clinical trial services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not separately presented.

Pfizer License Agreement

In May 2022, we entered into the Pfizer License Agreement. We have not included milestone or royalty payments or other contractual payment obligations under the Pfizer License Agreement as the timing and amount of such obligations are unknown or uncertain and are contingent upon the initiation and successful completion of future activities. See "*—License Agreements—Pfizer License Agreement*" included above for further details on the Pfizer License Agreement.

Critical Accounting Policies and Critical Accounting Estimates

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP") in the United States. principles. The preparation of our the financial statements and related disclosures requires us management to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe management believes 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 Management evaluates estimates and assumptions on an ongoing a periodic basis. Our actual results may differ from these estimates under different assumptions or conditions.

estimates.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

While our significant accounting policies are described in more detail in Note 2 the notes to our consolidated financial statements appearing at the end of elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Contract Costs Expenses

Expenditures relating to research and Accruals

development are expensed as incurred. Research and development expenses include external expenses incurred under arrangements with third parties; consulting costs; salaries and personnel-related costs, including non-cash stock-based compensation expense; license fees to acquire in-process research and development that does not have an alternative future use and other expenses. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Where contingent milestone payments are due to third parties under research and development or license agreements, the milestone payment obligations are expensed when the related milestone events are achieved.

As part of the process of preparing our the consolidated financial statements, we are required to estimate our accrued research and development expenses. expenses as of each balance sheet date. 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. This process involves reviewing open contracts, and purchase orders, communicating with our applicable internal 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 the 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 financial statements based on facts and circumstances known to us at that time. cost. We periodically confirm the accuracy of these our estimates with the our service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with clinical development activities; and
- CROs and investigative sites in connection with pre-clinical, non-clinical, and human clinical trials

We base the expense recorded related to external research and development on our estimates The majority of the our service providers invoice monthly in arrears for services received and efforts expended pursuant to quotes and contracts with multiple CROs that supply, conduct and manage clinical trials on our behalf. performed or when contractual milestones are met. The financial terms of agreements with these agreements service providers are subject to negotiation, vary from contract to contract contract-to-contract and may result in uneven payment flows. There may In circumstances where amounts have been paid in excess of costs incurred, we record a prepaid expense.

Stock-Based Compensation

We account for stock-based payments in accordance with ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). This guidance requires all stock-based payments, including grants of stock options and restricted common units, to be instances recognized as expense in which payments made the consolidated statements of operations and comprehensive loss based on their grant date fair values. For stock options granted to employees, non-employees and members of our vendors will exceed Board of Directors for their services on the level Board of services provided and result in a prepayment of the expense. In accruing service fees, Directors, 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 the amount of prepaid expenses 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 grant date there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation Expense

We measure stock-based awards granted to employees, directors, and nonemployees based on their fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. For stock-based awards with service-based vesting conditions, we recognize compensation expense using the straight-line method. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including model. For stock-based payments subject to service-based vesting conditions, we recognize stock-based compensation expense equal to the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. The grant date fair value of each option stock-based payment on a straight-line basis over the requisite service period.

Prior to purchase common stock award is being publicly-traded, we estimated on the date of grant based on the date fair value of our its common stock on that same date.

Determination of the Fair Value of Common Stock

As there had been no public market for our common stock prior to the closing of our IPO, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant with input from management, considering our most

recently available third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent using an appropriate valuation through the date of the grant. These independent third-party valuations of our equity instruments were performed contemporaneously with identified value inflection points. Our common stock valuation was prepared using the option-pricing method ("OPM"), which

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

used a market approach to estimate our enterprise value, as well as the probability-weighted expected return method ("PWERM") and the hybrid method, a combination of OPM and PWERM. The assumptions underlying these valuations were highly complex and subjective and represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could be materially different.

These third-party valuations were performed methodology, in accordance with the guidance outlined in framework of the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Technical Practice Aid, *Valuation of Privately-Held-Company Privately-Held Company Equity Securities Issued as Compensation. We account for equity-based compensation in accordance with ASC 718, Compensation-Stock Compensation* ("ASC 718"). In accordance with ASC 718, compensation cost is measured Each valuation methodology included estimates and assumptions that required our judgment. These estimates and assumptions included a number of objective and subjective factors, including external market conditions, guideline public company information, the prices at estimated fair value and is included as compensation expense over the vesting period during which service is provided in exchange for the award. Our common stock valuation was prepared using the OPM, which used a market approach to estimate our enterprise value.

The OPM treats common stock and we sold convertible preferred stock as call options on to third parties in arms' length transactions, the total equity value rights and preferences of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the senior to our common stock has value if the funds available for distribution to stockholders exceed the value of the liquidation preferences at the time and the likelihood of achieving a liquidity event such as a strategic sale an initial public offering or merger. The common stock is modeled as a call option on sale. Significant changes to the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value rather than, as assumptions used in the case of a regular option, a comparison with a per share stock price. Thus, common stock is considered to be a call option with a claim on the enterprise valuations could result in different fair values at an exercise price equal each valuation date.

In addition to the remaining value immediately after the preferred stock liquidation preference is paid. The OPM uses the Black-Scholes option pricing model to price the call options. This model defines the fair value of securities as functions of the current fair value of a company and uses assumptions such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities.

The PWERM is a scenario-based analysis that estimates the value per share of common stock based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes considered by the Company, as well as the economic and control rights of each share class. The OPM, PWERM and/or the hybrid methods were used for our January 2021 valuations.

The assumptions used to determine the fair values of stock options granted to employees and directors during the years ended December 31, 2022 and December 31, 2021, are presented as follows:

	December 31,	
	2022	2021
Fair value of common stock	$1.53-16.56	$5.72-17.00
Dividend yield	—%	—%
Volatility	82.29%-88.41%	80.6%-91.25%
Risk-free interest rate	1.46%-4.23%	0.50%-1.33%
Expected term (years)	5.38-6.25	6.25

Once a public trading market for our common stock was established in connection with the completion of our IPO, our board of directors no longer have to estimate the grant date fair value of our common stock, in connection with our accounting the Black-Scholes option pricing model requires the input of certain subjective assumptions, including (i) the calculation of expected term of the stock-based payment, (ii) the risk-free interest rate, (iii) the expected stock price volatility and (iv) the expected dividend yield. We use the simplified method as prescribed by SEC Staff Accounting Bulletin No. 107 to calculate the expected term for granted stock options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. We determine the risk-free interest rate based on a treasury instrument whose term is consistent with the expected term of the stock options. Because we have only been publicly-traded for a short period of time, there is a lack of company-specific historical and other such awards implied volatility data. Accordingly, we may grant, base our estimates of expected volatility on the historical volatility of a group of publicly-traded companies with similar characteristics to ourself, including stage of product development and therapeutic focus within the life sciences industry. Historical volatility is calculated over a period of time commensurate with the expected term of the stock-based payment. We use an assumed dividend yield of zero as the fair value of we have never paid dividends on our common stock, nor do we expect to pay dividends on our common stock in the foreseeable future.

We account for forfeitures of all stock-based payments when such forfeitures occur.

Recently Issued and Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and it establishes additional disclosure requirements related to credit risks. For available-for-sale debt securities with expected credit losses, this standard now determined based requires allowances to be recorded instead of reducing the amortized cost of the investment. This guidance was originally effective for annual reporting periods beginning after December 15, 2020 and interim periods within fiscal years beginning after December 31, 2021, and early adoption was permitted. In November 2019, the FASB

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

subsequently issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, whereby the effective date of this standard was deferred to annual reporting periods beginning after December 15, 2022, including interim periods within those annual reporting periods, and early adoption is still permitted. Accordingly, we adopted this new standard effective January 1, 2023, and the adoption of ASU 2016-13 did not have an impact on the quoted market price of consolidated financial statements.

Recent Accounting Pronouncements - Yet to be Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This guidance is intended to improve reportable segment disclosure requirements through enhanced disclosures as well as clarify that entities with a single reportable segment are subject to new and existing segment reporting requirements. This guidance is effective for annual periods in fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. Entities must apply this guidance on a retrospective basis. We are currently evaluating this guidance to determine the impact it may have on our common stock. consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*

. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the United States and in foreign jurisdictions. This guidance is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively, and early adoption is permitted. We are currently evaluating this guidance to determine the impact it may have on our consolidated financial statements.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, the Jumpstart Our Business Startups Act of 2012 (" ("JOBS Act" Act") was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" ("EGC" ("EGC") can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (" ("Securities Act" Act"), for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we it may adopt certain new or revised accounting standards early to the extent allowed by the standard.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700.0 million $700.0

million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates is less than $700 million $700.0 million and our annual revenue was less than $100 million $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million $250.0 million or (ii) our annual revenue was less than $100 million $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our financial statements appearing at the end of this Annual Report.

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

Our primary exposure

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to market risk relates to changes in interest rates. As of December 31, 2022 and 2021, we had cash and cash equivalents of $13.7 million and $18.6 million, respectively. As of December 31, 2022 and 2021, we had marketable securities of $167.6 million and $225.4 million, respectively. Our exposure to interest rate sensitivity is affected by changes in provide the general level of U.S. interest rates. If market interest rates were to increase immediately and uniformly by 100 basis points, or one percentage point, the net fair value of our interest sensitive marketable securities would not experience a material change in fair market value.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

All of our employees and our operations are currently located in the United States. We have, from time to time, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period between the date that transactions are initiated, and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe we do not have a material exposure to foreign currency risk.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2022 or 2021.

information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

Our consolidated

The financial statements together with the reports required to be filed pursuant to this Item 8 are appended to this Report. An index of our independent registered public accounting firms, appear beginning on page F-1 those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report for the years ended December 31, 2022 and December 31, 2021.

Report.

Item 9. Changes in and Disagreements with With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Company

Our management, with the participation and supervision of our Chief Executive Officer and our Interim Chief Financial Officer, has established evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023, the end of the period covered by this Report. Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the under the Exchange Act) are designed to ensure provide reasonable assurance that information required to be disclosed by a company in the reports that the Company 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, and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has 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, mean controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our a company's management, including our Chief Executive Officer its principal executive and Chief Financial Officer, principal financial officers, as appropriate to allow timely decisions regarding required disclosures.

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 judgement in evaluating the cost-benefit relationship of possible controls and procedures. disclosure.

Based on the their evaluation, of our disclosure controls and procedures as of December 31, 2022 our the Chief Executive Officer and Interim Chief Financial Officer have concluded that as of such date, our disclosure controls and procedures were not effective at as of December 31, 2023 because of the material weaknesses in our internal control over financial reporting described below.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

We identified material weaknesses in the design and operating effectiveness of our internal control over financial reporting primarily related to limited staffing levels within the finance and accounting departments that were not commensurate with our financial accounting and reporting requirements. We had to rely increasingly on outsourced service providers and specialists, without adequate resources to monitor such work and did not maintain appropriate segregation of duties. Based on this, we did not fully implement components of the COSO framework, resulting in material weaknesses either individually, or in the aggregate, in the control environment, risk assessment, control activities, information and communication, and monitoring components.

There were no adjustments that resulted from the above material weaknesses. However, these material weaknesses could, in the future, result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Remediation Plans

We have taken and will continue to take certain measures to remediate the material weaknesses described above.

As of December 31, 2023, we have continued with the remediation steps that were initiated in the third quarter of 2023, including, but not limited to, hiring additional accounting personnel with expertise commensurate with our financial accounting and reporting requirements and that have the requisite experience to oversee outsourced service providers and specialists, upgrading our financial systems and implementing information technology general controls, establishing controls to identify, assess, and respond to the risks of material misstatement, and establishing controls to identify and account for certain non-routine, unusual or complex transactions in a timely fashion.

The elements of our remediation plans can only be accomplished over time, and we can offer no assurance level.

Management's Annual that these initiatives will ultimately have the intended effects. As management continues to evaluate and work to improve our internal control over financial reporting, management may determine it is necessary to take additional measures to address the material weaknesses. These material weaknesses will not be considered remediated unless and until such time as management designs and implements effective controls that operate for a sufficient period of time and concludes, through testing, that these controls are effective. Until the controls have been operating for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively, the material weaknesses described above will continue to exist. Management is monitoring the progress of the remediation plan and reporting regularly to the audit committee of the board of directors on the progress and results of the remediation plan, including the identification, status and resolution of internal control deficiencies. We can provide no assurance that the measures we have taken and plan to take in the future will remediate the material weaknesses identified or that any additional material weakness or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future these controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our financial statements.

Management's Report on Internal Control Over over Financial Reporting

and Attestation Report of the Registered Public Accounting Firm

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, as such term is defined in Rules Rule 13a-15(f) and 15d-15(f) of under the Exchange Act. Because of its inherent limitations, Our internal control over financial reporting may is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

This Report does not prevent or detect misstatements. Also, projections include a report of any evaluation management's assessment regarding internal control over financial reporting as allowed by the SEC for reverse acquisitions between an issuer and a private operating company when it is not possible to conduct an assessment of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

Our management utilized the criteria established private operating company's internal control over financial reporting in the Internal Control – Integrated Framework (2013) issued by period between the Committee of Sponsoring Organizations consummation date of the Treadway Commission ("COSO") reverse acquisition and conducted an evaluation the date of management's assessment of internal control over financial reporting (see Question 215.02 of the effectiveness SEC Division of Corporation Finance's Regulation S-K Compliance & Disclosure Interpretations).

As discussed elsewhere in this Report, we completed the Merger on October 19, 2023, pursuant to which the Company acquired Legacy Tourmaline. Post Merger, the design of our internal control over financial reporting has required and will continue to require significant time and resources from management and other personnel to complete ongoing integration efforts. As a result, management was unable, without incurring unreasonable effort or expense, to complete an assessment of our internal control over financial reporting as of December 31, 2022 December 31, 2023. Based on the results of our evaluation under that framework, management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Attestation Report of the Registered Public Accounting Firm

This report Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting.

reporting as required by Section 404(c) of the Sarbanes Oxley Act of 2002. Because we qualify as an emerging growth company under the JOBS Act, management's report was not subject to attestation by our independent registered public accounting firm.

Changes in Internal Control over Over Financial Reporting

There has been were no change changes in our internal controls 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 that occurred during the fiscal year quarter ended December 31, 2022 December 31, 2023, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

On March 30, 2023, the compensation committee adopted the Company's Amended and Restated Executive Severance and Change in Control Plan (the "Severance Plan"), under which certain of the Company's executives, including its chief executive officer, chief financial officer and other named executive officers (collectively, the "Participants"), may become eligible to receive severance benefits upon certain qualifying terminations.

As amended, the Severance Plan clarifies that a "change in control" shall include any merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power and outstanding stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction.

In addition, the Severance Plan was amended to provide that the "change in control period" means the period of time commencing three months prior to the date of public announcement of any transaction that would constitute a change in control ("Announcement Date") or approval by the Board of a complete liquidation or dissolution of the Company (but no earlier than April 1, 2023) and ending 12 months after the Announcement Date, except for certain participants who have not been employed by the Company for at least 12 months preceding the Announcement Date.

The foregoing is only a brief description of certain terms of the Severance Plan and does not purport to be a complete description of its terms, and is qualified in its entirety by reference to the Severance Plan that is filed as Exhibit 10.5 to this Annual Report on Form 10-K and incorporated by reference herein.

Not applicable.

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

Inspections

Not applicable.

PART III

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

The information required under by this item Item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement information set forth in the sections titled "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors," "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance" appearing in the 2024 Proxy Statement that we will be filed with the SEC file in connection with our 2023 2024 Annual Meeting of Stockholders not later than 120 days after and is incorporated by reference herein.

Information regarding our Code of Conduct (the "Code of Conduct") required by this item will be contained in our 2024 Proxy Statement under the close caption "Information Regarding the Board of the Company's fiscal year ended December 31, 2022.

Directors and Corporate Governance – Code of Conduct," and is hereby incorporated by reference. We have adopted a the Code of Business Conduct and Ethics for applicable to all of our directors, employees, officers and employees as required by Nasdaq governance rules and as defined by applicable SEC rules. Stockholders may locate a copy directors. The audit committee of our board of directors is responsible for overseeing the Code of Business Conduct and Ethics on our website at www.talaristx.com or request a copy without charge from:

Talaris Therapeutics, Inc.
Attention: Investor Relations
93 Worcester St.
Wellesley, MA 02481

We will post to our website must approve any waivers of the Code of Conduct for executive officers and directors. If we make any substantive amendments to the Code of Business Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the amendment or waiver on our

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

website. The Code of Conduct is available on our website at www.tourmalinebio.com. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and Ethics, and any waivers that are required you should not consider it to be disclosed by the rules a part of either the SEC or Nasdaq.

this Report.

Item 11. Executive Compensation.

The information required under by this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement Item 11 will be filed with contained in the SEC sections entitled "Executive Compensation" and "Non-Employee Director Compensation" appearing in the 2024 Proxy Statement that we will file in connection with our 2023 2024 Annual Meeting of Stockholders not later than 120 days after the close of the Company's fiscal year ended December 31, 2022.

and is incorporated by reference herein.

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

The information required under by this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement Item 12 will be filed with contained in the SEC sections entitled "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans" appearing in the 2024 Proxy Statement that we will file in connection with our 2023 2024 Annual Meeting of Stockholders not later than 120 days after the close of the Company's fiscal year ended December 31, 2022.

and is incorporated by reference herein.

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

The information required under by this item Item 13 will be contained in the sections entitled "Transactions with Related Persons" and "Independence of the Board of Directors" appearing in the 2024 Proxy Statement that we will file in connection with our 2024 Annual Meeting of Stockholders and is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2022.

herein.

Item 14. Principal Accounting Fees and Services.

Information about aggregate fees billed to us

The information required by our independent principal accountant, Deloitte & Touche LLP (PCAOB ID No. 34), located in Boston, Massachusetts,this Item 14 will be presented contained in the section entitled "Ratification of Selection of Independent Auditors" appearing in the 2024 Proxy Statement that we will file in connection with our definitive proxy statement to be filed with the SEC with respect to our 2023 2024 Annual Meeting of Stockholders under the caption "Audit Committee Matters — Principal Accounting Firm Fees" and is incorporated herein by reference.

reference herein.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) **Financial Statements.**

For a list of the financial statements included herein, see See Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, which is incorporated into this Item item by reference.

(a)(2) Financial Statement Schedules.

(2) Financial statement All schedules have been omitted because they are either not required or not applicable or because the required information is included given in the consolidated financial statements Consolidated Financial Statements or the notes Notes thereto.

(a)(3) Exhibits.

10.8+	Tourmaline Bio, Inc. 2022 Equity Incentive Plan

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

	and forms of award agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-4 (File No. 333-273335), filed with the SEC on July 20, 2023).	
10.5#*10.9+	Tourmaline Bio, Inc. 2023 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K (File No. 001-40384), filed with the SEC on October 20, 2023).	Amended and Restated Executive Severance and Change

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

10.6#*10.10+	Second Amended Forms of Option Grant Notice, Option Agreement

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

and Restated Non-Employee Director Compensation Policy

Exhibit Number	Description of Exhibit		
Exhibit2.1 Number	Agreement and Plan of Merger and Reorganization, dated as of June 22, 2023, by and among Talaris Therapeutics, Inc., Terrain Merger Sub, Inc. and Tourmaline Bio	10.7	Lease Agree

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

	Voluntaire Bio, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-40384), filed with the SEC on June 22, 2023).	Description
3.1		Third Amended and Restated Certificate of Incorporation of the Registrant
		Amendment to the Registrant's Third Amended and Restated Certificate of Incorporation
		Notice of Louisville, dated

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

the Registrant, as amended through October 19, 2023 (incorporated by reference as of November 1, 2018, as amended on July 1, 2019, February 1, 2020, an

Agreement to Exhibit 3.1 to the Registrant's Registrant's Quarterly Report on Form dMay 15, 2020 Exercise under Tourmaline Bio, Inc. 2023 Equity Incentiv

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

8-K 10-Q (File No. 001-40384), filed with the SEC on May 11, 2021) Nov

ePlan (incorporated by reference to Exhibit 10.8 to our Registration Statement

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

3.2	Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form S-1/A (File No. 333-255	

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Related by reference to Exhibit 3.2 to the Registrant's Registrant's Current	10.7.1*10.11+	5316) 001-40384). filed with the SEC on May 3, 2021) Oct ober 20, 2023).	Th

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Report on Form 8-K (File No. 001-40384), filed with the SEC on May 11, 2021

Third Amendment to Lease For Restricted Stock Unit Grant Notice and Award

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

4.1	4.1*	))). Form of Specimen Common Stock Certificate of Tourmaline Bio, Inc.
4.2*		Description of Securities.
10.1+		Tourmaline Bio, Inc. Executive Severance and

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

	Change in Control Plan and Form of Participation Agreement (incorporated by reference to Exhibit 4.1 10.1 to our Registration Statement the Registrant's Current Report on Form S-1/A 8-K (File No. 333-255316) 001-40384), filed with the SEC on May 3, 2021) October 27, 2023).		
4.2	10.2+	Amended and Restated Investors' Rights Agreement	10.8#	Employment Agreement, by and between the Registrant and Mary Ellen Smith, dated as of March 1, 2023

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

amongthe Registrant and certain of its stockholders, effective as of Septembe

antandScottRegUadtedNovember1,2018 underTourmalineBio,Inc

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

egistrationStatementonForm_S-1(FileNo.333-255531 6)filedonApril16,2

togourRegistrationStatementontheRegistrant'sCurrentReportonForm_S-1

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

4.3	Description of Securities (incorporated by reference to Exhibit 4.3 to the Annual Report on Form 10-K (File No. 333-255316) filed with the SEC on May 3, 2021)	

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

3 of the Registrant's Annual Report on Form 10-K (File No. 001-40384), filed with the SEC on March 30, 2023).		
	10.9#10.12+	October 20, 2023). Tourmaline Bio, Inc. 2023 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Current Report on Form 8-K (File No. 001-40384), filed with the SEC on October 20, 2023).
	10.13+	Transition and General Release Agreement Side Letter, dated as of November 10, 2023, by and between the Registrant and Suzanne T. Ildstad, dated August 12, 2022 Ryan Robinson (incorporated by reference to Exhibit 10.01 10.14 to our the Registrant's Quarterly Report on Form 10-Q (File No. 001-40384), filed with the SEC on November 14, 2023).
	10.10#10.14††	Offe

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

10.1#	Stock Option and Incentive Plan and form of Notice of Restricted Stock Unit Award Agreement between the Registrant and Tourmaline Bio

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

award agreements the Required Non-Employee Director Compensation Policy (the

LLC and Nancy Krieger. Pfizer Inc. dated November 1, 2018 May 3, 2022 (in

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

olicy (incorporated by reference to Exhibit 10.2 to our Registration Statement

corporated by reference to Exhibit 10.11 10.4 to our the Registrant's R

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

statement the Registrant's Current Report Form S-1/A8-K (File No. 3333-255316) 333-273

egistration Statement on Form S-1/AS-4 (File No. 3333-255316) 333-273

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

25531 6) 001-40384). filed with the SEC on May 3, 2021)		_335). filed with the SEC on May 3, 2021) July 20, 2023). Offer Letter. License Ag

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

3).

10.2#10.3+	2021 Employee Stock Purchase Plan (incorporated by reference to Exhi	reement by and between the Registrant Tourmaline Bio, LLC and Michael Z

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Inbit10.3tourRegistrationStatementonForm S-1/A (File No. 333-255533 dan owski, Lonza Sales AG, dated September 29, 2020 May 16, 2022 (incor

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

16) filed with the SEC on May 3, 2021)

10.3# Form of Indemnification Agreement

. ported by reference to Exhibit 10.12 10.5 to our the Registrant's Regis

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

between the Registrant and each of its directors and executive officers (

Transaction Statement Form - S-1/AS-4 (File No. 333-255316) 333-273333

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Amendment to Articles of Incorporated by reference to Exhibit 10.4 to our Registrant's		), filed with the SEC on May 3, 2021) July 20, 2023). Offer Letter, by and between
	10.12#21.1*	

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Registration Statement on Form S-1/AS-4 (File No. 3333-255316) 3333-

in the Registrant and Mary Kay Fenton, as amended, dated January 21, 20

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

		273335), filed with the SEC on May 3, 2021) July 20, 2023).	21 (incorporated by reference to Exhibit 10.13 to our Registration Stat
10.4#10.4+	Offer Letter, dated as of October 18, 2023, by and between the Registrant and Sandeep Kulkarni, M.D. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K		

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

	on Form 8-K (File No. 001-40384), filed with the SEC on October 20, 2023).	
10.5+	Offer Letter, dated as of October 18, 2023, by and between the Registrant and Brad Middlekauff, J.D. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-40384), filed with the SEC on October 20, 2023).	
Senior Executive Cash Incentive Bonus Plan10.6+	Offer Letter, dated as of October 18, 2023, by and between the Registrant and Susan Dana Jones, Ph.D. (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-40384), filed with the SEC on October 20, 2023).	
10.7+	Offer Letter, dated as of June 7, 2023, by and between the Registrant and Ryan Robinson (incorporated by reference to Exhibit 10.5 to our Registration Statement the Registrant's Current Report on Form S-1/A 8-K (File No. 333-255316) 001-40384), filed with the SEC on May 3	

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

		May 3, 2021)	October 20, 2023).
(3)	The exhibits required by Item 601 of Regulation S-K and Item 15(b) to be filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The Exhibit Index is attached hereto and are incorporated herein by reference.	**Item 16.** **Form 10-K Summary**	None. **EXHIBIT INDEX**

10.13†	Amended and Restated Exclusive License Agreement, by and between the Registrant and University of Louisville Research Foundation, Inc., dated October 31, 2018 (incorporated by reference to Exhibit 10.14 to our Registration Statement on Form S-1/A (File No. 333-255316) filed with the SEC on May 3, 2021)		
10.14#	Deferred Compensation Plan for Non-Employee Directors of the Registrant (incorporated by reference to Exhibit 10.15 to our Registration Statement on Form S-1/A (File No. 333-255316) filed with the SEC on May 3, 2021)		
21.1	List of Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant's Annual Report on Form 10-K (File No. 001-40384) filed on March 17, 2022)		
23.1*	Consent of Deloitte & Touche		

* Filed herewith.

** This certification is being furnished solely to accompany this exhibit (indicated by asterisks) were omitted pursuant to Item 601(b)(10) of Regulation S-K.

† Portions of Report + The certifications furnished in Exhibit 32.1 18 U.S.C. Section 1350, and 32.2 hereto are deemed to be furnished with this Annual Report on Form 10-K and will is not be deemed to be "filed" being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the

† Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[*****]") because the identified confidential portions (i) are not material and (ii) is the type of information that the Company treats as private or confidential.

Indicate management contract or compensatory plan.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

uche LLP, independent registered public accounting firm.	date hereof, regardless of any general incorporation language in such filing.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

31.1*	Certification of Principal Executive Officer Pursuant to

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Rules

13a-14(a)

and

15d-14(a)

under the Securities Exch

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Exchange Act of 1934, as Adopted Pursuant to Section 302 of

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

31.2*	Certification of Principal Financial Officer of the Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

I

Financial

Officer

Pursuant

to

Rules

13a-14(a)

and

15d-

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

14(a) under the Securities Exchange Act of 1934, as Adop

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

ted

Pursuant

to

Section

302

of

the

Sarbanes-Oxley

Act

of

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

	32.1+32.1**	2002. Certification of Principal Executive Officer Pursu

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

ant

to

18

U.S.C.

Section

1350,

as

Adopted

Pursuant

to

Se

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

		certification 906 of the Sarbanes-Oxley Act of 2002.
32. 2+	Certification of 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.	

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

	101.INS*97*	Incentive Compensation Recoupment Policy of Tourmaline Bio, Inc.
	101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
		Document.
	101.SCH* 101.SCH	Inline XBRL Taxonomy Extension Schema Document
		Document.
	101.CAL* 101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

101.DEF*	101.DEF	Inline
		XBRL
		Taxonomy
		Extension
		Definition
		Linkbase
		Document
101.LAB*	101.LAB	Inline
		XBRL
		Taxonomy
		Extension
		Label
		Linkbase
		Document
101.PRE*	101.PRE	Inline
		XBRL
		Taxonomy
		Extension
		Presentation
		Linkbase
		Document

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

104*	104	Cover Page Interactive Data File (embedded within the Inline XBRL document) .

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

Interest and penalty charges, if any, related to income taxes would be classified as a component of the “Provision for income tax expense. The Company had no significant uncertain tax positions as taxes” in the consolidated statements of December 31, 2022 operations and December 31, 2021.

comprehensive loss.

Basic and Diluted Net Loss Per per Share

The Company calculates basic

Basic and diluted net loss per share using the two-class method. The two-class method requires income available attributable to common stockholders is presented in conformity with the two-class method required for the period participating securities. The Company considers its Series A convertible preferred stock and common stock issued subject to repurchase (related to early exercised stock options) to be allocated between participating securities. Net loss is attributed to common stock stockholders and participating securities based upon on their respective rights participation rights. Net loss attributable to receive dividends common stockholders is not allocated to the Series A convertible preferred stock or common stock issued subject to repurchase as if all income for these holders do not have a contractual obligation to share in any losses.

Under the period had been distributed. Accordingly, two-class method, basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period.

Diluted net loss per share attributable to common stockholders includes the effect, if any, from common stock issued subject to repurchase and the potential exercise or conversion of securities such as stock options and convertible preferred stock, which would result in the issuance of incremental shares of common stock. The Company has not adjusted its weighted average number of common shares outstanding during in the period, without consideration calculation of potential dilutive securities. Diluted net diluted loss per share is computed by dividing attributable to common stockholders as the net loss by the sum of the weighted average number of common shares outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include vested and unexercised stock options, restricted stock issued upon early exercise of stock options, convertible preferred shares and contingent stock liabilities. The dilutive effect of stock options and contingent stock liabilities are computed using the treasury stock method and the dilutive effect of convertible preferred shares is calculated using the if-converted method. The Company has generated reported a net loss for all periods presented therefore diluted net loss per share and the effect of the aforementioned securities is anti-dilutive.

Concentration of Credit Risk

Financial instruments that potentially expose the same as basic net loss per share since Company to concentrations of credit risk primarily consist of cash, cash equivalents and investments. Cash balances are deposited with federally-insured financial institutions in the inclusion of potentially dilutive securities would be anti-dilutive.

Segments

Operating segments United States and may, at times, exceed federally-insured limits. The Company maintains its cash, cash equivalents and investments with high-quality financial institutions and, consequently, the Company believes that such funds are defined as components of an entity for which separate financial information is made available and is regularly evaluated by the chief operating decision maker (“CODM”) in making decisions regarding resource allocation and assessing performance. subject to minimal credit risk.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

The Company's CODM cash equivalents are comprised of money market funds that are invested in U.S. Treasury and government agency obligations. The Company's investments are comprised of commercial paper, government securities, and corporate debt securities. Credit risk in these securities is the chief executive officer and operations are managed reduced as a result of the Company's investment policy to limit the amount invested in any single segment for the purposes issuer and to only invest in securities of assessing performance and making operating decisions.
a high credit quality.

Comprehensive Loss

Comprehensive loss represents net loss for the period plus the results of certain The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts or other changes in stockholders' equity. The Company's comprehensive loss included unrealized gains related to marketable securities for the years ended December 31, 2022 and 2021.
foreign hedging arrangements.

Recently Adopted Accounting Pronouncements

In February June 2016, the FASB issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and it establishes additional disclosure requirements related to credit risks. For available-for-sale debt securities with expected credit losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This guidance was originally effective for annual reporting periods beginning after December 15, 2020 and interim periods within fiscal years beginning after December 31, 2021, and early adoption was permitted. In November 2019, the FASB subsequently issued ASU No. 2016-02, 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, which requires lessees whereby the effective date of this standard was deferred to recognize annual reporting periods beginning after December 15, 2022, including interim periods within those annual reporting periods, and early adoption is still permitted. Accordingly, the right-of-use assets and related lease liabilities in the balance sheet. The Company adopted this new standard provides for a modified retrospective application. ASU 2016-02 is effective for interim January 1, 2023, and annual period beginning after December 15, 2021.

The Company determines if an arrangement is a lease at contract inception. The Company's contracts are determined to contain a lease when all of the following criteria based on the specific circumstances of the arrangement are met: (1) there is an identified asset for which there are no substantive substitution rights; (2) the Company has the right to obtain substantially all of the economic benefits from the identified asset; and (3) the Company has the right to direct the use of the identified asset.

At the commencement date, operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The Company's lease agreements do not provide an implicit rate. As a result, the Company utilizes an estimated incremental borrowing rate to discount lease payments, which is based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term. Certain adjustments to the right-of-use asset may be required for items such as lease incentives received. Operating lease cost is recognized over the expected term on a straight-line basis.

The expected lease term for those leases commencing prior to January 1, 2022 did not change with the adoption of the new leasing standards. The expected lease term for leases commencing after the adoption of the new leasing standards includes noncancelable lease periods and, when applicable, periods covered by an option to extend the lease if the Company is reasonably certain to exercise that option, as well as periods covered by an option to terminate the lease if the Company is reasonably certain not to exercise that option.

As a result of the adoption of the new leasing standards, on January 1, 2022, the Company recorded right-of-use assets of $3.4 million and operating lease liabilities of $3.5 million. The adoption ASU 2016-13 did not have a material impact on the statement of operations or the statement of cash flows. For additional information on the adoption of the new leasing standard, refer to Note 8.

The following table presents the cumulative effect of adoption of ASC 842 on January 1, 2022 *(in thousands)*:

	January 1, 2022 (in thousands)		
	Prior to adoption of new leasing standards	Adjustment for adoption of new leasing standards	As adjusted
Right-of-use assets (1)	$ —	$ 3,422	$ 3,422
Deferred rent (2)	$ 105	$ (105)	$ —
Operating lease liability (3)	$ —	$ 645	$ 645
Operating lease liability, net of current portion (3)	$ —	$ 2,882	$ 2,882

(1) Represents capitalization of operating right-of-use assets

(2) Represents reclassification of deferred rent and incentives as a reduction of operating right-of-use assets

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

(3) Represents recognition of operating right-of-use assets

3. Fair Value of Financial Assets and Liabilities

The following table presents information about the Company's financial instruments that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the inputs the Company utilized to determine such fair value *(in thousands)*:

	December 31, 2022			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	$ 12,309	$ 12,309	$ —	$ —
Marketable securities	167,612	31,718	135,894	—
Total financial assets measured at fair value	$ 179,921	$ 44,027	$ 135,894	$ —

	December 31, 2021			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	$ 10,319	$ 10,319	$ —	$ —
Marketable securities	225,357	27,186	198,171	—
Total financial assets measured at fair value	$ 235,676	$ 37,505	$ 198,171	$ —

The contingent stock liability in the table below represents the fair value of contingent equity consideration equal to 65,186 shares of common stock contingently issuable to the University of Louisville Research Foundation Inc. ("ULRF") in connection with its amended and restated exclusive license agreement with the Company (see Note 8). In conjunction with the Company's IPO, the Company issued 48,889 shares of common stock and paid the cash equivalent fair value of 16,297 shares, or $0.3 million, to ULRF in May 2021 (see Note 8). A rollforward of the contingent common stock liability, which is measured at fair value for the year ended December 31, 2021, is represented as follows *(in thousands)*:

Fair value as of January 1, 2021	$ 373
Change in fair value	735
Share issuance in partial settlement of contingent stock	(831)
Cash payment in partial settlement of contingent stock	(277)
Fair value as of December 31, 2021	$ —

Valuation techniques used to measure fair value maximize the use of relevant observable inputs and minimize the use of unobservable inputs. Prior to the Company's IPO, the Company's contingent stock liability was classified within Level 3 of the fair value hierarchy because its fair value measurement is based, in part, on significant inputs not observed in the market, which incorporates assumptions and estimates to value the Company's common stock. As there was no public market for the Company's common stock prior to May 2021, the estimated fair value was determined by the Company's board of directors with input from management, considering the most recently available third-party valuations of common stock, and the board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of each valuation. Historically, these third-party valuations of the Company's common stock were performed contemporaneously when events occurred which management believed would have an impact on the valuation consolidated financial statements.

Recent Accounting Pronouncements - Yet to be Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This guidance is intended to improve reportable segment disclosure requirements through enhanced disclosures as well as clarify that entities with a single reportable segment are subject to new and existing segment reporting requirements. This guidance is effective for annual periods in fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. Entities must apply this guidance on a retrospective basis. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the United States and in foreign jurisdictions. This guidance is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively, and early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

3. Reverse Merger

As described in Note 1, “Nature of Business”, Merger Sub merged with and into Legacy Tourmaline, with Legacy Tourmaline surviving as a wholly owned subsidiary of the Company. Company on October 19, 2023. The Company’s common Reverse Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP with Legacy Tourmaline as the accounting acquirer of Talaris. Under reverse recapitalization accounting, the assets and liabilities of Talaris were recorded at their fair value in Tourmaline’s financial statements at the effective time of the Merger. No goodwill or intangible assets were recognized. Consequently, the consolidated financial statements of the Company

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

reflect the operations of Legacy Tourmaline for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders of Talaris, the legal acquirer, and a recapitalization of the equity of Legacy Tourmaline, the accounting acquirer.

The Company acquired the following assets and liabilities as part of the Reverse Merger (in thousands):

	Amount
Cash and cash equivalents	$ 392
Short-term investments	65,515
Prepaid expenses and other current assets	4,254
Accounts payable	(726)
Accrued expenses	(543)
Net assets acquired	$ 68,892

The Company incurred $2.9 million in stock-based compensation expense as a result of the acceleration of vesting and settlement of Talaris share-based awards at the time of the Reverse Merger. In the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023, $1.4 million and $1.5 million were recorded as research and development expense and general and administrative expense, respectively. Additionally, the Company incurred transaction costs of $6.1 million, which were recorded as a reduction to additional paid-in capital in the consolidated statement of convertible preferred stock valuation was prepared and stockholders' equity for the year ended December 31, 2023.

4. Pfizer License Agreement

using

On May 3, 2022 (the "Effective Date"), the option-pricing method, Company entered into a License Agreement (the "Pfizer License Agreement") with Pfizer Inc. ("OPM" Pfizer"), pursuant to which the Company obtained an exclusive, sublicensable, royalty-bearing, worldwide right to use and license under certain know-how for the development, commercialization and manufacture of PF-04236921 (the "Compound", now known as TOUR006) and any pharmaceutical or biopharmaceutical product incorporating the Compound (the "Product"), for the treatment, diagnosis, or prevention of any and all diseases, disorders, illnesses and conditions in humans and animals. In consideration for the license and other rights the Company received under the Pfizer License Agreement, the Company paid Pfizer an upfront payment of $5.0 million and issued to Pfizer 7,125,000 Series A preferred units of Tourmaline Bio, LLC (the predecessor of Legacy Tourmaline), which uses subsequently converted to 7,125,000 shares of Series A convertible preferred stock of Legacy Tourmaline, representing a market approach to estimate enterprise value. 15% interest in

the Company on a fully-diluted basis at the time of issuance. The units were issued for $1.00 per unit, representing a total value of $7.1 million. In accordance with ASC Topic 805, *Business Combinations*, the Pfizer License Agreement was accounted for as an asset acquisition as the licensed compound represented substantially all of the fair value of the Company's common stock used to value gross assets acquired. On the contingent stock liability as of January 1, 2021 was $5.72. The Company's IPO price of $17.00 was used to determine Effective Date, the contingent stock value prior to settlement in cash licensed compound had not yet received regulatory approval and share issuance.

4. Marketable Securities

The fair value of the Company's marketable securities as of December 31, 2022 and 2021 is based on level 1 and level 2 inputs. The Company's investments consist mainly of U.S. government and agency securities, government-sponsored bond obligations and certain other corporate debt securities. Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs. There were no transfers between levels within the hierarchy during the years ended December 31, 2022 and 2021. The Company has assessed U.S. government treasuries as level 1 and all other marketable securities as level 2 within the fair value hierarchy of ASC 820. The Company classifies its entire investment portfolio as available-for-sale as defined in ASC 320, *Debt Securities*. Securities are carried at fair value with the unrealized gains (losses) reported in other comprehensive loss.

As of December 31, 2022 and 2021, none of the Company's investments were determined to be other than temporarily impaired.

The following table summarizes the Company's investments *(in thousands)*:

	December 31, 2022			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial paper	$ 119,313	$ 19	$ (365)	$ 118,967
Government and agency securities	43,016	—	(368)	42,648

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Corporate debt securities	6,004	—	(7)	5,997
Total	$ 168,333	$ 19	$ (740)	$ 167,612

	December 31, 2021			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial paper	$ 179,151	$ 38	$ (47)	$ 179,142
Corporate debt securities	31,244	—	(58)	31,186
Government and agency securities	15,040	—	(11)	15,029
Total	$ 225,435	$ 38	$ (116)	$ 225,357

The fair values of available-for-sale debt securities as of December 31, 2022, by contractual maturity, are summarized as follows *(in thousands)*:

	December 31, 2022
Due in one year or less	$ 165,648
Due after one year through two years	1,964
	$ 167,612

The aggregate fair value of available-for-sale securities in an unrealized loss position as of December 31, 2022 was $130.5 million. The Company has reviewed its portfolio of available-for-sale debt securities and determined that the decline in fair value below cost did not result from credit-loss related factors. As such, no allowance for credit losses have an alternative use. Accordingly, the total consideration transferred of $12.1 million was recorded as of December 31, 2022.

5. Prepaid and Other Current Assets

Prepaid and other current assets consisted of the following *(in thousands)*:

	December 31,	
	2022	2021
Prepaid insurance	$ 1,037	$ 1,121
Prepaid research and development expenses	2,426	782
Other current assets	868	640
Total prepaid and other current assets	$ 4,331	$ 2,543

6. Property and Equipment, Net

Property and equipment, net consisted of the following *(in thousands)*:

	December 31,	
	2022	2021
Equipment	$ 6,562	$ 4,449
Leasehold improvements	1,191	821
Computer equipment	859	953
Furniture and fixtures	674	426
Construction in progress	242	952
Total property and equipment	9,528	7,601
Less accumulated depreciation	(4,180)	(2,797)
Property and equipment, net	$ 5,348	$ 4,804

Depreciation expense was $1.4 million and $0.6 million for the years ended December 31, 2022 and 2021, respectively.

In July 2022, the Company received a notice from a third party vendor indicating the decommissioning of its software platform. As a result, the Company recorded a $0.2 million non-cash impairment expense in research and development operating expense in the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2022.

As additional consideration for the license, the Company is obligated to pay Pfizer up to $128.0 million upon the achievement of specific development and regulatory milestones. The Company is also obligated to pay Pfizer up to $525.0 million upon the first achievement of specific sales milestones. The Company is also obligated to pay Pfizer a marginal royalty rate in the low double digits (less than 15%), subject to specified royalty reductions. The royalty term, on a Product-by-Product and country-by-country basis, begins on the first commercial sale of such Product and expires upon the later of twelve years following the date of the first commercial sale or the expiration of regulatory exclusivity protecting such Product. In the event the Company completes a Significant Transaction (as defined in the Pfizer License Agreement), the Company will be obligated to pay Pfizer a one-time payment in the low-eight digits (up to $20.0 million); the amount of such payment is based on the timing of the transaction.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

As of December 31, 2023, the Company does not owe any milestone or royalties under the Pfizer License Agreement and no such milestones or royalties have been paid to date.

The Pfizer License Agreement originally contained an anti-dilution provision allowing Pfizer to maintain a 15% interest in the Company on a fully-diluted basis unless and until certain thresholds are met, whereupon the anti-dilution provision would no longer apply. As outlined further within Note 9, “Convertible Preferred Stock”, on May 2, 2023, the Company issued 8,823,529 additional shares of Series A convertible preferred stock to Pfizer pursuant this anti-dilution provision. The Company recognized research and development expense of $8.8 million related to this issuance of Series A convertible preferred stock. Subsequent to the issuance of these additional shares of Series A convertible preferred stock, the anti-dilution provision is no longer in force and effect.

5. Fair Value Measurements

The Company measures the fair value of money market funds based on quoted prices in active markets for identical securities. Investments also include commercial paper and government securities which are valued either based on recent trades of securities in inactive markets or based on quoted market prices of similar instruments and other significant inputs derived from or corroborated by observable market data. The carrying amounts reflected in the consolidated balance sheets for cash, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values, due to their short-term nature.

Assets measured at fair value on a recurring basis as of December 31, 2023 were as follows (in thousands):

	Total	Level 1	Level 2	Level 3
Money market funds, included in cash and cash equivalents	$ 4,604	$ 4,604	$ —	$ —
Short-term investments:				
Commercial paper	32,555	—	32,555	—
Government securities	26,724	7,907	18,817	—
Corporate debt securities	2,947	—	2,947	—
Total	$ 66,830	$ 12,511	$ 54,319	$ —

The Company maintained no cash equivalents or investments as of December 31, 2022. There were no liabilities measured at fair value on a recurring basis as of December 31, 2023 or 2022. There were no changes in valuation techniques, nor were there any transfers among the fair value hierarchy levels during the year ended December 31, 2023.

6. Investments

Cash equivalents and short-term investments as of December 31, 2023 were comprised as follows (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds, included in cash and cash equivalents	$ 4,604	$ —	$ —	$ 4,604
Short-term investments:				
Commercial paper	32,515	44	(4)	32,555
Government securities	26,703	25	(4)	26,724
Corporate debt securities	2,941	6	—	2,947
Total	$ 66,763	$ 75	$ (8)	$ 66,830

The Company maintained no cash equivalents or investments as of December 31, 2022.

As of December 31, 2023, the aggregate fair value of securities that were in an unrealized loss position for less than twelve months was $49.3 million. The Company held no securities that were in an unrealized loss position for more than twelve months as of December 31, 2023. Based upon its assessment of securities in an unrealized loss position, the Company did not record any allowances for credit losses during the year ended December 31, 2023.

7. Property and Equipment, Net

Property and equipment, net as of December 31, 2023 and 2022 was comprised as follows (in thousands):

	Estimated Useful Life (in Years)	December 31, 2023	December 31, 2022
Leasehold improvements	Shorter of useful life or remaining lease term	$ 74	$ 64
Computer and office equipment	3 years	49	23
Total property and equipment, gross		123	87
Less: accumulated depreciation		(38)	(6)
Total property and equipment, net		$ 85	$ 81

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Depreciation expense was less than $0.1 million for each of the years ended December 31, 2023 and 2022.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses consisted and other current liabilities as of the following December 31, 2023 and 2022 were comprised as follows (in thousands):

	December 31,	
	2023	2022
Accrued bonus	$ 1,994	$ 446
Accrued clinical and manufacturing costs	438	185
Accrued consulting fees	692	81
Accrued legal fees	237	54
Other accrued expenses and other current liabilities	349	34
Total accrued expenses and other current liabilities	$ 3,710	$ 800

9. (in thousands) Convertible Preferred Stock:

	December 31,	
	2022	2021
Compensation and benefit costs	$ 3,566	$ 3,320
Research and development expenses	1,978	854
Professional fees, consulting and other	1,121	1,257
Total accrued expenses	$ 6,665	$ 5,431

8. Commitments and Contingencies

Leases

The Company currently has four active lease agreements for office and laboratory space and related equipment. The Company's cell processing facility lease is located on the University of Louisville campus in Louisville, Kentucky (the “Louisville Lease”). This lease has a termination date in November 2023On April 18, 2022, with an option to extend for three additional years at the Company’s discretion. In May 2020, the Company added additional office and laboratory space to the Louisville Lease. In September 2021, the Company entered into a sublease agreement Securities Purchase Agreement (the “Initial Series A Securities Purchase Agreement”) with various entities and individuals for separate office space in Louisville, Kentucky. This sublease has a termination date in November 2023.

The Company maintains a lease for office space in Wellesley, Massachusetts (the "Boston Lease"), that had an original termination date in March 2021. In April 2021, the Company entered into an amended lease agreement providing for temporary space from April 2021 until an expansion purchase of Series A convertible preferred units. As part of the Boston Lease was complete, from which the lease term extends 39 months from the expansion completion date. The expansion was completed in June 2022, resulting in the lease term extending to September 2025.

In July 2021, the Company entered into a lease agreement for laboratory space in Houston, Texas (the “Houston Lease”). The Houston Lease commenced in January 2022. The term of the lease is 36 months from the commencement date, terminating December 2024.

The future minimum rent payments relating to all four of the Company’s ongoing facility operating leases under the terms and conditions existing as of December 31, 2022, as well as amendments the Company has entered into between the date of these financial statements and the date they were available to be issued (as described in Note 16), are summarized as follows *(in thousands)*:

Years Ending December 31,	
2023	$ 1,064
2024	935
2025	756
2026	437
Total lease payments	$ 3,192
Less: imputed interest	(308)
Present value of lease liabilities	$ 2,884

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

The Company incurred rent expense of $1.0 million and $0.7 million for the years ended December 31, 2022 and 2021, respectively.

The following table summarizes the operating lease term and discount rate as of December 31, 2022:

	As of December 31, 2022
Weighted-average remaining lease term (years)	3.3
Weighted-average discount rate	6.5%

Cash paid for amounts included in the measurement of the Company's operating lease liability was $0.9 million for the year ended December 31, 2022.

License Agreement

In October 2018, the Company entered an amended and restated exclusive license agreement with the ULRF related to certain licensed patent rights and know-how related to human facilitating cells for its Facilitated Allo-HSCT Therapy approach. Pursuant to the ULRF License Agreement, ULRF granted the Company an exclusive, worldwide license under such patents and a nonexclusive royalty-bearing, worldwide license for such know-how to research, develop, commercialize and manufacture FCR001 and products containing FCR001 in all fields, without limitation. ULRF also granted the Company the right to grant sublicenses in accordance with the ULRF License Agreement. Under the terms of the agreement, the Company is obligated to compensate ULRF three percent of net sales of all licensed products sold, one third of any non-royalty sublicensing income, and up to $1.625 million in regulatory and sales milestones on each licensed product upon the occurrence of specific events as outlined in the license agreement; and annual license maintenance fees.

In addition, upon execution of the ULRF License Initial Series A Securities Purchase Agreement, the Company granted contingent equity consideration equal authorized the issuance and sale of up to 65,18620,000,000 shares of common stock its Series A convertible preferred units at a price of $1.00 per unit for total proceeds of $20.0 million. The Series A convertible preferred units were convertible into the Company's Common Units at a 1:1 ratio. The obligations of the parties to ULRF. On or prior purchase and sell the Series A convertible preferred units were subject to the Company's first underwritten public offering or any transaction that is treated as a deemed liquidation event, Company entering into the Pfizer License Agreement. As outlined further within Note 4, "Pfizer License Agreement", the Company may either issue also issued to ULRF Pfizer 7,125,000 Series A convertible preferred units in May 2022 conjunction with the 65,186 shares in common stock or make Pfizer License Agreement.

On September 2, 2022, Legacy Tourmaline converted from Tourmaline Bio, LLC, a cash payment equal Delaware limited liability company, to Tourmaline Bio, Inc., a Delaware corporation (the "Conversion"). As part of the 65,186Conversion, Series A convertible preferred units were converted at a 1:1 ratio to shares of common stock multiplied by either Series A convertible preferred stock. Upon the price per share of common stock in the underwritten public offering or by the price per share of common stock received in connection with such deemed liquidation event.

Coincident with the completion of the Company's IPO, Conversion, the Company issued 48,889was authorized to issue up to 27,125,000 shares of common stock to ULRF and provided a cash payment of approximately $0.3 million in lieu of issuing the remaining 16,297 shares of common stock. As of December 31, 2022 and 2021, the contingent stock liability was fully satisfied.

The Company incurred $0.1 million in expense in February 2022 related to an annual maintenance fee pursuant to the license agreement for the year ended December 31, 2022. The Company also incurred $0.1 million in expense in February 2021 related to the annual maintenance fee for the year ended December 31, 2021.

Legal Proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether 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 the costs related to its legal proceedings as incurred.

The Company may be involved in litigation arising in the ordinary course of conducting business. The Company reviews all litigation on an ongoing basis when making accrual and disclosure decisions. The Company, in accordance with current accounting

standards for loss contingencies and based upon information currently known by the Company, will establish reserves for litigation when it is probable that a loss associated with a claim or proceeding has been incurred and the amount of the loss or range of loss can be reasonably estimated. When no amount within the range of loss is a better estimate than any other amount, we accrue the minimum amount of the estimable loss. To the extent that such litigation against the Company may have an exposure to a loss in excess of the amount accrued, the Company believes that such excess would not be material to our financial condition, results of operations, or cash flows.

9. Convertible Preferred Stock

Upon closing of the Company's IPO on May 11, 2021, all 130,499,993 shares of Series A convertible preferred stock that were outstanding immediately prior to the closing of the IPO automatically converted into 23,242,498 shares of common stock and 1,150,000 shares of non-voting common stock.

Convertible preferred stock prior to conversion was as follows *(in thousands, except share amounts)*:

	Series A	Series A-1	Series B
Preferred shares authorized, issued and outstanding prior to conversion	40,000,000	28,000,000	62,499,993
Aggregate liquidation preference	$ 40,000	$ 35,000	$ 114,994

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Under the Third Amended and Restated Certificate of Incorporation, filed upon the Company's IPO, the Company authorized 10,000,000 shares of undesignated preferred stock, $0.0001 par value per share ("Preferred Stock"), of which no shares were outstanding at December 31, 2022 and 2021.

10. Common Stock

Common Stock

On April 30, 2021, the Company's stockholders approved the third amended and restated certificate of incorporation of the Company, which included the authorization of 10,000,000 shares of undesignated preferred stock with a par value of $ $0.0001.

The Company subsequently entered into a Series A Preferred Stock Purchase Agreement on May 2, 2023 (the "Closing Date") with various entities and individuals for the purchase of additional shares of Series A convertible preferred stock (the "Series A Extension"). On the Closing Date, the Company authorized the issuance and sale of 92,200,000 shares of Series A convertible preferred stock at a price of $1.00 per share for total gross proceeds of $92.2 million. In addition, pursuant to the anti-dilution provision of the Pfizer License Agreement, the Company issued 8,823,529 additional shares of Series A convertible preferred stock to Pfizer in connection with the Series A Extension and recognized corresponding research and development expense of $8.8 million during the second quarter of 2023. The additional shares of Series A convertible preferred stock had the same terms, conditions, rights and preferences as the Series A convertible preferred stock issued during the year ended December 31, 2022. Upon consummation of the Series A Extension, the anti-dilution provision of the Pfizer License Agreement was no longer in force and effect.

Prior to the completion of the Reverse Merger, the Company classified its Series A convertible preferred stock outside of permanent equity as the shares had redemption features that were not entirely within the control of the Company.

Upon the consummation of the Reverse Merger, all outstanding shares of Series A convertible preferred stock were converted into 10,222,414 shares of common stock. No shares of preferred stock were outstanding as of December 31, 2023.

Subsequent to consummation of the Reverse Merger, the Company is authorized to issue 10,000,000 shares of undesignated preferred stock, however no such shares were issued or outstanding as of December 31, 2023.

10. 0.0001 Common Stock

On May 3, 2022, authorization the Company effected a stock split, and each common unit in Tourmaline Bio, LLC was exchanged for 6.39697802 common units. Subsequently, as part of the September 2, 2022 Conversion outlined within Note 9 "Convertible Preferred Stock", the Company converted all its equity interests of Tourmaline Bio, LLC into equity interests of Tourmaline Bio, Inc. Each common unit in the LLC was exchanged for 1.00 shares of the Company's common stock.

As of December 31, 2023, the Company was authorized to issue 140,000,000 shares of voting common stock and 10,000,000 shares of non-voting common stock. Holders of voting common stock are entitled to one vote per share. In addition, holders of voting common stock are entitled to receive dividends, if and when declared by the Company's Board of Directors. As of December 31, 2022 December 31, 2023, no dividends had been declared.

As of December 31, 2023 and 2022, the Company had reserved for future issuance the following number of shares of common stock:

	December 31,	
	2023	2022
Conversion of outstanding Series A convertible preferred stock	—	2,163,764
Exercises of outstanding stock options under 2022 Equity Incentive Plan	1,403,409	404,673
Exercises of outstanding stock options under 2023 Equity Incentive Plan	1,042,291	—
Vesting of restricted stock units under 2023 Equity Incentive Plan	19,113	—
Common stock subject to repurchase related to early exercised stock options	388,943	—
Future issuances under 2022 Equity Incentive Plan	—	353,142
Future issuances under 2023 Equity Incentive Plan	971,444	—
Future issuances under 2023 Employee Stock Purchase Plan	203,367	—
Total shares reserved for future issuance	4,028,567	2,921,579

11. no Stock-Based Compensation undesignated preferred

2022 Equity Incentive Plan

On September 2, 2022, the Board of Directors and the stockholders of the Company adopted the 2022 Equity Incentive Plan (the "2022 Plan"), which provided for the grant of incentive stock was outstanding.

Shelf Registration Statement

options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock awards to employees, consultants, and non-employee directors of the Company.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

2023 Equity Incentive Plan

On August 15, 2022 October 17, 2023, the Company filed a registration statement on Form S-3 adopted the 2023 Equity Incentive Plan (the "registration statement" "2023 Plan") pursuant which became effective upon completion of the Reverse Merger. The 2023 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to which employees, consultants, and non-employee directors of the Company may issue Company. The terms of stock award agreements, including vesting requirements, are determined by the Company's Board of Directors and sell, from time to time, in one or more series or classes, up to $250.0 million in aggregate principal amount of common stock, preferred stock, debt securities, warrants and/or units, in any combination, together or separately, in one or more offerings in amounts and on such minimum prices and terms the Company will determine at the time of offering. Each time the Company sells securities pursuant are subject to the registration statement, a supplemental prospectus specifying provisions of the 2023 Plan. The term of each stock option shall be no more than ten years from the date of grant. Following the effectiveness of the 2023 Plan, no further grants will be made under the 2022 Plan; however, any outstanding equity awards granted under the 2022 Plan will continue to be governed by the terms of the securities being offered will be filed with 2022 Plan.

The 2023 Plan initially provided for the SEC. No shares have been sold under the registration statement as issuance of December 31, 2022.

Sales Agreement

On August 15, 2022, the Company entered into an At-the-Market Sales Agreement (the "2022 Sales Agreement") with SVB Securities LLC ("SVB"), pursuant up to which the Company may elect to issue and sell 2,033,677 shares of common stock having an (the "Initial EIP Share Reserve"). Subject to any other adjustments as defined in the 2023 Plan, such aggregate offering price of up to $75.0 million in such quantities and on such minimum price terms as the Company sets from time to time through SVB as the sales agent. The Company agreed to pay SVB an aggregate commission rate of up to 3.0% of the gross proceeds of the sales price per share for common stock sold through SVB under the 2022 Sales Agreement. The registration statement filed by the Company on August 15, 2022 includes a prospectus pursuant to which the Company may offer and sell, from time to time, shares of common stock having an aggregate offering price of up to $75.0 million under the 2022 Sales Agreement. No shares have been sold under the 2022 Sales Agreement as of December 31, 2022.

Common Stock Reserved

The number of shares of common stock that have been reserved will automatically increase on January 1st of each year for the potential conversion a period of Preferred Stock, outstanding stock options granted ten years commencing on January 1, 2024 and stock options available for grant under the Company's 2021 Stock Option and Incentive Plan (the "2021 Plan") and

the 2018 Equity Incentive Plan (the "2018 Plan") and shares reserved for issuance under the Company's 2021 Employee Stock Purchase Plan (the "2021 ESPP") are as follows:

	December 31,	
	2022	2021
Restricted stock related to early exercise of common stock options	158,154	538,340
Restricted stock units outstanding	1,144,994	—
Outstanding common stock options	6,264,898	3,643,796
Shares reserved for issuance under equity incentive plans	758,434	2,702,995
Shares reserved for issuance under the 2021 Employee Stock Purchase Plan	1,166,444	837,088
Total	9,492,924	7,722,219

11. Stock-Based Compensation

2021 Employee Stock Purchase Plan

In April 2021, the Company's board of directors and stockholders approved the 2021 ESPP. The 2021 ESPP became effective immediately prior ending on (and including) January 1, 2033, in an amount equal to the effectiveness 5% of the Company's registration statement on Form S-1 for its IPO. The 2021 ESPP provides employees the opportunity to purchase shares at a 15% discount at the lower of the share price at the beginning or end of six-month offering periods. 852,971 shares have been reserved and approved for this purpose for the 2021 plan year. The number of shares reserved and available for issuance under the plan will increase on January 1, 2022, and each January 1 thereafter through January 1, 2031, by the lesser of (A) 3,000,000 shares of common stock, (B) 1% of the cumulative total number of shares of common stock issued and outstanding determined as of the day prior to such increase; provided, however that the board of directors may act prior to January 1st of a given year to provide that the increase for such year will be a lesser number of shares of common stock. The aggregate maximum number of shares of common stock that may be issued pursuant to the exercise of incentive stock options is three multiplied by the Initial EIP Share Reserve.
As of December 31, 2023, there were 971,444 shares available for issuance under the 2023 Plan.

2023 Employee Stock Purchase Plan

On October 17, 2023, the Company adopted the 2023 Employee Stock Purchase Plan (the "2023 ESPP"), which became effective upon completion of the Reverse Merger. The maximum number of shares of common stock that may be issued under the 2023 ESPP will not exceed 203,367 shares (the "Initial ESPP Share Reserve"), plus the number of shares of common stock that are automatically added on January 1st of each year for a period of up to ten years commencing on January 1, 2024 and ending on (and including) January 1, 2033, in an amount equal to the immediately preceding December 31st lesser of (x) 1% of the total number of shares of common stock issued and outstanding determined as of the day prior to such increase and (y) a number of shares equal to three times the Initial ESPP Share Reserve. Notwithstanding the foregoing, the board of directors may act prior to the first day of any calendar year to provide that there will be no January 1st increase in the share reserve for such calendar year or (C) that the increase in the share reserve

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

for such calendar year will be a lesser number of shares of common stock as determined by the Board. On January 1, 2022, an additional 414,513 shares were added than would otherwise occur pursuant to the 2021 preceding sentence. No offering periods under the 2023 ESPP representing 1% had been initiated as of total common shares outstanding at December 31, 2021 December 31, 2023. The

Total stock-based compensation expense incurred under this plan recognized in the consolidated statements of operations and comprehensive loss for the year years ended December 31, 2022 December 31, 2023 and 2022 was not material to the financial statements. as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 2,322	$ 165
General and administrative	3,447	30
Total stock-based compensation expense	$ 5,769	$ 195

Stock Option Activity

The amounts have been included in the total stock-based compensation line items in the accompanying financial statements and disclosures.

Equity Incentive Plans

In April 2021, the Company's board of directors and stockholders approved the 2021 Plan and terminated the 2018 Plan with respect to any unissued awards. The 2021 Plan became effective immediately prior to the effectiveness estimated grant-date fair value of the Company's registration statement on Form S-1 for its IPO. The 2021 Plan provides for the issuance of up to 3,015,907 new share-based awards, as well as the 3,381,382 options to purchase common stock then outstanding under the 2018 Plan, for a total of 6,397,289 shares. To the extent outstanding options granted under the 2018 Plan are cancelled, forfeited, or otherwise terminated without being exercised and would otherwise have been returned to the share reserve under the 2018 Plan, the number of shares underlying such awards will be available for future grant under the 2021 Plan. Beginning on January 1, 2022, the number of shares reserved and available for issuance under the 2021 Plan will increase on each January 1 through January 1, 2031 by the lesser of (A) 5% percent of the number of shares of stock issued and outstanding on the immediately preceding December 31st or (B) such lesser number of shares of common stock as determined by the Board. On January 1, 2022 an additional 2,072,569 shares were added to the 2021 Plan, representing 5% of total common shares outstanding at December 31, 2021.

As of December 31, 2022, 758,434 shares remained available for future grant under the 2021 Plan. 6,190,132 options were outstanding under the 2021 Plan and 2018 Plan as of December 31, 2022.

The Company's 2021 Plan provides for the Company to sell or issue common stock or restricted common stock or to grant incentive stock options or nonqualified stock options for was calculated using the purchase of common stock, to employees, nonemployees and members of the board of directors of the Company. The 2021 Plan is administered by the board of directors or at the discretion of the board of directors by the compensation committee of the board. The exercise prices, vesting periods, and other restrictions are determined at the discretion of the compensation committee of the board of directors, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the contractual term of stock Black-Scholes option may not be greater than 10 years. Stock options granted to date typically vest over four years.

Stock Option Valuation

The assumptions used to determine the fair values of stock options granted to employees and directors are presented as follows:

	For the years ended December 31,	
	2022	2021
Fair value of common stock	$1.53-16.56	$5.72-17.00
Dividend yield	—%	—%
Volatility	82.29%-88.41%	80.6%-91.25%
Risk-free interest rate	1.46%-4.23%	0.50%-1.33%
Expected term (years)	5.38-6.25	6.25

Summary of Option Activity

The Company's stock option activity regarding employees, directors, and nonemployees is summarized as follows (*in thousands excepts share and per share amounts*):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate intrinsic value
Options outstanding—January 1, 2021	2,745,185	$ 4.20	9.40	$ 4,183
Granted	1,076,022	9.19		

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Exercised	(149,707)	2.12		
Cancelled	(7,605)	1.38		
Forfeited	(20,099)	5.79		
Options outstanding—December 31, 2021	3,643,796	$ 5.75	8.69	$ 34,754
Granted	3,252,866	8.12		
Exercised	(96,646)	1.12		
Cancelled	(57,434)	5.25		
Forfeited	(477,684)	7.55		
Options outstanding—December 31, 2022	6,264,898	$ 6.92	8.43	$ 42
Options exercisable—December 31, 2022	1,838,406	$ 5.23	7.56	

Additional information with regard to stock option activity involving employees and directors is as follows (*in thousands except per share amounts)*:

	For the years ended December 31,	
	2022	2021
Weighted-average grant-date fair value per option of total options granted	$ 5.82	$ 6.69
Aggregate intrinsic value of stock options exercised	291	1,616

As of December 31, 2022, total unrecognized compensation cost related to the unvested awards to employees, directors, and nonemployees is $20.0 million, which is expected to be recognized over a weighted-average period of 2.7 years.

Summary of Restricted Stock Unit Activity

The fair values of restricted stock units (“RSUs”) are pricing model, based on the following assumptions:

	Year Ended December 31,	
	2023	2022
Risk-free interest rate	3.4% – 4.8%	3.7% – 4.4%
Dividend yield	—%	—%
Volatility	82.2% – 86.1%	83.1% – 86.3%
Expected term (in years)	5.5 – 6.1	3.3 – 6.1

The weighted-average fair market value of the Company’s common stock on utilized in the valuation of stock options granted during the years ended December 31, 2023 and 2022 was $8.33 and $4.39 per share, respectively. Using the Black-Scholes option pricing model, the weighted-average grant date fair value of grant. Each RSU represents a contingent right to receive one stock options granted during the year ended December 31, 2023 and 2022 was $6.60 and $4.26 per share, of the Company’s common stock upon vesting. In general, RSUs vest (i) annually in four equal installments on the grant anniversary or (ii) incrementally over two years. respectively.

The following table summarizes the Company’s RSU changes in stock option activity for during the year ended December 31, 2023:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	404,673	$ 0.14	7.2	$ 1,722
Granted	2,736,169	$ 8.33		
Exercised	(695,142)	$ 0.21		
Cancelled	—	$ —		
Outstanding as of December 31, 2023	2,445,700	$ 9.29	9.6	$ 41,320
Exercisable as of December 31, 2023	23,896	$ 11.02	9.7	$ 362

The aggregate intrinsic value of stock options exercised during the year ended December 31, 2023 was $1.8 million. No stock options were exercised during the year ended December 31, 2022.

As of December 31, 2023, the total unrecognized stock-based compensation expense related to unvested stock options was $16.8 million, which the Company expects to recognize over a weighted-average period of approximately 3.5 years.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Early Exercise of Stock Options

The 2022 Plan and certain stock options issued under the 2022 Plan were amended in February 2023 to permit the stock option holder to early exercise at any time between the grant date and the vesting date. The amendment did not result in any incremental stock-based compensation expense. For the year ended December 31, 2023, certain employees, advisors and non-employee directors early exercised 647,386 stock options. In the event of termination of an employee, advisor or non-employee director, the Company can repurchase early exercised and unvested stock options for a period of six months following the later of (i) the termination date of the employee or non-employee director or (ii) the exercise date. The Company received $0.1 million in cash proceeds related to the early exercise of stock options during the year ended December 31, 2023.

As a result of the aforementioned repurchase right, the Company initially records the proceeds received from the early exercise of stock options as a liability in the consolidated balance sheets. Amounts are reclassified to additional paid-in capital when the underlying stock options vest and the Company's right of repurchase lapses. The aggregate liability associated with the early exercise of stock options was $0.1 million as of December 31, 2023. As of December 31, 2023, 388,943 early exercised stock options remain unvested. No stock options were early exercised during the year ended December 31, 2022, and consequently there were no unvested early exercised stock options as of that date. The shares of common stock subject to repurchase related to early exercised stock options are legally outstanding, as each holder is deemed to be a common stockholder that has dividend and voting rights during the vesting term.

Restricted Stock Unit Activity

The following table summarizes changes in restricted stock unit activity during the year ended December 31, 2023:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2022	—	$ —
Granted	1,391,906	7.17
Vested	(154,388)	9.10
Forfeited	(92,524)	8.98
Outstanding at December 31, 2022	1,144,994	$ 6.76

	Shares	Weighted-Average Grant Date Fair Value per Share
Unvested as of December 31, 2022	—	$ —
Granted	19,943	11.89
Vested	(830)	11.89
Cancelled	—	—
Unvested as of December 31, 2023	19,113	$ 11.89

The total grant date fair value of restricted stock units vested during for the year ended December 31, 2022 December 31, 2023 was $0.7 less than $0.1 million.

As of December 31, 2022 December 31, 2023, the total unrecognized stock-based compensation cost expense related to the unvested awards to employees is $6.9 restricted stock units was $0.2 million, which is expected the Company expects to be recognized recognize over a weighted-average period of approximately 3.7 years.

12. 1.7 Income Taxes years.

Stock-Based Compensation

The Company recorded stock-based compensation expense regarding its employees, directors, and nonemployees as follows *(in thousands)*:

	For the years ended December 31,	
	2022	2021
Research and development expense	$ 6,558	$ 1,848
General and administrative expense	4,598	1,930
Total	$ 11,156	$ 3,778

12. Income Taxes

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

The Company recorded no income tax benefit for the net loss incurred for the years ended December 31, 2022 December 31, 2023 and 2021, 2022 due to its uncertainty of realizing a benefit from such losses. 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 tax rate is as follows:

	For the years ended December 31,	
	2022	2021
Federal statutory rate	21.0%	21.0%
Federal research tax credit/orphan drug credit	0.3%	2.4%
Permanent items, including stock compensation	(0.9)%	(0.6)%
Change in valuation allowance	(20.7)%	(22.0)%
Other	0.2%	(0.9)%
	0.0%	0.0%

Significant

	Year Ended December 31,	
	2023	2022
U.S. federal statutory income tax rate	21.0%	21.0%
LLC period net book loss	—%	(14.9%)
Federal valuation allowance	(22.4%)	(5.9%)
Tax credit carryforwards	1.6%	—%
Permanent items, including stock-based compensation	(0.2%)	(0.2%)
Effective tax rate	—%	—%

The principal components of the Company's deferred tax assets are included and liabilities as of December 31, 2023 and 2022 were comprised as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Capitalized research and development expenses	$ 28,753	$ 3,462
Net operating loss carryforwards	5,483	261
Tax credit carryforwards	693	—
Stock-based compensation expense	781	—
Operating lease liability	114	106
Accrued expenses	—	93
Other	61	32
Total deferred tax assets	35,885	3,954
Less: valuation allowance	(34,040)	(3,851)
Net deferred tax assets	1,845	103
Deferred tax liabilities:		
Operating lease right-of-use asset	(100)	(103)
Accretion	(1,745)	—
Total deferred tax liabilities	(1,845)	(103)
Net deferred taxes	$ —	$ —

As of December 31, 2023, the Company had federal and state net operating loss ("NOL") carryforwards of $16.7 million and $28.2 million respectively. Federal NOLs may be carried forward indefinitely. State NOLs expire at various dates from 2038 through 2043. As of December 31, 2023, the Company had federal research and development tax credit carryforwards of $0.7 million which expire in the table below *(in thousands)*:

	For the years ended December 31,

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

	2022	2021
Deferred tax assets:		
Net operating loss and capital loss carryforwards	$ 25,875	$ 20,815
Capitalized research and development expenses	14,500	—
Research and development credit carryforwards	2,610	2,359
Accrued expenses	127	1,377
Stock-based compensation	2,894	876
Operating lease right-of-use assets	68	—
Total deferred tax assets	46,074	25,427
Deferred tax liabilities:		
Depreciation	(179)	(80)
Accretion	(331)	—
Total deferred tax assets	(510)	(80)
Less valuation allowance	(45,564)	(25,347)
Net deferred tax assets	$ —	$ —

2043.

The Company's management Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are composed primarily of net operating loss ("NOL") carryforwards and capitalized research and development credit expenses and net operating loss carryforwards. Management has considered the Company's history of net losses incurred since inception and the probability of future losses to conclude it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. As a result, the Company has established a valuation allowance for the full amount of the its net deferred tax assets as of December 31, 2022 and December 31, 2021 December 31, 2023. The increase in the valuation allowance increased by $20.2 million and $13.2 of $30.2 million during the years year ended December 31, 2022 December 31, 2023 was primarily due to the additional operating loss generated by the Company.

NOL and December 31, 2021 tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Internal Revenue Code ("IRC"). This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the Company's value immediately prior to the ownership change. As a result of ownership changes in the Company from its inception through December 31, 2023, respectively.

As of December 31, 2022, the Company's NOL and tax credit carryforwards allocable to the periods preceding each such ownership change could be subject to limitations under IRC Section 382, however the Company has $96.9 million of US federal NOLs and $97.1 million of Kentucky state NOL carryforwards that have no expiration dates. not yet completed an IRC Section 382 study.

The Company does had not have any US federal unrecognized tax benefits as of either December 31, 2023 or state capital loss carryforwards that expire in 2023. In addition, the 2022. The Company had a US federal research and development tax credit carryforward of $2.6 million, which may be available to reduce future tax liabilities which start to expire in 2039.

Through December 31, 2022, the Company has generated research and development tax credits but has not conducted a study to document the qualified activities. Such of its research and development credit carryforwards generated during any year. This study, once completed, may result in an adjustment to the Company's research and development credit carryforwards. Since However, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits, any reduction in the gross deferred tax asset established for the research and development credit carryforwards, and if an adjustment is required, this adjustment would not result in any net be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the Company's financial statements.

Effective January 1, 2022, the 2017 Tax Cuts consolidated statements of operations and Jobs Act ("TCJA") requires research and experimenatal ("R&E") expenses under Internal Revenue Code Section 174 to be capitalized. R&E expenses are required to be amortized over a five-year period for domestic expenses and over a fifteen-year period for foreign expenses. Prior to the TCJA being effective, businesses had the option of deducting Section 174 expenses in the year incurred or capitalizing and amortizing the costs over five years. The Company has reflected this change in treatment of R&E expenses in the current tax provision.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the NOL carryforward period. Under the provisions of Sections 382 and 383 of the Internal Revenue Code ("IRC"), and corresponding provisions of state law, certain substantial changes in the Company's ownership, including a sale of the Company or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of NOL carryforwards, which could be used annually to offset future taxable income. No study has been completed as of the date of these financial statements to determine whether a change in control, as defined by Section 382 of the IRC, has occurred. If it is determined the Company has experienced a change in control at any time since inception, realization of the NOL carryforwards or research and development tax credit carryforwards may be subject to comprehensive loss if an annual limitation. Any limitation may result in the expiration of a portion of NOL or research and development tax credit carryforwards before they are realized.

adjustment were required.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

The Company files US federal and state income tax returns in the United States. All States federal tax years since incorporation remain open jurisdiction and various state jurisdictions. Since the Company is in a loss carryforward position, it is generally subject to examination by federal and state tax authorities for all tax years in which a loss carryforward is available.

As of December 31, 2023, the major taxing jurisdictions (state Company has not incurred any material interest or penalty charges.

13. Commitments and federal) Contingencies

Litigation

From time to time, the Company may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. From time to time, the Company may be involved in legal proceedings arising in the ordinary course of its business.

Between July 25 and October 3, 2023, Talaris received eleven demand letters (the “Demands”) regarding the Proxy Statement (as defined below). In addition, three lawsuits were filed (captioned Wieder v. Talaris Therapeutics, Inc., et al., No. 1:23-cv-08355 (S.D.N.Y. filed Sept. 21, 2023), Carlisle v. Talaris Therapeutics, Inc., et al., No. 1:23-cv-08520 (S.D.N.Y. filed Sept. 27, 2023), and Roberts v. Talaris Therapeutics, Inc., et al., No. 1:23-cv-01063 (D. Del. filed Sept. 27, 2023)) (the “Lawsuits,” and together with the Demands, the “Actions”), in each case, by purported stockholders of Talaris challenging the proposed Reverse Merger and the disclosures in the definitive proxy statement filed by Talaris with the SEC on July 20, 2023, and as amended on August 25, 2023 and September 11, 2023 (the “Proxy Statement”). The Actions generally alleged that certain disclosures in the Proxy Statement were false or misleading and asserted claims against Talaris and its Board of Directors for violations of Sections 14(a) and 20(a) of the Exchange Act of 1934. The purported stockholders sought unspecified monetary damages and an award of costs and expenses, including reasonable attorney’s fees. On October 10, 2023, Talaris filed a Form 8-K to update and supplement the Proxy Statement, which contained certain additional disclosures relating to the Reverse Merger (the “Supplemental Disclosures”). Thereafter, plaintiffs in the Lawsuits voluntarily dismissed their complaints, and opposing counsel (for the stockholders in the Actions) requested a mootness fee in connection with the Supplemental Disclosures. The Reverse Merger subsequently closed on October 19, 2023.

Thereafter, the parties engaged in a negotiation over payment of a potential mootness fee(s) to resolve all the fee demands. On February 13, 2024, the parties entered into an agreement, under which the Company is subject, agreed to pay a total of approximately $0.2 million to resolve all the fee demands and the stockholders released all claims in connection with the Reverse Merger. This amount was recognized as carryforward attributes generated in years past may still be adjusted upon examination general and administrative expense by the Internal Revenue Service ("IRS") or Company during the year ended December 31, 2023 and has been included within “Accrued expenses and other authorities if they have or will be used current liabilities” on the consolidated balance sheet as of December 31, 2023.

New York Office Lease

During the year ended December 31, 2022, the Company entered into a non-cancelable operating lease for its corporate offices in a future period. New York, New York (the “New York Office Lease”). The lease expires on February 28, 2026. The Company provided the landlord of the New York Office Lease with a security deposit in the form of a $0.2 million letter of credit, which is not currently under examination by recorded as restricted cash on the IRS or any other jurisdictions for any tax year.

consolidated balance sheets as of December 31, 2023 and 2022.

13. Defined Contribution Plan

The Company established recorded an ROU asset and corresponding lease liability related to the New York Office Lease on the consolidated balance sheets as of December 31, 2023 and 2022. As there was no rate implicit in the New York Office Lease, the Company estimated its incremental borrowing rate. Based on this analysis, the Company calculated a defined contribution discount rate of 15.6% for the New York Office Lease.

As of December 31, 2023, the future minimum lease payments due under the New York Office Lease are as follows (in thousands):

Year Ending December 31,	Amount
2024	$ 221
2025	227
2026	38
Total lease payments	486
Less: effect of discounting	(71)
Total operating lease liability	$ 415

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

The Company recorded operating lease expense of $0.2 million and less than $0.1 million for the years ended December 31, 2023 and 2022, respectively. Cash paid for operating lease liabilities for the year ended December 31, 2023 was $0.2 million. The Company did not incur any short-term or variable lease costs during the years ended December 31, 2023 or 2022. As of December 31, 2023, the remaining lease term of the New York Office Lease is 2.2 years.

14. 401(k) Savings Plan

The Company implemented a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan IRC (the "401(k) Plan") during the year ended December 31, 2023. The 401(k) Plan covers substantially all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation, on a pretax basis. Current subject to statutory limitations. The Company match did not make any matching contributions to the plan are made to employees who meet minimum service requirements in 401(k) Plan during the amount of year ended December 31, 2023.

15. 100 Related Party Transactions%

On October 1, 2021, and April 4, 2022, the Company entered into promissory note agreements with an equity investor, KVP Capital LP ("KVP"), for $0.2 million and $0.3 million aggregate principal amounts, payable on demand. The promissory notes were recorded at carrying value and did not bear interest. The issuance of the first 3%, and 50% Series A convertible preferred units on April 18, 2022 triggered the repayment of the next 2% promissory notes. There was no gain or loss recognized upon the extinguishment of employee contributions, subject the promissory notes during the year ended December 31, 2022.

In May 2023, an advisor affiliated with Fourth Avenue FF Opportunities LP – Series Z, previously a beneficial owner the Company's outstanding capital stock, exercised stock options to certain limitations. For purchase 75,782 shares of the years ended December 31, 2022 and 2021, Company's common stock for $0.13 per share. The Company subsequently repurchased the shares from the advisor at $2.76 per share, equivalent to fair value as of the repurchase date, for an aggregate purchase price of $0.2 million. Fourth Avenue FF Opportunities LP – Series Z then purchased the shares from the Company made contributions in at the same amount $2.76 per share for an aggregate purchase price of $0.6$0.2 million .

As of December 31, 2023 and $0.4 million, respectively.

2022, there were no amounts due to or from any related party.

14. Net Loss Per Share Attributable to Common Stockholders 16.

Net Loss Per per Share

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company *(in thousands except share and per share amounts)*.

	For the years ended December 31,	
	2022	2021
Net loss and net loss attributable to common stockholders	$ (73,894)	$ (47,833)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.79)	$ (1.64)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	41,248,392	29,126,373

The Company's potential dilutive securities, which include unvested RSUs, restricted stock related to early exercise of common stock options and common stock options, equivalents have been excluded from the computation calculation of diluted net loss per share as the because their effect would be antidilutive. 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. anti-dilutive:

	December 31,	
	2023	2022
Series A convertible preferred stock	—	2,163,764
Outstanding stock options under 2022 Equity Incentive Plan	1,403,409	374,282
Outstanding stock options under 2023 Equity Incentive Plan	1,042,291	—
Unvested restricted stock units under 2023 Equity Incentive Plan	18,697	—
Common stock subject to repurchase related to early exercised stock options	388,943	—
Total	2,853,340	2,538,046

17. The following potential dilutive securities, presented on an as converted basis, were excluded from the calculation of net loss per share due to their anti-dilutive effect:

	For the years ended December 31,	
	2022	2021
Options to purchase common stock	6,264,898	3,643,796

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Restricted stock units outstanding	1,144,994	—
Restricted stock related to early exercise of options to purchase common stock	158,154	538,340
	7,568,046	4,182,136

15. Related Party Transactions

The Company engaged a firm managed by a former executive of the company for professional services related to accounting, finance and other administrative functions during the year ended December 31, 2021. The costs incurred under this arrangement totaled $0.1 million, which were recorded as general and administrative expense in the accompanying statements of operations. No services were provided under this arrangement for the year ending December 31, 2022 and there are no amounts owed under this arrangement.

16. Subsequent Events

The Company has evaluated subsequent events for recognition and disclosure purposes through March 31, 2023 March 19, 2024, the filing date of this Annual Report on Form 10-K. Except for the financial statements were available to be issued. The matters described below, the Company has concluded that no subsequent other events or transactions have occurred that require disclosure except for those referenced below.

Strategic Alternatives and Restructuring Plan

In February 2023, the Company announced the discontinuation of its FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001's ability to induce durable tolerance in living donor kidney transplant recipients. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones. The Company initiated a comprehensive review of strategic alternatives focused on maximizing shareholder value, including possible business combinations and/or a divestiture of the Company's cell therapy CMC capabilities.

In connection with the discontinuation of FREEDOM-1 and FREEDOM-2 noted above, the Company implemented a restructuring plan. As part of this plan, the Company approved a reduction in the Company's workforce by approximately one-third across different areas and functions in the Company (the "Workforce Reduction"). The Workforce Reduction was substantially completed in the first quarter of 2023.

Affected employees were offered separation benefits, including severance payments. The Company estimates that retention, severance, and termination-related costs will total approximately $2.9 million in the aggregate and expects to record these charges in the first and second quarters of 2023. The Company expects that payments of these costs will be substantially complete through the end of the second quarter of 2023. The Company's estimates are subject to a number of assumptions, and actual costs may differ.

Leases

consolidated financial statements.

January 2024 Offering

On March 1, 2023 January 25, 2024, the Company entered into an amended lease underwriting agreement for (the "Underwriting Agreement") with Jefferies LLC, Piper Sandler & Co., Guggenheim Securities, LLC and Truist Securities, Inc. (collectively, the Louisville Lease. The amendment increased "Underwriters") in connection with the number offering, issuance and sale by the Company of successive one-year renewal terms from three 4,615,384 shares of the Company's common stock at a public offering price of $32.50 per share, less underwriting discounts and commissions, pursuant to five an effective shelf registration statement on Form S-3 (Registration No. 333-266875). The amendment also reduced Company granted the written renewal notice period for underwriters a 30-day option to purchase up to 692,307 shares of common stock at the successive one-year terms public offering price, less the underwriting discounts and commissions, which was exercised by the Underwriters in full on January 25, 2024. The January 2024 Offering closed on January 29, 2024.

Total gross proceeds from six months in advance the January 2024 Offering were approximately $172.5 million, including the full exercise by the Underwriters of their option to three months in advance. The amendment is not expected to have a material impact purchase additional shares. Net proceeds were approximately $161.3 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

slide1

ZQ|CERT#|COY|CLS|RGSTRY|ACCT#|TRANSTYPE|RUN#|TRANS# mil i COMMON STOCK COMMON STOCK imn -.t“ >>>>OS ^z o o o o m tho o o o co ^ S W N3 - o £ g 2; 1 g ls ! PAR VALUE $0.0001 Mm: TOURMALINEc Certificate Number Shares |:J5 oooooo1Ji= > *000000*ZQ00000000l 2 **000000* ff oooooo*I TOURMALINE BIO, INC. > '000000*I “lllNCORPORATED UNDER THE LAWS OF THE STATE OF DELAWAREI f~ SEE REVERSE FOR CERTAIN DEFINITIONS** Mr. *"* Mssasss^ra^sfKffisaieis—s Mr. Alexander David Sample *"*Mn Alexander David Sample*"* Mr. Alexander David Sampte ****Mr. Alexander David Sampte Mr. Alexander David Sample Alexander David Sample *"* Mr. Alexander David Sample **** Mr. Alexander David Sample **** Mr. Alexander David Sample **** Mr. Alexander David Sample **** Mr. Alexander David Sample **“ Mr. Alexander David Sample **** Mr. Alexander David Sample **“ Mr. Alexander David Sample **** Mr. Sample **** Mr. Sample I THIS CERTIFIES THAT mmz Z CUSIP 89157D 10 5Z 1^11 tipi ^pi SfSfesjji ggliagfi g m= o His the owner of OOQD‘*Shares-**‘OOOOoSRS?‘ToO§,4hare3raTOj*sSres^*looSb!^ifr "**Oo!ooEt^s^*oMo^^^e^l*QOTOTB^hares‘"*QOQ ares**""000000**Shares****000000"*Shares**""000000*frShares"***000000"*Shares**"*000000**Shares""**000000**Shares****000000*"Shares*** THIS CERTIFICATE IS TRANSFERABLE IN CITIES DESIGNATED BY THE TRANSFER AGENT, AVAILABLE ONLINE AT www.computershare.com;0*^ *Shares**"00000 Shares****DG0O0C IO**Shares“**00 0**Shares"**00i 0000**Shares**"000 0000**Shares****000G i000**Shares"**000000**Shares**"0(000**Shares*"*000000"Shares****00 00000**Shares"**000000“Shares****000000**Shares****000000** l0000**shares*"*000000"shares****000000**shares****000000**s Mm FULLY-PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK OF mm ■ Tourmaline Bio, Inc. (hereinafter called the “Company”), transferable financial statements.

Exhibit 10.5

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

AMENDED AND RESTATED

EXECUTIVE SEVERANCE AND CHANGE IN CONTROL PLAN

Effective Date: April 15, 2021

Amendment Effective Date: March 30, 2023

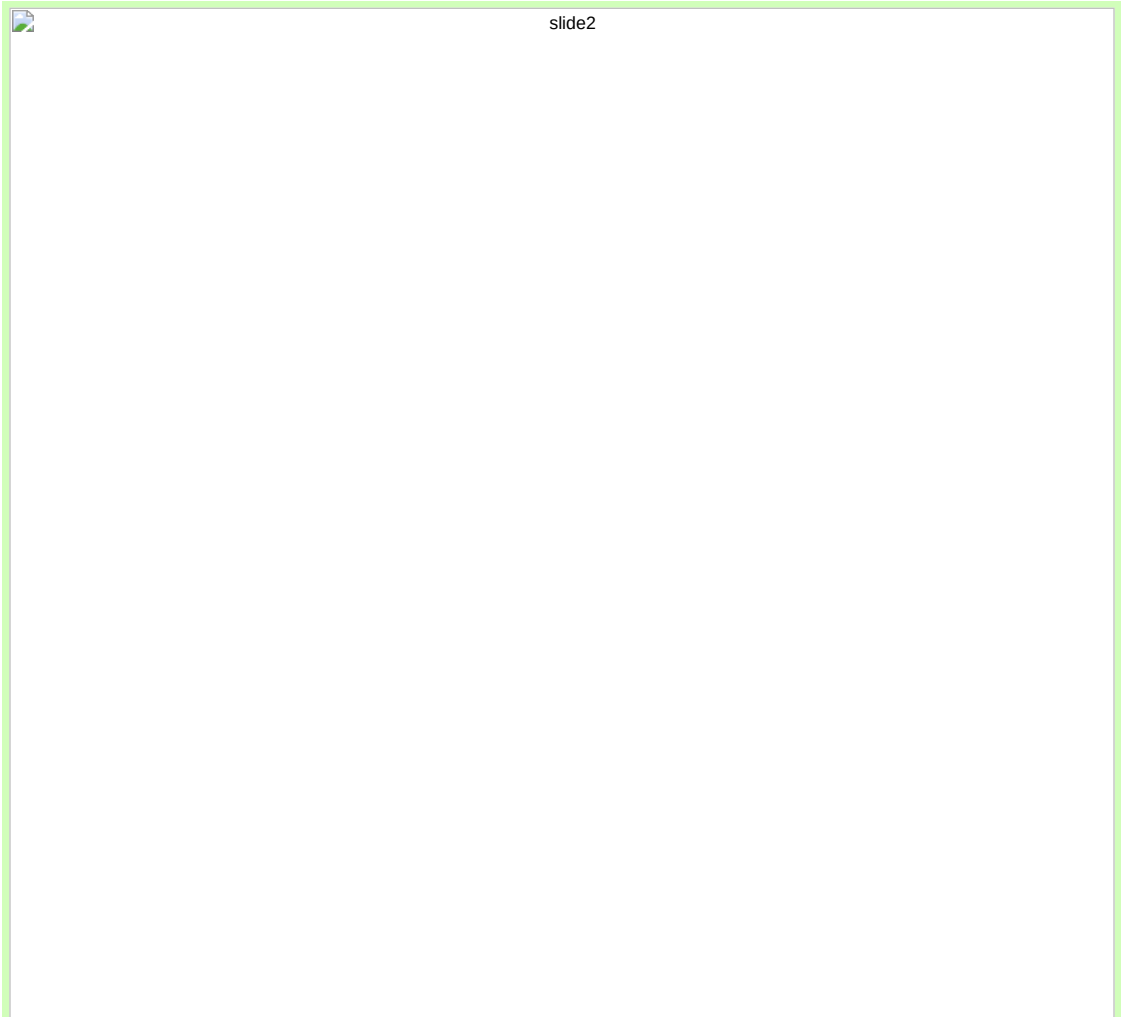
Talaris Therapeutics, Inc. (the "Company") sets forth herein books of the terms of its Amended and Restated Executive Severance and Change Company in Control Plan (the "Plan") as follows:

SECTION 1. PURPOSE.

The purpose person or by duly authorized attorney, upon surrender of this Plan is Certificate properly endorsed. This Certificate and the shares represented hereby, are issued and shall be held subject to establish all of the conditions under provisions of the Articles of Incorporation, as amended, and the By-Laws, as amended, of the Company (copies of which Eligible Executives will receive severance pay and benefits if employment are on file with the Company (or its successor, following a Change in Control) terminates under and with the circumstances specified herein.

SECTION 2. DEFINITIONS.

(a) "Accrued Obligations" means, with respect Transfer Agent), to an Eligible Executive, (i) the Eligible Executive's Base Salary through the Date all of Termination, (ii) an amount equal to the value of the Eligible Executive's accrued but unused paid time off days, if any, which each holder, by acceptance hereof, assents. This Certificate is not valid unless countersigned and (iii) the amount of any business expenses properly incurred registered by the Eligible Executive on behalf Transfer Agent and Registrar. alSSSSSS® | || IHIlasaassa 58°° IS cog? 3O -^ ^ ^ ^ ^ ^ c 3" IZ3 a*. IOIOIOIOIOIO3 Tl S® mcncncncncncn© <0 jo CD C5D CD CD CD CD — ^1 ^1 ^1 ^1 ^1 ^1 CO CO CO CO CO OO co co co co co co oooooo .... 1W1 a&ssgas^l# mMmA 3 Witness the facsimile seal of the Company prior and the facsimile signatures of its duly authorized officers. DATED DD-MMM-YYYY COUNTERSIGNED AND REGISTERED: COMPUTERSHARE TRUST COMPANY, N.A. TRANSFER AGENT AND REGISTRAR, illZ £c 83 ; SEAL : -I a FACSIMILE SIGNATURE TO COMEC75 cn -P^ OO N3 w President ® I O5O1-^0ON3—'■q 05 J-4, 3 00 o ■ CO o 1 Ups \ 2/15/2002 / ^AVV^I wmmmmMmm msmmMFACSIMILE SIGNATURE TO COME 05 cn 05 N5 -»■ By.x Secretary AUTHORIZED SIGNATURE A123456 Exhibit 4.1



©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

The IRS requires that the named transfer agent (“we”) report the cost basis of certain shares or units acquired after January 1, 2011. If your shares or units are covered by the legislation, and you requested to sell or transfer the shares or units using a specific cost basis calculation method, then we have processed as you requested. If you did not specify a cost basis calculation method, then we have defaulted to the Date first in, first out (FIFO) method. Please consult your tax advisor if you need additional information about cost basis. If you do not keep in contact with the issuer or do not have any activity in your account for the time period specified by state law, your property may become subject to state unclaimed property laws and transferred to the appropriate state. For value received,_____ hereby sell, assign and transfer unto

_____

_____

_____

_____ Shares

_____ Attorney Dated:

_____ 20_____ Signature:_____

Signature:_____ Notice: The signature to this assignment must correspond with the name as written upon the face of Termination the certificate, in every particular, without alteration or enlargement, or any change whatever. PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE (PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING POSTAL ZIP CODE, OF ASSIGNEE) of the common stock represented by the within Certificate, and do hereby irrevocably constitute and appoint to transfer the said stock on the books of the within-named Company with full power of substitution in the premises. . TOURMALINE BIO, INC. THE COMPANY WILL FURNISH WITHOUT CHARGE TO EACH SHAREHOLDER WHO SO REQUESTS, A SUMMARY OF THE POWERS, DESIGNATIONS, PREFERENCES AND RELATIVE, PARTICIPATING, OPTIONAL OR OTHER SPECIAL RIGHTS OF EACH CLASS OF STOCK OF THE COMPANY AND THE QUALIFICATIONS, LIMITATIONS OR RESTRICTIONS OF SUCH PREFERENCES AND RIGHTS, AND THE VARIATIONS IN RIGHTS, PREFERENCES AND LIMITATIONS DETERMINED FOR EACH SERIES, WHICH ARE FIXED BY THE ARTICLES OF INCORPORATION OF THE COMPANY, AS AMENDED, AND THE RESOLUTIONS OF THE BOARD OF DIRECTORS OF THE COMPANY, AND THE AUTHORITY OF THE BOARD OF DIRECTORS TO DETERMINE VARIATIONS FOR FUTURE SERIES. SUCH REQUEST MAY BE MADE TO THE OFFICE OF THE SECRETARY OF THE COMPANY OR TO THE TRANSFER AGENT. THE BOARD OF DIRECTORS MAY REQUIRE THE OWNER OF A LOST OR DESTROYED STOCK CERTIFICATE, OR HIS LEGAL REPRESENTATIVES, TO GIVE THE COMPANY A BOND TO INDEMNIFY IT AND ITS TRANSFER AGENTS AND REGISTRARS AGAINST ANY CLAIM THAT MAY BE MADE AGAINST THEM ON ACCOUNT OF THE ALLEGED LOSS OR DESTRUCTION OF ANY SUCH CERTIFICATE. Signature(s) Guaranteed: Medallion Guarantee Stamp THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (Banks, Stockbrokers, Savings and Loan Associations and Credit Unions) WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO S.E.C. RULE 17Ad-15. The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations: TEN COM - as tenants in common UNIF GIFT MIN ACT -.....Custodian..... (Cust) (Minor) TEN ENT - as tenants by the entireties under Uniform Gifts to Minors Act..... (State) JT TEN - as joint tenants with right of survivorship UNIF TRF MIN ACT -.....Custodian (until age.....) and not yet reimbursed, if any. as tenants in common (Cust) ..... under Uniform Transfers to Minors Act..... (Minor) (State) Additional abbreviations may also be used though not in the above list.

(b)

"Announcement Date” means

Exhibit 4.2

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

DESCRIPTION OF SECURITIES

The following description of our capital stock is intended as a summary only and therefore is not a complete description of our capital stock. This description is based upon, and is qualified by reference to, our certificate of incorporation, our bylaws, and applicable provisions of Delaware General Corporation Law. You should read our certificate of incorporation and our bylaws, in each case, as amended and supplemented, each of which is filed as an exhibit to our Annual Report on Form 10-K, and are incorporated by reference herein. We encourage you to read our certificate of incorporation, our bylaws and the date of public announcement of any transaction that, once consummated, results in a Change in Control.

(c) "Base Salary" means, with respect to an Eligible Executive, the annual base salary payable to the Eligible Executive by the Company and its Subsidiaries as applicable provisions of the Date of Termination (or, if higher, the annual base salary payable to the Eligible Executive by the Company and its Subsidiaries as of immediately prior to the Change in Control Date).

(d) "Board" means the Board of Directors Delaware General Corporation Law for a complete description of the Company.rights and preferences of our securities.

(e) **General**

"Cause" means Our authorized capital stock consists of 140,000,000 shares of common stock, par value $0.0001 per share, 10,000,000 shares of non-voting common stock, par value $0.0001 per share and shall be limited to: (i) a willful 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share, all of which shares of preferred stock are undesignated. The following description of our capital stock and material act provisions of dishonesty our certificate of incorporation and bylaws are summaries and are qualified by the Eligible Executive; (ii) the Eligible Executive's indictment for, conviction reference to our certificate of incorporation and our bylaws, in each case, as amended and supplemented.

Common Stock

The holders of our common stock and non-voting common stock have identical rights subject to two exceptions. First, except as otherwise expressly provided in our certificate of incorporation or plea of guilty or nolo contendere as required by applicable law, on any matter that is submitted to a felony or vote by our stockholders, holders of our common stock are entitled to one vote per share of common stock, and holders of our non-voting common stock are not entitled to any crime involving fraud, embezzlement or any willful act votes per share of moral turpitude; (iii) a violation non-voting common stock, including for the election of a federal or state law by directors. Second, holders of our common stock have no conversion rights, while holders of our non-voting common stock shall have the Eligible Executive right to convert each share of our non-voting common stock held into one share of common stock at such holder's election, provided that the Company reasonably determines may have a detrimental effect on the Company's reputation or business; (iv) the Eligible Executive's misconduct or gross negligence in the performance of the Eligible Executive's duties as an employee of the Company; (v) the Eligible Executive's unauthorized use or disclosure of any proprietary information or trade secrets of the Company that damages the Company or any other party to whom the Eligible Executive owes an obligation of nondisclosure as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of 9.9% of our common stock following such conversion, unless otherwise expressly provided for in our certificate of incorporation. However, this ownership limitation may be increased to any other percentage designated by such holder of non-voting common stock upon 61 days' notice to us or decreased at any time. Holders of our non-voting common stock are also permitted to make certain transfers to non-affiliates upon which, such transferred shares would immediately convert to shares of our common stock.

Except as otherwise provided by law, our third amended and restated certificate of incorporation or our bylaws, in all matters other than the Eligible Executive's relationship election of directors, the affirmative vote of the majority of the shares present in person or represented by proxy at a meeting at which a quorum is present and entitled to vote on the subject matter shall be the act of the stockholders. Directors shall be elected by a plurality of the shares present in person or represented by proxy at a meeting at which a quorum is present and entitled to vote on the election of directors.

Holders of our common stock and non-voting common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock and non-voting common stock have no preemptive rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock and non-voting common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. Holders of shares of our common stock and non-voting common stock are not required to make additional capital contributions. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our Company or other corporate action.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Anti-takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the Company; (vi) limitations on removal of directors and treatment of vacancies, has the Eligible Executive's breach effect of any obligations under any written agreement or covenant with making it more difficult for stockholders to change the Company; (vii) the Eligible Executive's engaging in any other conduct composition of our board of directors.

No Written Consent of Stockholders

Our certificate of incorporation provides that in the determination all stockholder actions are required to be taken by a vote of the Company, is materially injurious stockholders at an annual or detrimental special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the Company amendment of our bylaws or any removal of its affiliates; or (viii) the Eligible Executive's continued willful failure to perform the Eligible Executive's employment duties (other than as directors by our stockholders without holding a result meeting of stockholders.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only a majority of the Eligible Executive's death or Disability) after notice.

(f) "Change members of our board of directors then in Control" shall have the meaning office may call special meetings of stockholders and only those matters set forth in the Company's Second Amended and Restated 2018 Equity Incentive Plan (the "Equity Plan"); providednotice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the avoidance preceding year. Our bylaws specify the requirements as to form and content of doubt, any merger, reorganization all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or consolidation pursuant special meeting.

Amendment to which the holders Certificate of the Company's outstanding voting power Incorporation and outstanding stock immediately prior to such transaction do not own Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding voting power shares of capital stock (other than the non-voting common stock) entitled to vote on the amendment and outstanding stock or other equity interests a majority of the resulting or successor entity (or its ultimate parent, if

---

applicable) immediately upon completion outstanding shares of such transaction shall constitute each class entitled to vote thereon as a "Change in Control;" providedfurtherclass, except that such Change in Control is also a "change in control event" within the meaning of Section 409A amendment of the Code.

(g) "Change in Control Date" means, with respect provisions relating to stockholder action, board composition, and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a Change in Control, the date of consummation of such Change in Control.

(h) "Change in Control Period" means

(i) with respect to an Eligible Executive employed class. Our bylaws may be amended by the Company at the level affirmative vote of executive-level manager or higher (a "C-Level Eligible Executive"), the period of time commencing 3 months prior to the Announcement Date or approval by the Board of Directors a majority of the Company of a complete liquidation or dissolution of the Company (but no earlier than April 1, 2023) and ending 12 months after the Announcement Date; and

(ii) with respect directors then in office, subject to any other Eligible Executive, (x) who has been employed by the Company for at least 12 months preceding the Announcement Date, the period of time commencing 3 months prior to the Announcement Date or approval by the Board of Directors of the Company of a complete liquidation or dissolution of the Company (but no earlier than April 1, 2023) and ending 12 months after the Announcement Date and (y) who has not been employed by the Company for at least 12 months preceding the Announcement Date (a "New Hire Eligible Executive"), the period of time commencing on the Change in Control and ending 12 months thereafter.

(i) "Code" means the Internal Revenue Code of 1986, as amended from time to time, and any regulations promulgated thereunder.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

(j) "Company" means Talaris Therapeutics, Inc., or, from and after a Change in Control, the successor to the Company in any such Change in Control.

(k) "Continuing Obligations" means an Eligible Executive's obligations to the Company pursuant to the Eligible Executive's Confidential Information, Inventions Assignment, and Restrictive Covenant Agreement and/or any other agreement relating to confidentiality, assignment of inventions, or other restrictive covenants (each such agreement, including, without limitation, the Confidential Information, Inventions Assignment, and Restrictive Covenant Agreement, a "Restrictive Covenant Agreement").

(l) "Date of Termination" means, with respect to an Eligible Executive, the effective date of termination of the Eligible Executive's employment with the Company and all of its Subsidiaries.

(m) "Disability" shall have the meaning limitations set forth in the Equity Plan.

(n) "Eligible Executive" means a United States employee bylaws; and may also be amended by the affirmative vote of not less than two-thirds of the Company outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class, or, any if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class. Any amendments of the provisions relating to the rights on non-voting common stock requires the unanimous approval of all outstanding shares of non-voting common stock.

Undesignated Preferred Stock Our certificate of incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its Subsidiaries (A) who fiduciary obligations, our board of directors were to determine that a takeover proposal is an employee not in the best interests of the Company as our stockholders, our board of the Amendment Effective Date and (B) who is employed at the level directors could cause shares of Vice President or above at the time of the Date of Termination (or, if applicable, at the time of a Change preferred stock to be issued without stockholder approval in Control); provided that, unless otherwise determined by the Administrator, a Vice President who (i) becomes a Vice President after the Amendment Effective Date and (ii) has not occupied the position of Vice President for at least three months at the time of the Date of Termination or Change in Control (as applicable) shall not be an Eligible Executive. Notwithstanding anything to the contrary herein, if an Eligible Executive is party to an employment or letter agreement with the Company (collectively, "Employment Agreement") that, as of the Effective Date of this Policy, contains a more favorable definition of a defined term in this Policy or provides for more favorable terms or provisions than provided under this Plan, then the more favorable definition, term or provision, or relevant combination thereof, shall be applicable for the benefit of the Eligible Executive; provided, however, that in no event shall there be duplication of payments or benefits under this Plan and the Employment Agreement.

(o) "Good Reason" means:

(i) with respect to any C-Level Eligible Executive either during or outside of the Change in Control Period, the occurrence of one or more private offerings or other transactions that might dilute the voting or other rights of the following, without proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation gran our board of directors broad power to establish the Eligible Executive's written consent: (A) rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock and non-voting common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a mate reduction change in control of us.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

(ii) with respect to any Eligible Executive other than a C-Level Eligible Executive within the Change in Control Period only, the occurrence of one or more of the following, without th Eligible Executive's written consent: (A) a material reduction in the Eligible Executive's Base Salary; (B) a material diminution of the Eligible Executive's duties, responsibilities or authority; or (C) a material change in the principal geographic location of the principal office of the Company to which the Executive is assigned and at which the Eligible Executi required to spend a majority of the Eligible Executive's working time such that there is an increase of at least 50 miles of driving distance to such location from the Eligible Executive's principal residence as of such change that materially increases the Eligible Executive's commuting time;

provided, however, that any such event shall not constitute Good Reason unless and until the Eligible Executive has provided the Company with written notice thereof no later than 30 days following the initial occurrence of such event and the Company shall have failed to remedy such event (if capable of being remedied) within 30 days of receipt of such notice, and the Eligible Executive must terminate the Eligible Executive's employment with the Company within 30 days after the expiration of such 30-day remedial period.

(p) "Subsidiary" means any subsidiary of the Company or, from and after a Change in Control, any subsidiaries of the successor to the Company.

(q) "Target Bonus" means, with respect to an Eligible Executive, the Eligible Executive's target annual performance bonus for the year in which the Date of Termination occurs (or, if higher, the target annual performance bonus in effect as of immediately prior to the Change in Control Date).

SECTION 3. SEVERANCE BENEFITS OUTSIDE OF THE CHANGE IN CONTROL PERIOD.

(a) If an Eligible Executive's employment is terminated by the Company without Cause or, with respect to a C-Level Eligible Executive, if the C-Level Eligible Executive terminates employment for Good Reason and in each case the Date of Termination occurs outside of the Change in Control Period, then, in addition to theAccrued Obligations, and subject to (i) the Eligible Executive signing a separation agreement and release in a form and manner satisfactory to the Company, which shall include, without limitation, a general release of claims against the Company and all related persons and entities, a non-disparagement provision, a return of property provision, a reaffirmation of all of the Executive's Continuing Obligations, a confirmation of the Eligible Executive's resignation from all officer, trustee and board member positions that the Eligible Executive holds with the Company or any of its respective Subsidiaries and affiliates, if applicable, and, at the Company's sole discretion, a 1-year post-employment non-competition agreement, and which shall provide that if the Eligible Executive breaches any of the Continuing Obligations, all payments of the severance payments and benefits shall immediately cease (such separation agreement and release, the "Separation Agreement"), and (ii) the Separation Agreement becoming irrevocable, all within the time frame set forth in the Separation Agreement but in no event more than 60 days after the Date of Termination, such Eligible Executive shall be entitled to receive the following severance payments and benefits:

(i) continuation of the Eligible Executive's Base Salary for the applicable Salary Continuation Period, as set forth on Schedule A, to be paid in substantially equal installments over the Salary Continuation Period (the "Severance Amount"); provided, however, that in the event the Eligible Executive is entitled to any payments pursuant to any Restrictive Covenant Agreement, the Severance Amount received in any calendar year will be

reduced by the amount the Eligible Executive is paid in the same calendar year pursuant to such Restrictive Covenant Agreement (the "Restrictive Covenant Agreement Setoff");

(ii) continuation of group health plan benefits to the extent authorized by and consistent with 29 U.S.C. § 1161 et seq. (commonly known as "COBRA"), with the cost of the regular premium for such benefits shared in the same relative proportion by the Company and the Eligible Executive as in effect on the Date of Termination until the earlier of: (A) the end of the applicable Benefit Continuation Period, as set forth on Schedule A, and (B) the date the Eligible Executive or the Eligible Executive's spouse becomes eligible for health benefits through another employer or otherwise become ineligible for COBRA; and

(iii) solely in the case of a New Hire Eligible Executive, (A) acceleration of any outstanding equity awards as if such New Hire Eligible Executive has served at least 12 months from start date and (B) the exercise period of any outstanding options or stock appreciation rights shall be extended through the date of consummation of a Change in Control (but in event later than the original expiration date of such options or stock appreciation rights).

(b) The amounts payable under Section 3(a)(i) shall be paid out in substantially equal installments in accordance with the Company's payroll practice over the applicable Salary Continuation Period commencing within 60days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments, to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

day immediately following the Date of Termination. Each payment pursuant to this Policy is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

SECTION 4. SEVERANCE BENEFITS WITHIN THE CHANGE IN CONTROL PERIOD.

The provisions of this Section 4 shall apply in lieu of, and expressly supersede, the provisions of Section 3 if (i) an Eligible Executive's employment is terminated either (a) by the Company without Cause or (b) by the Eligible Executive for Good Reason, and (ii) the Date of Termination is within the Change in Control Period and a Change in Control is consummated. complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the benefits underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in this Section 4 shall apply solely a venue other than those designated in the event exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a Change court in Control is consummated within those other jurisdictions. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these forum provisions. These forum provisions may impose additional costs on stockholders, may limit our stockholders' ability to bring a claim in a forum they find favorable, and the Change in Control Period. These provisions shall terminate and be designated courts may reach different judgments or results than other courts.

Section 203 of no further force or effect after the Change in Control Period. In the event an Eligible Executive is entitled to the severance payments benefits under this Section 4 but has already begun receiving severance payments and benefits pursuant Delaware General Corporation Law

We are subject to the provisions of Section 3, then 203 of the Eligible Executive will receive the severance payments and benefits set forth Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in this Section 4 a "business combination" with an "interested stockholder" for a three-year period following the occurrence time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of a Change in Control; provided that the lump sum amount under this Section 4 to be paid to following conditions:

- before the Eligible Executive following stockholder became interested, our board of directors approved either the occurrence of a Change in Control will be decreased by any severance pay and benefits previously paid to business combination or the Eligible Executive pursuant to Section 3, and the Eligible Executive will receive no further severance pay and benefits pursuant to Section 3. In no event may there be duplication of severance pay and benefits under Section 3 and Section 4.

(a) If an Eligible Executive's employment is terminated by the Company without Cause or an Eligible Executive terminates employment for Good Reason and in each case the D of Termination occurs within the Change in Control Period, then, in addition to the Accrued Obligations, and subject to (i) the Eligible Executive signing the Separation Agreement, and (ii) the Separation Agreement becoming irrevocable, all within the time frame set forth transaction which resulted in the Separation Agreement but in no even more than 60 days after the Date of Termination, such Eligible Executive shall be entitled to receive the following severance payments and benefits:

(i) a lump sum in cash in stockholder becoming an amount equal to the applicable Multiplier, as set forth on Schedule B, times the sum of (A) the Eligible Executive's Base Salary plus (B) the Eligible Executive's Target Bonus (such product, the "Change in Control Payment"); provided, however, that the Change in Control Payment shall be reduced by the amount of any Restrictive Covenant Agreement Setoff, if applicable; interested stockholder;

(ii)

- a lump sum upon consummation of the transaction which resulted in cash equal to a pro rata portion (based on the number stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of days the Eligible Executive was employed voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the Company during interested stockholder; or

- at or after the calendar year in which time the Date stockholder became interested, the business combination was approved by our board of Termination occurs) directors and authorized at an annual or special meeting of the Eligible Executive's Target Bonus; stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

(iii)
continuation

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of group health plan benefits 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the extent authorized by and consistent with 29 U.S.C. § 1161 et seq., with interested stockholder;

- subject to exceptions, any transaction involving the cost corporation that has the effect of increasing the proportionate share of the regular premium for such benefits shared in stock of any class or series of the same relative proportion corporation beneficially owned by the Company interested stockholder; and the Eligible Executive as in effect on the Date of Termination until the earlier of: (A) the end of the applicable Benefit Continuation Period, as set forth on Schedule B, and (B) the date the Eligible Executive or the Eligible Executive's spouse becomes eligible for health benefits through another employer or otherwise become ineligible for COBRA; and

(iv)

full accelerated vesting with respect to any of

- the Eligible Executive's then outstanding stock options, restricted stock units or other equity incentive awards, which shall immediately accelerate and become fully exercisable or nonforfeitable as of the later of the Date of Termination and the effective date of the Separation Agreement. The forfeiture of any unvested equity will be delayed to the extent necessary to effectuate this provision and will not occur if the acceleration pursuant to this provision occurs, and the exercise period of any outstanding options or stock appreciation rights shall be extended through the date of consummation of such Change in Control (but in no event later than the original expiration date of such options or stock appreciation rights).

(b) The amounts payable under Section 4(a)(i) shall be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall be paid in the second calendar year receipt by the last day interested stockholder of such 60-day period.

SECTION 5.CONTINUING OBLIGATIONS.

An Eligible Executive's eligibility to participate in this Plan and receive the severance benefits provided under Section 3 or Section 4 (as applicable) is in consideration of the Eligible Executive entering into and/or otherwise being party to a Restrictive Covenant Agreement in a form provided by the Company. All severance benefits provided under Section 3 or Section 4 (as applicable) are in consideration of the Eligible Executive's timely execution of and compliance with the Separation Agreement and the Eligible Executive's continued compliance with the Continuing Obligations. If the Eligible Executive fails to comply with (a) the terms of the Separation Agreement or (b) the terms of the Continuing Obligations, the Company reserves the right to withhold or terminate any unpaid severance payments or benefits (with the exception of legally-mandated benefits), including, without limitation, all severance payments and benefits provided under Section 3 or Section 4 (as applicable), and require the Eligible Executive to repay any amounts the Eligible Executive may have previously received under this Plan. Neither the Company's termination of any such unpaid severance payments or benefits nor the Eligible Executive's repayment of any such amounts the Eligible Executive may have previously received under this Plan shall affect the Eligible Executive's continuing obligations under this Plan, the Separation Agreement or the Continuing Obligations.

SECTION 6.SECTION 280G LIMITATION.

Anything in this Plan to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the Eligible Executive, whether paid corporation.

In general, Section 203 defines an interested stockholder as any entity or payable person beneficially owning 15% or distributed or distributable pursuant to the terms of this Plan or otherwise, calculated in a manner consistent with Section 280G more of the Code and the applicable regulations thereunder (the "Severance Payments"), would be subject to the excise tax imposed by Section 4999 outstanding voting stock of the Code, the following provisions shall apply:

(a) If the Severance Payments, reduced corporation and any entity or person affiliated with or controlling or controlled by the sum of (i) entity or person. **Listing on The Nasdaq Global Select Market** Our common stock is listed on The Nasdaq Global Select Market under the Excise Tax symbol "TRML." **Transfer A and (ii) th total of th Federal, state, Reg**

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Exhibit 10.6

TALARIS THERAPEUTICS, INC.

AMENDED AND RESTATED

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

The purpose 23.1

Consent of this Amended and Restated Non-Employee Director Compensation Policy (the "Policy") of Talaris Therapeutics, Inc. (the "Company") is to provide a total compensation package that enables the Company to attract and retain, on a long-term basis, high-caliber directors who are not employees or officers of the Company or its subsidiaries ("Outside Directors"). In furtherance of the purpose stated above, all Outside Directors shall be paid compensation for services provided to the Company as set forth below:

Cash Retainers

Annual Retainer for Board Membership: $35,000 for general availability and participation in meetings and conference calls of our Board of Directors, to be paid quarterly in arrears, pro-rated based on the number of actual days served by the director during such calendar quarter. No additional compensation will be paid for attending individual meetings of the Board of Directors.

Additional Annual Retainer for Non-Executive Chair: $40,000

Additional Annual Retainers for Committee Membership:

Audit Committee Chair: $15,000

Audit Committee member: $7,500

Compensation Committee Chair: $10,000

Compensation Committee member: $5,000

Nominating and Corporate Governance Committee Chair: $8,000

Nominating and Corporate Governance Committee member: $4,000

Chair and committee member retainers are in addition to retainers for members of the Board of Directors. No additional compensation will be paid for attending individual committee meetings of the Board of Directors.

Equity Retainers

Initial Award: An initial, one-time stock option award (the "Initial Award") to purchase 41,000 shares will be granted to each new Outside Director upon his or her election to the Board of Directors, which shall vest in equal annual installments over three years from the date of grant, provided, however, that all vesting shall cease if the director ceases to provide services to the Company in any capacity. The Initial Award shall expire ten years from the date of grant, and shall have a per share exercise price equal to the Fair Market Value (as defined in the Company's 2021 Stock Option and Incentive Plan) of the Company's common stock on the date of grant.

Annual Award: On each date of each Annual Meeting of Stockholders of the Company (the "Annual Meeting"), each continuing Outside Director, other than a director receiving an Initial Award, will receive an annual stock option award to purchase/covering 20,500 shares and the Non-Executive Chair who will receive an annual stock option award to purchase/covering 41,000 shares (in each case, the "Annual Award"), which shall vest in full upon the earlier of (i) the first anniversary of the date of grant or (ii) the date of the next Annual Meeting;

---

provided, however, that all vesting shall cease if the director ceases to provide services to the Company in any capacity, unless the Board of Directors determines that the circumstances warrant continuation of vesting. Such Annual Award shall expire ten years from the date of grant, and shall have a per share exercise price equal to the Fair Market Value (as defined in the Company's 2021 Stock Option and Incentive Plan) of the Company's common stock on the date of grant.

Sale Event Acceleration: All outstanding Initial Awards and Annual Awards held by an Outside Director shall become fully vested and exercisable upon a Sale Event (as defined in the Company's 2021 Stock Option and Incentive Plan).

Expenses

The Company will reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending meetings of the Board of Directors or any committee thereof.

Maximum Annual Compensation

The aggregate amount of compensation, including both equity compensation and cash compensation, paid by the Company to any Outside Director in a calendar year for services as an Outside Director shall not exceed $800,000; provided, however, that such amount shall be $1,200,000 for the calendar year in which the applicable Outside Director is initially elected or appointed to the Board of Directors; (or such other limits as may be set forth in Section 3(b) of the Company's 2021 Stock Option and Incentive Plan or any similar provision of a successor plan). For this purpose, the "amount" of equity compensation paid in a calendar year shall be determined based on the grant date fair value thereof, as determined in accordance with FASB ASC Topic 718 or its successor provision, but excluding the impact of estimated forfeitures related to service-based vesting conditions.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Adopted April 15, 2021, as amended by the Board of Directors on January 27, 2022.

Exhibit 10.7.1

UNIVERSITY OF LOUISVILLE LEASE AGREEMENT

TALARIS THERAPEUTICS

THIS THIRD AMENDMENT TO LEASE AGREEMENT ("Third Amendment") is effective as of the 1st day of March, 2023 ("Effective Date"), by and between the University of Louisville ("Lessor"), and Talaris Therapeutics, Inc. ("Lessee") (collectively the "Parties").

W I T N E S E T H:

WHEREAS, Lessor and Lessee are parties to that certain Lease Agreement dated November 1, 2018 ("Original Lease Agreement"), as subsequently amended on July 1, 2019 ("Amendment") and on February 1, 2020 ("Second Amendment") (collectively, the "Agreement"); and

WHEREAS, the parties mutually desire to modify the Agreement upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Lessor and Lessee hereby agree as follows:

Independent Registered Public Accounting Firm

1.**Defined Terms**. Capitalized terms contained but not defined in this Third Amendment shall have the meaning ascribed to such terms in the Agreement.

2. **Modification to Section 5.**Section 5, *Term*, is hereby amended and restated in its entirety as follows:

The initial term of this Agreement shall commence as of November 1, 2018 and shall last for a period of five (5) years ("Term"). This Agreement may be renewed by Lessee by providing not less than three (3) months' prior written notice to Lessor, for up to five (5) successive one (1) year renewal periods (each a "Renewal Term"). The rent for the Leased Premises set forth in Exhibit F to the Lease Agreement, as stated in the Amendment of July 1, 2019, shall remain in effect for each of the first three (3) Renewal Terms. If the Lessee elects to renew beyond the third Renewal Term, the rent for the fourth Renewal Term shall increase over the rent for the third Renewal Term by the lesser of three percent (3%) or Consumer Price Index (CPI) – January of current year to Janaury of previous year; All Urban Consumers. The rent for the fifth Renewal Term shall increase over the rent for the fourth Renewal Term by the lesser of three percent (3%) or CPI. For purposes of this Agreement, references to the Term shall include a Renewal Term.

3. **Modification to Section 13.**Section 13, *Assignment*, is hereby amended and restated in its entirety as follows:

Lessee may assign this Agreement upon prior written notice to Lessor, provided that the assignee assumes in writing all obligations under this Agreement and provided further that Lessee must obtain Lessor's prior written consent to such assignment, which Lessor shall not unreasonably withhold, condition or delay.

4. **Modification to Section 20.**Section 20, *Notices*, is hereby amended and restated in its entirety as follows:

Any notices required or desired to be given under this Agreement shall be in writing and shall be deemed given when hand-delivered, or mailed postage prepaid registered or certified mail return receipt requested to the following address:

To LESSOR: University of Louisville 421 Cardinal Blvd

Louisville, KY 40208 Attn: Lease Administration

To LESSEE: Talaris Therapeutics, Inc.

570 S. Preston St., Suite 400

Louisville, KY 40202 Attn: Contracts

5. **Modification to Section 22.** Section 22 is deleted in its entirety; provided, however, that the deletion of Section 22 shall not alter or amend any existing license or other agreement between the parties relating to intellectual property rights, or the relative rights and obligations of the parties as set forth thereunder.

6. **Modification to Exhibit B.**The first paragraph of Exhibit B, *Permitted Use(s)*, is hereby replaced in its entirety with the following:

Lessee shall use the Leased Premises for the purpose of development of cellular or gene therapeutics and/or for drug discovery.

7. **Miscellaneous.**This Third Amendment may be executed by the parties hereto individually or in combination, in one or more counterparts, each of which shall be an original and all of which will constitute one and the same Third Amendment and may be delivered by facsimile or PDF via electronic mail in a legally binding manner. This Third Amendment shall be governed and construed in accordance with the laws of the Commonwealth of Kentucky and shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, executors, administrators, personal representatives, successors and permitted assigns.

8. **No Further Modification.** In the event of any inconsistency between the Original Lease Agreement, the Amendment, the Second Amendment, and this Third Amendment, the terms of this Third Amendment shall control. Except as otherwise modified herein, all terms and conditions in the Agreement shall remain in full force and effect.

[Signatures appear on next page.]

IN WITNESS WHEREOF, Lessor and Lessee have executed this Third Amendment effective as of the date first shown above.

LESSOR: University of Louisville

By: /s/ Meg Campbell

Meg Campbell

Assistant Vice President of Planning, Design, and Construction

Date: 3/10/2023

Recommended By: /s/ Kevin Gardner

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Kevin Gardner
Executive Vice President Research & Innovation

Date: 3/10/2023

LESSEE: Talaris Therapeutics, Inc.

By: /s/ Scott Requadt

Scott Requadt
Chief Executive Officer
Date: 3/10/2023

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-266875on Form S-3 and Registration Statement Nos. 333-255835, 333-263647, 333-271033, and 333-263647 333-275131 on Form S-8 of our report dated March 31, 2023March 19, 2024, relating to the consolidated financial statements of Talaris Therapeutics, Tourmaline Bio, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023.

/s/ DELOITTE Deloitte & TOUCHE Touche LLP

Boston, Massachusetts

Morristown, NJ
March 31, 2023

19, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, Scott Requadt, Sandeep Kulkarni, certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2022 of Talaris Therapeutics, Tourmaline Bio, 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 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 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

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

(d)

(c) Disclosed in this report any change in the registrant's registrant's internal control over financial reporting that occurred during the registrant's registrant's most recent fiscal quarter (the registrant's 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 registrant's internal control over financial reporting; and

5. The registrant's 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 registrant's auditors and the audit committee of the registrant's 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 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 registrant's internal control over financial reporting.

/s/Scott Requadt Sandeep Kulkarni

Date: March 31, 2023
March 19, 2024

By:

By:

Scott Requadt Sandeep

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

pKulkarni **President and** Chief Executive Officer *(Principal Executive Officer)*

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, Mary Kay Fenton, Ryan Robinson, certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2022 of Talaris Therapeutics, Tourmaline Bio, 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 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 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)

   (c) Disclosed in this report any change in the registrant's registrant's internal control over financial reporting that occurred during the registrant's registrant's most recent fiscal quarter (the registrant's 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 registrant's internal control over financial reporting; and

5. The registrant's 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 registrant's auditors and the audit committee of the registrant's 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 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 registrant's internal control over financial reporting.

/s/Mary Ka..

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

Date: March 31, 2023
March 19, 2024

By:

By:

Ryan Robinson
Mary Kay Fenton Ryan Robinson Interim Chief Fina

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

ncial Officer,

(Principal Accounting Officer Vice President, Finan

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

nce and

Controller (*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

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Pursuant to the Annual Report requirement set forth in Rule 13a-14(b) of Talaris Therapeutics, the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350),Sandeep Kulkarni, Chief Executive Officer of Tourmaline Bio, Inc. (the "Company"), and Ryan Robinson, Interim Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ending December 31, 2022 fiscal year ended December 31, 2023, to which this Certification is attached as filed with the Securities and Exchange Commission on the date hereof Exhibit 32.1 (the "Report" "Annual Report"). I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

(2)

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

In Witness Whereof, the undersigned have set their hands hereto as of March 19, 2024.

By: /s/ Scott Requadt Sandeep Kulkarni

President

Date: March 31, 2023

/s/ Ryan Robinson

Scott Requadt Ryan Robinson

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

e n t a n d C h i e f E x e c u t i v e O f f i c e r

(P r i n c i p a l E x e c u t i v e O f f i c e r)

Interim Chief Financial Officer, Vice President, Finance and Controller *(Principal Financial Officer)*

Exhibit 32.2

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

This certification accompanies the Annual Report of Talaris Therapeutics, Inc. (the “Company”) on Form 10-K for the period ended December 31, 2022 as to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Tourmaline Bio, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

Exhibit 97

TOURMALINE BIO, INC.

Incentive Compensation Recoupment Policy

1. Introduction

The Board of Directors (the "***Board***") of Tourmaline Bio, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. Effective Date

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 20, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. Definitions

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date hereof (the "Report") on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. Recoupment

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, I certify, pursuant base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to 18 U.S.C. § 1350, all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

5. Administration

Except as adopted pursuant specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to § 906 make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to my knowledge:

(1) the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time.

8. Amendment; Termination

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

The Report fully complies Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the requirements of section 13(a) extent required by Rule 10D-1 and/or 15(d) of the Securities Exchange Act of 1934; applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and

(2) The information contained in filings with respect to this Policy that are required by law, including as required by the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 31, 2023

By: /s/ Mary Kay Fenton

Mary Kay Fenton

Chief Financial Officer

(Principal Accounting Officer and Principal Financial Officer)

SEC.

* * * * *

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2024, Refinitiv. All rights reserved. Patents Pending.

©2024 Refinitiv. All rights reserved. Republication or redistribution of Refinitiv content, including by framing or similar means, is prohibited without the prior written consent of Refinitiv. 'Refinitiv' and the Refinitiv logo are registered trademarks of Refinitiv and its affiliated companies.

REFINITIV