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DELTA REPORT

10-K

SRRK - SCHOLAR ROCK HOLDING CORP

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

The following comparison report has been automatically generated

TOTAL DELTAS	5856
CHANGES	263
DELETIONS	3322
ADDITIONS	2271

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31,, 2022 2023

OR

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

For the Transition Period from to

Commission File Number: 001-38501

SCHOLAR ROCK HOLDING CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware	**82-3750435**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

301 Binney Street, 3rd Floor

Cambridge, MA 02142

(857) 259-3860

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	SRRK	The Nasdaq Global Select Market

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-accelerated Filer	☒	Smaller Reporting Company	☒
		Emerging growth company	☒ ☐

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

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

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

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

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

As of June 30, 2022 June 30, 2023, the last day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $109.5 million $158.3 million based on the closing price of the registrant's common stock on June 30, 2022 June 30, 2023. The calculation excludes shares of the registrant's common stock held by current executive officers, directors and stockholders that the registrant has concluded are affiliates of the registrant. This determination of affiliate status is not a determination for other purposes.

As of March 2, 2023 March 14, 2024, there were 51,985,072 77,866,281 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report"), including the documents incorporated by reference, contains forward-looking statements within the meaning of the federal securities laws, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are including this statement for purposes of complying with those safe harbor provisions. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "intends", "plans", "anticipates", "believes", "estimates", "predicts", "potential", "continue" or the negative of these terms or other comparable terminology. Some of the risks and uncertainties that may cause our actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements include, among others, the following:

- the success, cost and timing of clinical trials for apitegromab (such as our Phase 3 SAPPHIRE clinical trial) and SRK-181, including the progress, and completion, of clinical trials, and the results, and the timing of results, from these and actual results of our clinical trials;
- our success in identifying and executing a development program for additional indications for apitegromab and SRK-181 and in identifying product candidates from our preclinical programs;
- the clinical utility of our product candidates and their potential advantages over other therapeutic options;
- our ability to obtain, generally or on terms acceptable to us, funding for our operations, including funding necessary to complete further development and, upon successful development, if approved, commercialization of apitegromab, SRK-181 or any of our future product candidates;
- timing of and costs associated with our restructuring, and the savings benefits we expect to receive from the restructuring;
- risks associated with impact of global economic and political developments on our business, including rising inflation and capital market disruptions, the current conflict in Ukraine, economic sanctions and economic slowdowns or recessions the COVID-19 pandemic or other public health pandemics, which may adversely impact our workforce, global supply chain, business, preclinical studies, clinical trials, our research and development efforts, the value of our common stock and our ability to access capital markets, and financial results;
- the potential for our identified research priorities to advance our proprietary platform by identifying future product candidates;

- the timing, scope, or likelihood of our ability to obtain and maintain regulatory approval from the U.S. Food and Drug Administration ("FDA"), the European Commission ("EC") and other regulatory authorities for apitegromab SRK-181 and any future product candidates, following completion of our Phase 3 SAPPHIRE clinical trial, and any related restrictions, limitations or warnings in the label of any approved approval for apitegromab;
- our success in identifying and executing a development program for our preclinical product candidate; candidates, including SRK-439 and identifying additional product candidates from our preclinical programs and research pipeline;
- our success in identifying and executing development programs for additional indications for apitegromab and SRK-181;
- the clinical utility of our product candidates and their potential advantages over other therapeutic options;
- our ability to continue obtain, generally or on terms acceptable to grow us, funding for our organization, operations, including funding necessary to complete further development and, upon successful development, if approved, commercialization of apitegromab, SRK-181, SRK-439 or any of our personnel, systems and relationships with third parties; future product candidates;
- our ability to retain our executives and highly skilled technical and managerial personnel, which could be affected due to any transition in management, or if we fail to recruit additional highly skilled personnel;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and the duration of such protection and our ability to operate our business without infringing on the intellectual property rights of others;

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- our ability, and the potential through third party manufacturers to successfully manufacture our product candidates for clinical trials and for commercial use, if approved;
- our ability to successfully build a commercial infrastructure to launch and market apitegromab, or otherwise provide access to apitegromab, if approved; and when it is approved or receives pricing or reimbursement approval;
- our ability to establish or maintain collaborations or strategic relationships;
- our expectations relating to the potential of our proprietary platform technology;
- our ability to obtain additional funding when necessary;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in combination with others;

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- our expectations related to the use of our cash reserves;
- the impact of new laws and regulations or amendments to existing laws and regulations in the United States and foreign countries;
- risks associated with the impact of global economic and political developments on our business, including rising inflation and capital market disruptions, economic sanctions and economic slowdowns or recessions or public health pandemics;
- developments and projections relating to our competitors and our industry;
- our estimates and expectations regarding cash, cash reserves, and expense levels, future revenues, capital requirements and needs for additional financing, including our expected use of proceeds from our public offerings, and liquidity sources;
- our expectations regarding the period during which we qualify as an emerging growth company ("EGC") under the Jumpstart Our Business Startups Act or as a "smaller reporting company" as defined by Rule 12b-2 of the Securities Exchange Act of 1934; and
- other risks and uncertainties, including those listed under the caption Part II, Item 1A "Risk Factors".

The risks set forth above are not exhaustive. Other sections of this report may include additional factors that could adversely affect our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for management to predict all risk factors, nor can we assess the impact of all risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results. Investors should also refer to our most recent Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q for future periods and Current Reports on Form 8-K as we file them with the SEC, and to other materials we may furnish to the public from time to time through Current Reports on Form 8-K or otherwise, for a discussion of risks and uncertainties that may cause actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements. We expressly disclaim any responsibility to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events, or otherwise, and you should not rely upon these forward-looking statements after the date of this report.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence

rates and market size, may differ materially from the information reflected in this Annual Report. Unless otherwise expressly stated, we obtained this industry data, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

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PART I

Item 1. Business

I. Overview

We are a late-stage biopharmaceutical company focused on the discovery, development and development delivery of innovative medicines for the treatment of serious diseases in which signaling by protein growth factors plays a fundamental role. As a global leader in transforming growth factor beta (“TGFβ”) superfamily biology, our novel understanding of the molecular mechanisms of growth factor activation enabled us to develop a proprietary platform for the discovery and development of monoclonal antibodies that locally and selectively target the precursor, or latent, forms of growth factors. By targeting the signaling proteins at the cellular level and acting in the disease microenvironment, we believe we may avoid the historical dose-limiting safety challenges associated with inhibiting growth factors for therapeutic effect. We believe our focus on biologically validated growth factors may facilitate a more efficient development path.

Based on this proprietary and scalable technology platform, we are building a growing portfolio of novel product candidates with the aim of transforming the lives of patients suffering from a wide range of serious diseases,

including neuromuscular disorders, cardiometabolic disorders, cancer, fibrosis and iron-restricted anemia. We have discovered and progressed the development of:

- Apitegromab, an inhibitor investigational, fully human monoclonal antibody that inhibits myostatin activation by selectively binding the pro- and latent forms of the activation of latent myostatin in skeletal muscle and is being developed for the treatment of spinal muscular atrophy ("SMA"). We also believe apitegromab could have potential in the treatment of other neuromuscular disorders where the inhibition of myostatin may be beneficial.

- SRK-439, a novel, preclinical, investigational myostatin inhibitor that has high invitro affinity for pro- and latent myostatin and maintains myostatin specificity and is being developed for the treatment of cardiometabolic disorders.

- SRK-181, an inhibitor of the activation of latent transforming growth factor beta-1 ("TGFβ1"), that is being developed for the treatment of cancers that are resistant to anti-PD-(L)1 antibody therapies.

- Potent and selective inhibitors of the activation of TGFβ for the treatment of fibrotic diseases. We are advancing multiple antibody profiles toward product candidate selection including antibodies that selectively inhibit the activation of latent TGFβ1 in the context of fibrotic extracellular matrix and that avoid perturbing TGFβ1 presented by cells of the immune system.

- Additional discovery and early preclinical programs related to the selective modulation of growth factor signaling including bone morphogenetic protein 6 ("BMP6") and other growth factors.

Our first product candidate, apitegromab, is a highly selective, fully human, monoclonal antibody, with a unique mechanism of action that results in inhibition of the activation of the growth factor, myostatin, in skeletal muscle. Apitegromab is being developed as a potential first muscle-targeted therapy for the treatment of SMA. We are conducting SAPPHIRE, a pivotal Phase 3 clinical trial to evaluate the efficacy and safety of apitegromab in patients with nonambulatory Type 2 and Type 3 SMA (which is estimated to represent the majority of the current prevalent SMA patient population in the U.S. and Europe). We expect to complete completed enrollment of SAPPHIRE in 2023, with the top-line data readout expected in the fourth quarter of 2024. If successful and if apitegromab is approved, we expect to initiate a commercial product launch in 2025.

Apitegromab was evaluated in our Phase 2 TOPAZ proof-of-concept clinical trial for the treatment of patients with Type 2 and Type 3 SMA. Positive 12-month top-line results were initially announced in April 2021. In June 2022, we We have subsequently presented 24-month efficacy data from the TOPAZ trial over 24-months (June 2022) and safety extension data of apitegromab from TOPAZ. These data36-months (July 2023), which showed sustained and that continued improvement treatment with apitegromab for nonambulatory over the extended period was associated with substantial and sustained improvement in motor function and patient-reported outcomes (via caregiver proxy)in patients with nonambulatory

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Types 2 and 3 SMA receiving an SMN therapy (see “Phase 2 TOPAZ Trial Analysis” below). We expect to report 36-month Additionally, we have a long-term extension data study, ONYX, for patients from both the TOPAZ and SAPPHIRE studies, who are receiving apitegromab in mid-2023. conjunction with an approved SMN therapy. The FDA granted fast track designation, rare pediatric disease designation and orphan drug designation to apitegromab for the treatment of SMA in May 2021, August 2020 and March 2018, respectively. The European Medicines Agency (“EMA”) granted PRIority MEdicines Priority Medicines (“PRIME”) designation in March 2021 and the European Commission (“EC”) EC granted orphan medicinal product designation in December 2018 to apitegromab for the treatment of SMA.

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Table In October 2023, we announced an expansion of Contents our therapeutic focus into cardiometabolic disorders by advancing our anti-myostatin program with SRK-439, a novel, fully human anti-myostatin monoclonal antibody, for evaluation in cardiometabolic disorders, including obesity. We are developing SRK-439 towards a potential investigational new drug application (“IND”) submission in 2025. To inform the development of SRK-439, we plan to initiate a Phase 2 proof-of-concept trial of apitegromab in combination with GLP-1 receptor agonist (GLP-1 RA) in 2024 with data expected in mid-2025.

Our second product candidate, SRK-181, a highly selective inhibitor of the activation of latent TGFβ, is being developed for the treatment of cancers that are resistant to checkpoint inhibitor therapies (“CPI therapies”), such as anti-PD-1 or anti-PD-L1 (“antibody therapies (referred to together as anti-PD-(L)1”) 1 antibody therapies. therapies). SRK-181 is a highly selective inhibitor of the activation of latent TGFβ1 that is being investigated was evaluated in our Phase 1 DRAGON proof-of-concept clinical trial in patients with locally advanced or metastatic solid tumors that exhibit resistance to anti-PD-(L)1 antibodies. antibody therapies. We completed enrollment of the DRAGON trial in December 2023. This two-part clinical trial consists of a dose escalation portion (Part A) and a dose expansion portion evaluating SRK-181 in combination with an approved anti-PD-(L)1 antibody therapy (Part B). Part B commenced in 2021 and includes the following active cohorts: urothelial carcinoma, cutaneous melanoma, non-small cell lung cancer, clear cell renal cell carcinoma (“ccRCC”) and head and neck squamous cell carcinoma (“HNSCC”). Initial clinical Safety, efficacy and biomarker data from Part A were presented in November 2021 2023 at the Society for Immunotherapy of Cancer (“SITC”) 36 38th Annual Meeting and additional clinical data were presented at Meeting. We believe that the 2022 SITC Annual Meeting in November 2022. The Phase 1 DRAGON trial continues achieved its study objectives by showing objective, durable clinical responses in patients with ccRCC resistant to advance, and we PD-1 therapy above what is expected from continuing PD-1 alone. We expect to provide biomarker and clinical updates present emerging data from the DRAGON trial at medical meetings in 2023. the future.

Beyond these programs, we continue to discover and develop highly specific monoclonal antibodies to selectively modulate growth factor signaling. Growth factors are naturally occurring proteins that typically act as signaling molecules between cells and play a fundamental role in regulating a variety of normal cellular processes, including cell growth and differentiation. Current therapeutic approaches to treating diseases in which growth factors play a fundamental role involve directly targeting the active form of the growth factor or its receptor systemically throughout the body. These approaches have suffered from a variety of shortcomings, including lack of pathway selectivity, lack of target selectivity, and non-localized target inhibition.

Our innovative approach is rooted in our structural biology insights into the mechanism by which certain growth factors are activated in close proximity to the cell surface. We integrate these insights with sophisticated protein expression, assay development and monoclonal antibody discovery capabilities. capabilities, and assay development to test the characteristics of our monoclonal antibodies. We believe our proprietary platform can address the challenges of treating diseases in which growth factors play a fundamental role by:

- targeting the natural activation mechanism to prevent activation of the growth factor rather than attempting to inhibit the growth factor after activation;
- achieving heightened specificity for the targeted growth factor while minimizing interactions with structurally similar and related growth factors, thereby potentially reducing the risk of unintended systemic adverse events; and
- targeting the disease microenvironment, where we believe we can interfere with the disease process while minimizing the effects on the normal physiological processes mediated by the same growth factors.

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Our structural insights and unique antibody discovery capabilities can be applied to other protein classes beyond growth factors, with an aim of generating differentiated candidates targeting cell surface receptors such as immune cell receptors or G-protein coupled receptors, where selectivity remains challenging.

II. Our Approach and Proprietary Platform

Our innovative approach is rooted in our novel understanding of the molecular mechanisms of growth factor activation and signaling and is designed to discover and develop monoclonal antibody product candidates that can inhibit the activation of a growth factor with an unprecedented degree of selectivity. Our proprietary platform is designed to generate product candidates that target the growth factor's latent precursor form prior to its activation within the disease microenvironment, or tissue where it is localized.

Growth factors are naturally occurring proteins that typically act as signaling molecules between cells and play a fundamental role in regulating a variety of normal cellular processes. Members of the TGFβ superfamily of growth factors, for example, can mediate diverse biological functions, including cell growth and differentiation, tissue homeostasis, immune modulation and extracellular matrix remodeling. Growth factors have also been shown to play a fundamental role in a variety of disease processes. Because of the importance of growth factors in multiple diseases, the pharmaceutical industry has made many attempts to inhibit growth factors in a variety of therapeutic settings. However, products utilizing conventional approaches have seen only limited success. Current therapeutic approaches to treating

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diseases in which growth factors play a fundamental role involve directly targeting an activated growth factor or its receptor systemically throughout the body and have suffered from a variety of shortcomings:

- Lack of pathway selectivity—multiple growth factors often signal through the same or overlapping sets of related receptors, making it difficult to specifically modulate one pathway over another;
- Lack of target selectivity—members of the same growth factor superfamily share considerable structural similarities, making it difficult to achieve specific inhibition of the targeted growth factor; this can result in broad systemic inhibition that can cause undesirable, and in many cases toxic, side effects; and
- Lack of disease microenvironment localization—systemic and non-selective inhibition of a growth factor can block the growth factor's role in the disease process, but can also simultaneously interfere with its other normal physiological roles.

Our approach to the discovery and development of growth factor targeted drugs is fundamentally new and different from traditional approaches. Our approach of targeting the precursor, or latent forms of growth factors is based on the breakthrough discovery by the laboratory of our cofounder, Timothy A. Springer, Ph.D. of Harvard Medical School and Boston Children's Hospital.

Unlike many other proteins that are produced and secreted by cells in a mature, or active, form, many growth factors are expressed by cells in a latent form. For example, TGFβ1 is produced by cells as a single protein which is then enzymatically processed by the cells into two distinct and physically separated domains — the mature growth factor and the remaining portion of the original protein, referred to as the prodomain — which remain associated as part of a complex. This secreted complex is latent, or inactive, and must first be activated to carry out its normal function in a highly localized tissue or disease microenvironment. In a seminal peer-reviewed publication in 2011, Dr. Springer elucidated a new understanding of the mechanism of activation of the latent growth factor complex among members of the TGFβ superfamily by solving a high-resolution x-ray crystal structure of this latent form of TGFβ1 (as illustrated in the graphic below).

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Graphic

Structural representation of the latent form of TGFβ1 wherein the prodomain wraps around the active growth factor

This research explained at a molecular level why the secreted form of TGFβ1 is inactive. The prodomain, though physically separated from the mature growth factor domain, forms a “cage” around the active form of TGFβ1, blocking

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the growth factor from signaling through its receptor. Only when the cage is “unlocked” by a precursor activation event can the growth factor be released and mediate its effects in the local microenvironment. Dr. Springer further hypothesized that this phenomenon likely holds true for most members of the TGFβ superfamily, though the exact nature of the activation event, such as integrin binding or enzymatic cleavage, may differ among members of the superfamily. Importantly, while many growth factors are structurally very similar, their cages are structurally diverse, and this provides the basis for our approach to improved selectivity.

We believe that there are several important advantages to our approach of targeting the precursor, or latent, forms of growth factors over conventional therapeutic approaches, which inhibit mature growth factors or their receptors systemically throughout the body:

- targeting the latent precursor allows intervention at the site of action, within the microenvironment of the diseased tissue. Because our antibodies specifically bind the latent forms of the growth factors, we can prevent the activation of the growth factors. Given that many growth factors act primarily within the microenvironment where they are activated, as opposed to exerting their effects systemically, we believe that prevention of activation is a preferred mode of action for achieving improved outcomes. In contrast, traditional approaches to targeting growth factor signaling are focused on inhibiting the growth factor after it has been activated and released systemically;

- targeting the latent precursor allows heightened selectivity among structurally related growth factors, which we believe could limit off-target off target effects. For example, two members of the TGFβ superfamily, myostatin and GDF11, are 90% identical in their growth factor domains. Therefore, many of the traditional inhibitors that target myostatin also inadvertently inhibit GDF11. Similarly, most of the known inhibitors of TGFβ are pan-inhibitors, paninhibitors, meaning that they do not distinguish among the three isoforms of TGFβ, namely, TGFβ1, TGFβ 2 and TGFβ3. Despite the sequence similarities of the active forms of these growth factors, their cages are structurally diverse. We have been able to harness this diversity to generate antibodies that specifically bind the

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inactive growth factor precursors and inhibit activation of a particular growth factor of interest, but not others that are closely related; and

- targeting these precursor forms in the disease microenvironment, we believe we can interfere with the disease process while minimizing the effects on the normal physiological processes mediated by growth factors.

To enable our novel approach, we have built a proprietary platform that is rooted in our structural biology insights into activation of latent growth factor precursors. We integrate these insights with sophisticated protein expression, assay development and monoclonal antibody discovery capabilities. capabilities, and assay development to test the characteristics of our monoclonal antibodies. In addition to this expertise, know-how, our proprietary platform is covered by two patent families, with issued patents projected to expire well into the 2030s, excluding any patent term adjustments or extensions. The key elements of our proprietary platform include the following:

- focusing on growth factor targets with a high degree of evidence implicating them in a disease process or processes;

- utilizing structural biology insights to generate recombinant versions of the latent forms of targeted growth factors, as well as versions of closely related growth factors utilizing proprietary technology and in-house expertise;

- developing proprietary assays in which we are able to recapitulate the natural activation mechanism that these growth factors undergo in the human body;

- designing sophisticated selection strategies utilizing recombinant antibody libraries such as phage and yeast display that allow us to identify monoclonal antibodies, a well-established therapeutic modality, that can modulate the activation of these growth factors without having an effect on the activation of other closely related growth factors; and

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- optimizing the output of such selections to ensure that our product candidates have the appropriate characteristics for manufacturability and further development.

Using our innovative approach and proprietary platform, we are creating a pipeline of novel product candidates that selectively modulate the activation of growth factors implicated in a variety of serious diseases. Our structural insights and unique antibody discovery capabilities can also be applied to other protein classes beyond growth factors, with an aim of generating differentiated candidates targeting cell surface receptors such as immune cell receptors or G-protein coupled receptors, where selectivity remains challenging.

III. Our Expertise

We have assembled an experienced management team, board of directors, and scientific founders and advisory board who bring extensive industry experience to our company. The members of our team have deep experience in discovering, developing and commercializing therapeutics, having worked at companies such as: Acceleron Pharma, Inc.; Alnylam Pharmaceuticals, Inc.; AMAG Pharmaceuticals, Inc.; Celgene Corporation; Foundation Medicine, Inc.; Krystal Biotech, Inc.; and Novartis Pharmaceuticals; and Ocata Therapeutics, Inc. Pharmaceuticals. We were founded by internationally respected scientists, Drs. Timothy A. Springer and Leonard I. Zon of Harvard Medical School and Boston Children's Hospital.

IV. Our Strategy

Using our proprietary platform to unlock the therapeutic potential of targeting growth factor signaling in the disease microenvironment, our goal is to deliver novel therapies to underserved patients suffering from a wide range of serious diseases, including neuromuscular disorders, cardiometabolic disorders, cancer, fibrosis and iron-restricted anemia. To achieve this goal, we plan to:

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- ***Continue advancing apitegromab through its registrational program in SMA to characterize its potential to offer meaningful benefit to patients.*** We are developing our first product candidate, apitegromab, for the treatment of patients with SMA. By targeting the latent form of myostatin and specifically inhibiting its activation in muscle, we believe apitegromab holds considerable promise in improving motor function in patients with SMA. We are currently conducting SAPPHIRE, a pivotal Phase 3 trial to evaluate the efficacy and safety of apitegromab in patients with nonambulatory Type 2 and Type 3 SMA being treated with survival motor neuron ("SMN") therapy (e.g., therapies that upregulate the expression of SMN, such as SMN splicing modulators).

- ***Identify the next indication(s) for apitegromab.*** Our goal is to maximize the value of apitegromab by exploring its potential across SMA types and in other myostatin-related indications. We believe that the role of apitegromab as a muscle-targeted therapy could have broad potential beyond SMA, spanning a number of multiple muscle disorders in which fast-twitch fibers may play an important role in motor function. There is also increasing recognition of the important role of skeletal muscle in modulating metabolic physiology, highlighting a potential therapeutic opportunity for myostatin blockade. We have efforts underway to evaluate these opportunities, including preclinical and translational research, development path assessments, and commercial evaluations.

- ***Leverage anti-myostatin expertise to expand into cardiometabolic disorders.*** Muscle plays a key role in metabolic functions and energy homeostasis. Leveraging the effect of anti-myostatin on increasing muscle mass and our expertise in selectively targeting anti-myostatin, we have been developing myostatin-selective inhibitors to address cardiometabolic disorders, including obesity. Our platform has generated multiple anti-myostatin antibodies, including apitegromab, that selectively target pro- and latent forms of myostatin. SRK-439, a novel anti-myostatin antibody in preclinical development by us, has attractive properties, including high in vitro affinity for pro- and latent myostatin, maintenance of myostatin specificity (i.e., no GDF11 or Activin-A binding), and robust in vivo efficacy in preclinical models. We believe the selectivity of these product candidates enables a favorable risk-benefit profile for patients with cardiometabolic disorders.

- ***Advance our TGFβ1 product candidate, SRK-181, through clinical proof-of-concept.*** Our second antibody program is focused on the discovery and development of potent and selective inhibitors of the activation of latent TGFβ1. We believe that the selectivity of SRK-181, as observed in preclinical studies, is a significant differentiator in our efforts to address the historical dose-limiting safety challenges resulting from non-selectively inhibiting multiple isoforms that activate the TGFβ signaling pathway. We are conducting a have completed enrollment of the Phase 1 proof-of-concept clinical trial of SRK-181 in patients with locally advanced or metastatic solid tumors that are experiencing resistance to anti-PD-(L)1 antibody therapy. Data from the DRAGON trial supports proof-of-concept for SRK-181 in heavily pre-treated patients with ccRCC resistant to anti-PD-(L)1 therapy. Additionally, we believe that SRK-181 has the potential to address unmet medical needs in other oncology indications, and we will endeavor to maximize the value of this product candidate by exploring its potential in additional oncology indications. candidate.

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- ***Continue to leverage our proprietary platform to expand our pipeline beyond current lead programs.*** We will continue to leverage and expand our proprietary platform to selectively target the activation of additional growth factors, both within and beyond the TGFβ superfamily. Given the established role of signaling by protein growth factors in numerous diseases, we believe that these efforts could result in new opportunities to treat diseases with unmet medical need. In order to support our pipeline expansion and intention to be the leader in the field of growth factor-targeted drug development, we are investing in the technologies supporting our proprietary platform. We have designed a proprietary, state of the art, antibody display library to more efficiently identify differentiated candidate antibodies. Furthermore, we believe that our structural insights have applicability beyond growth factor activation to include other cell signaling mechanisms.

  We believe that additional product candidates in the TGFβ portfolio have the potential to address other disorders associated with increased TGFβ signaling, including tissue and organ fibrosis. To advance the discovery and development of selected inhibitors originating from our TGFβ program that we believe have the potential to address unmet medical needs in non-oncology indications, we entered into a three-year fibrosis-focused collaboration with Gilead Sciences, Inc. ("Gilead"). in 2018. At the conclusion of the agreement in

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January 2022, the rights to the respective antibodies reverted to us. We have identified a suite of anti-fibrotic antibodies with novel selectivity profiles that were discovered over the course of the collaboration including those which may have therapeutic potential for the treatment of organ fibrosis by inhibiting TGFβ1 function in connective tissue while having no impact on the activation or signaling of TGFβ1 in the immune system. We plan to continue the advancement of these assets as part of our growing preclinical pipeline.

In addition, using our structural insight, we have identified modulators of BMP 6 (a TGFβ superfamily growth factor) by selectively inhibiting its co-receptor RGMc or hemojuvelin which is required for activation. BMP6 functions as a critical control point in iron modulation via regulation of hepcidin. Traditional approaches to inhibiting the signaling of BMP6 systemically would likely perturb the numerous different physiological processes in which BMP6 is involved. Our approach could provide the potential for tissue specific modulation of BMP signaling and iron regulation.

- ***Selectively seek strategic collaborations to maximize the value of our proprietary platform and pipeline.*** Given the potential of our proprietary platform to generate novel product candidates that could treat a wide variety of diseases, we believe that we can maintain in-house discipline with respect to our key development and commercialization efforts, while at the same time maximizing the full potential of our proprietary platform for other disease areas and indications. As a result, we may seek to form additional strategic collaborations around certain targets, product candidates or disease areas that we believe could benefit from the resources of either larger biopharmaceutical companies or those specialized in a particular area of relevance.

V. Our Pipeline

Using our innovative approach and proprietary platform, we are creating a differentiated pipeline of novel product candidates that selectively inhibit the activation of latent growth factors believed to be important drivers in a variety of diseases, including neuromuscular disorders, cardiometabolic disorders, cancer, fibrosis, and iron-restricted anemia. Our proprietary platform includes (i) our know-how enabling expression and purification of latent protein growth factor complexes in quantity and quality sufficient to enable antibody discovery; (ii) strategies to identify rare antibodies that selectively bind targeted latent protein growth factor complexes using our own proprietary antibody libraries; complexes; and (iii) assays developed by us to test the highly selective antibodies' ability to modulate the activation of specific latent growth factors. We have worldwide rights to our proprietary platform and all of our product candidates.

The following summarizes our pipeline programs:

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The following summarizes our pipeline programs:

Graphic

VI. Our Product Candidates

a. Latent Myostatin

Utilizing our proprietary platform, we targeted the precursor form of myostatin and Additional Programs

Apitegromab — Our Inhibitor of Latent Myostatin Activation generated two novel antibodies, each with a design tailored for SMA

We are developing specific patient populations: apitegromab a for SMA and SRK-439 for obesity. Both antibodies are novel, highly selective inhibitor of the activation of the growth factor myostatin, as a potential first muscle-targeted therapy for the treatment of SMA. Myostatin, a member of the TGFβ superfamily of growth factors, is expressed primarily in skeletal muscle cells and the absence of its gene is associated with an increase in muscle mass and strength in multiple animal species. We believe that inhibition inhibitors of the activation of myostatin may promote a clinically meaningful increase from its inactive precursor in motor function. skeletal muscle, where myostatin resides and signals upon activation. While mature myostatin is 90% identical in the growth factor domain to its most closely related TGFβ superfamily member, GDF11, the prodomain that cages mature myostatin and keeps it in its latent precursor form is only 52% identical to the GDF11 prodomain.

In preclinical studies, we have shown that apitegromab selectively avoids interaction with other closely related growth factors that play distinct physiological roles. We observed multi-fold increases in serum latent myostatin levels in mouse models of both early and late SMN restoration and that apitegromab promoted increased strength (as measured by torque generation) in SMN-deficient mice. In a Phase 1 clinical trial designed to evaluate the safety, tolerability, and pharmacokinetic (“PK”) /pharmacodynamic (“PD”) profile of apitegromab in adult healthy volunteers, there were no dose-limiting toxicities and we observed robust and sustained target engagement following administration of apitegromab was observed. Apitegromab was evaluated apitegromab.

SRK-439 has also shown robust preclinical efficacy, as detailed in our Phase 2 TOPAZ proof-of-concept clinical trial for the treatment “Cardiometabolic Disorders – SRK-439 (inhibitor of patients with Type 2 and Type 3 SMA

and positive 12-month top-line results were announced in April 2021. See “Phase 2 TOPAZ Trial Analysis” latent myostatin)” section below. We are currently conducting SAPPHIRE, a pivotal Phase 3 clinical trial to evaluate the efficacy and safety of apitegromab in patients with nonambulatory Type 2 and Type 3 SMA receiving SMN therapy. We expect to complete enrollment of SAPPHIRE in 2023, with the top-line data readout expected in 2024. If successful and if apitegromab is approved, we expect to initiate a commercial product launch in 2025.

We believe that apitegromab has these results, from two diet-induced obesity (“DIO”) mice models provide the potential to be scientific rationale and support the first muscle-targeted therapy which is aimed at improving motor function in patients with SMA and could be used in conjunction with SMN therapies or as a monotherapy. We have identified multiple other diseases for which the selective hypothesis that inhibition of the activation myostatin in combination with GLP-1 receptor agonist (“RA”)-driven weight loss may lead to retention of myostatin may offer therapeutic benefit, including additional patient populations in SMA (such as Type 1 SMA and ambulatory SMA) and indications outside lean muscle.

i. Role of SMA. Myostatin

Background on SMA

SMA is a rare, and often fatal, genetic disorder that typically manifests in young children. It is characterized by the loss of motor neurons, atrophy of the voluntary muscles of the limbs and trunk and progressive muscle weakness. Disease severity in SMA can range from patients who die soon after birth to patients who live into adulthood with varying degrees of morbidity. The underlying pathology of SMA is caused by insufficient production of a protein known as

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“survival of motor neuron,” or SMN. The SMN protein, essential for the survival of motor neurons, is encoded by two genes, SMN1 and SMN2.

- SMN1 genes produce the majority of functional SMN protein; healthy individuals have one or two functional copies of SMN1, while patients with SMA have mutations in or deletions of both copies of the gene.
- SMN2 genes produce only 10% to 20% of functional SMN protein and an individual’s copy number of the SMN2 gene can range from zero to eight. In SMA patients, the number of SMN2 genes present in their genome is correlated with disease onset and severity; patients who have a lower number of SMN2 gene copies generally develop earlier and more severe SMA, because they produce less SMN protein.

SMA Natural History and Epidemiology

SMA, the most common monogenic cause of death in infants, is a rare neuromuscular disorder. An estimated 30,000 to 35,000 patients suffer from SMA in the U.S. and Europe alone. Patients with SMA can be categorized as one of four types, Type 1 through Type 4. The majority of SMA patients currently living in the U.S. and

Europe are estimated as having Type 2 or Type 3 disease, although it should be noted that this percentage may evolve over time. Nonambulatory Type 2 and Type 3 SMA will be the initial focus of investigation in the development program.

- Type 1 disease is the most severe form, with clinical signs emerging at or shortly following birth. Patients with Type 1 SMA suffer from respiratory compromise and often require mechanical ventilation shortly after birth. Without intervention, Type 1 infants are not able to sit without support. Type 1 patients begin to lose motor neurons and muscle mass before birth.
- Type 2 disease manifests in early childhood and is less severe than Type 1 disease, although patients exhibit profound deficits in motor function. Patients with Type 2 disease may be able to sit independently but they are typically unable to walk without assistance.
- Type 3 disease manifests usually in childhood. While Type 3 SMA patients develop the ability to walk unaided, many individuals lose that ability over time. Ambulatory Type 3 SMA patients commonly suffer from substantial motor functional impairment, as evidenced by Expanded Hammersmith Functional Motor Scale (“HFMSE”) scores and Six Minute Walk Test distances, two commonly used measures of motor function.
- Type 4 disease is the mildest form of SMA, and its population is not well characterized. After symptom onset, which is most commonly reported between 20 and 30 years of age, patients experience mild to moderate muscle weakness and increasing disabilities. Patients are ambulatory and their life expectancy is normal.

Unmet Medical Need in SMA

We view the emerging landscape for the development of novel medicines for SMA as being classified into two distinct but complementary therapeutic strategies: 1) SMN therapy (also known as SMN corrector therapy or SMN-directed therapy) and 2) muscle-targeted therapy. Despite progress in the development of SMN therapies, a high unmet medical need to improve motor function remains. We believe that the advancement of muscle-targeted therapy will be necessary to address this important gap.

SMN therapies are aimed at addressing the SMN deficiency to prevent further motor neuron deterioration. This category includes antisense oligonucleotide and small molecule approaches to increase SMN2 expression as well as gene therapy to deliver the SMN1 gene. The primary benefit of such an approach appears to be to address the SMN deficiency and to modify the course of disease. Early intervention at a very young age is therefore thought to be essential to prevent significant motor functional deterioration. However, for the vast majority of SMA patients living today, this early intervention window has been missed, and such individuals suffer from severe functional impairment. Thus, regardless of the precise nature or mechanism of action for any given SMN therapy, we believe that most SMA patients will continue to experience clinically significant functional deficits.

To address this need, apitegromab is being developed as a potential first muscle-targeted therapy for SMA. We envision the potential for apitegromab to be a critical complement to any SMN therapy in patients with Type 2 and 3 SMA in

order to drive absolute increases in functional performance over baseline. We also view apitegromab as having potential in the treatment of Type 1 SMA as well as presymptomatic SMA in conjunction with SMN therapy.

Myostatin in SMA and Challenges with Traditional Approaches

Apitegromab is a highly selective inhibitor of the activation of latent myostatin that acts locally within skeletal muscle. Myostatin, also known as growth differentiation factor 8 ("GDF8"), is a member of the TGFβ superfamily and is produced by skeletal muscle cells. As with other tissues and organs in the human body, healthy muscle homeostasis is maintained by a proper balance of growth signals, or anabolic stimuli, and breakdown signals, or catabolic stimuli. In

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humans, the anabolic stimuli that drive muscle growth are proteins, such as the human growth hormone and the insulin like growth factor 1. In contrast, myostatin is a catabolic agent that functions as a negative regulator of muscle mass.

Skeletal muscle fibers are generally classified as fast-twitch fast twitch or slow-twitch. Fast-twitch slow twitch. Fast twitch fibers play a key role in motor activities, such as those involving quick bursts of strength. In contrast, slow-twitch slow twitch fibers are important for endurance activities. Animals lacking functional myostatin genes, or its receptor, have larger muscles and increased strength compared to normal animals. While the absence of myostatin does lead to overall increases in muscle mass, a preferential effect on muscles enriched for fast-twitch fast twitch muscle fibers has been observed in animals. Such animals are otherwise healthy and live a normal lifespan.

ii. Traditional Approaches and Challenges

Because of its role in regulating muscle mass, myostatin has been a popular target for a variety of drug development programs. There have been two general approaches to trying to inhibit the signaling of myostatin in humans. The first is to develop an antibody, or an antibody-like molecule, that binds to mature myostatin in circulation and prevents its ability to signal through its receptor, the ActRIIb receptor. The second is to develop an antibody to the ActRIIb receptor itself, or a soluble decoy of the ActRIIb receptor, with a goal of preventing myostatin signaling through its receptor. Both of these approaches, however, have significant limitations.

As a member of the TGFβ superfamily, mature myostatin shares considerable structural similarity with other family members. For example, the active form of myostatin and its most closely related family member, GDF11, are 90% identical in the growth factor domains, making it extremely challenging to identify antibodies that are truly specific for myostatin and do not interfere with other targets. Moreover, attempts to interrupt myostatin signaling through its receptor are complicated by the fact that the ActRIIb receptor, in addition to being the receptor for myostatin, is also the receptor for a number of related family members, including GDF11, activins and other growth factors. Attempts to block the signaling of myostatin by targeting its receptor therefore inevitably interfere with the signaling of these other growth factors, many of which are involved in normal biological processes unrelated to muscle.

There are multiple examples of clinical trials demonstrating the risk of non-selective inhibition of myostatin. For example, in a Phase 2 clinical trial in Duchenne Muscular Dystrophy reported in 2017, a soluble decoy of the ActRIIb receptor resulted in bleeding side effects believed by the sponsor to be unrelated to inhibition of myostatin signaling, but instead related to the inhibition of signaling by certain other members of the TGFβ superfamily known to be important in the maintenance of vascular integrity. These side effects resulted in termination of the clinical program. More recently, results from a clinical trial were reported showing that treatment of patients with an antibody to the ActRIIb receptor resulted in suppression of the levels of follicle stimulating hormone, an important reproductive hormone. In this clinical trial, the sponsor believed that these effects were likely related to inhibition of signaling through the ActRIIb receptor.

Our Solution

Utilizing our proprietary platform, we targeted the precursor form*iii. Spinal Muscular Atrophy: Apitegromab (inhibitor of myostatin and generated apitegromab, a novel, highly selective inhibitor of the activation of myostatin from its inactive precursor in skeletal muscles, where myostatin resides and signals upon activation. While mature myostatin is 90% identical in the growth factor domain to its most closely related TGFβ superfamily member, GDF11, the prodomain that cages mature myostatin and keeps it in its latent precursor form is only 52% identical to the GDF11 prodomain. In preclinical studies, we observed that apitegromab bound to latent myostatin with a high level of selectivity, while having no binding to, and no effect on, the activation of related TGFβ family members. activation)*

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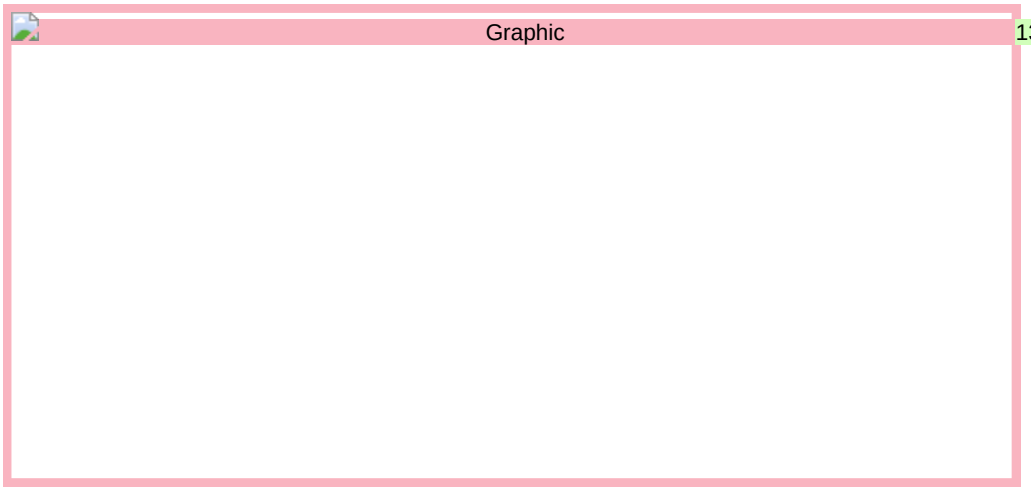
We believe that the therapeutic potential for apitegromab in improving motor function is more optimal when a given disease bears certain features. Based on our translational and preclinical efforts, we have formulated a set of guiding principles to inform indication selection within the category of neuromuscular disease. As summarized in the table below, we believe that the pathobiological and clinical characteristics of SMA are well-aligned with these guiding principles. Since myostatin regulates muscle catabolism rather than anabolism, we believe that having a background of anabolic capacity is important to drive muscle growth in the setting of

myostatin inhibition. Anabolic capacity is most robust in younger individuals and diminishes as one ages. SMA is a genetic disorder with onset commonly in childhood, and the initial focus of the development program will be in children and young adults. Furthermore, in SMA, there is a significant but incomplete loss of motor neurons, ensuring at least some intact signaling between skeletal muscle and nerve. In addition, generally, there are also no apparent structural abnormalities in the skeletal muscle. The partial loss of motor neurons causes substantial atrophy of fast-twitch muscle fibers that in turn leads to many of the motor function impairments. Validated outcome measures are available for SMA clinical trials that are relevant to fast-twitch fiber activity. These outcome measures, such as the HFMSE, Hammersmith Functional Motor Scale – Expanded ("HFMSE"), assess motor activities that involve short-term bursts of strength, which are driven by fast-twitch muscle fibers. These endpoints therefore measure an outcome that may be more likely to be directly affected by apitegromab.



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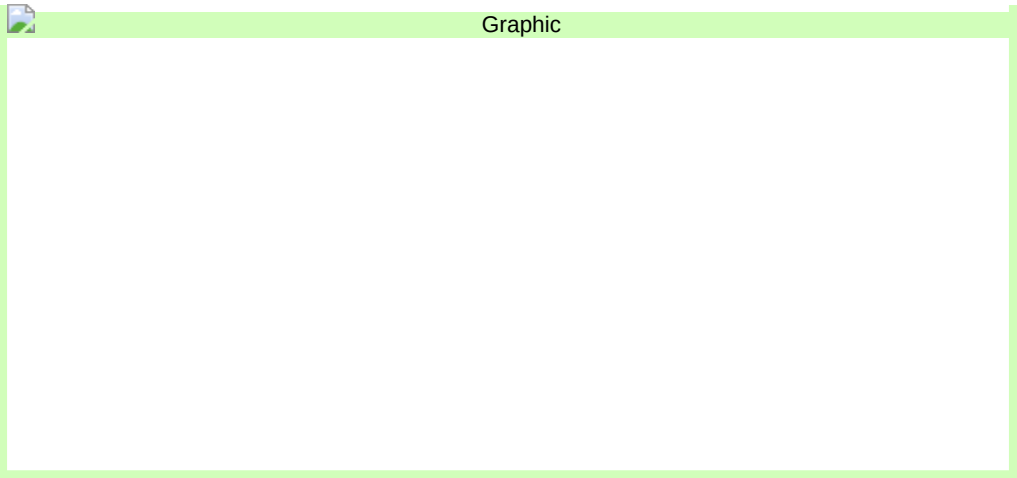

Key disease features of SMA are aligned with Scholar Rock's guiding principles for neuromuscular indication selection for apitegromab

We are developing apitegromab as a selective muscle-targeted therapy for the treatment of SMA. Myostatin, a member of the TGFβ superfamily of growth factors, is expressed primarily in skeletal muscle cells and the absence of its gene is associated with an increase in muscle mass and strength in multiple animal species. We believe that inhibition of the activation of myostatin may promote a clinically meaningful increase in motor function.

Apitegromab was evaluated in our Phase 2 TOPAZ proof-of-concept clinical trial for the treatment of patients with Type 2 and Type 3 SMA and positive 12-month top-line results were announced in April 2021. See "Phase 2 TOPAZ Trial Analysis" below. We are currently conducting SAPPHIRE, a pivotal Phase 3 clinical trial to evaluate the efficacy and safety of apitegromab in patients with nonambulatory Type 2 and Type 3 SMA receiving SMN therapy. We completed enrollment of SAPPHIRE in 2023, with the top-line data readout expected in the fourth quarter of 2024. If successful and if apitegromab is approved, we expect to initiate a commercial product launch in 2025.

We believe that apitegromab has the potential to be the first muscle-targeted therapy which is aimed at improving motor function in patients with SMA who are receiving an SMN therapy. We have identified multiple other diseases for which the selective inhibition of the activation of myostatin may offer therapeutic benefit, including additional patient populations in SMA (such as patients under the age of two with SMA and ambulatory patients with SMA) and indications for other neuromuscular disorders beyond SMA.

1. Background on SMA

SMA is a rare, and often fatal, genetic disorder that typically manifests in young children. It is characterized by the loss of motor neurons, atrophy of the voluntary muscles of the limbs and trunk and progressive muscle weakness. Disease severity in SMA can range from patients who die soon after birth to patients who live into adulthood with varying degrees of morbidity. The underlying pathology of SMA is caused by insufficient production of a protein known as "survival of motor neuron," or SMN. The SMN protein, essential for the survival of motor neurons, is encoded by two genes, SMN1 and SMN2.

- SMN1 genes produce the majority of functional SMN protein; healthy individuals have one or two functional copies of SMN1, while patients with SMA have mutations in or deletions of both copies of the gene.

- SMN2 genes produce only 10% to 20% of functional SMN protein and an individual's copy number of the SMN2 gene can range from zero to eight. In SMA patients, the number of SMN2 genes present in their genome

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is correlated with disease onset and severity; patients who have a lower number of SMN2 gene copies generally develop earlier and more severe SMA, because they produce less SMN protein.

2. SMA Natural History and Epidemiology

SMA, the most common monogenic cause of death in infants, is a rare neuromuscular disorder. An estimated 20,000 patients suffer from SMA in the U.S. and Europe alone. Patients with SMA can be categorized as one of four types, Type 1 through Type 4. The majority of SMA patients currently living in the U.S. and Europe are estimated as having Type 2 or Type 3 disease, although it should be noted that this percentage may evolve over time and the definitions of traditional SMA types are themselves evolving. Nonambulatory Type 2 and Type 3 SMA, as they have traditionally been defined, is the initial focus of investigation in our SMA development program.

3. Unmet Medical Need in SMA

We view the emerging landscape for the development of novel medicines for SMA as being classified into two distinct but complementary therapeutic strategies: 1) SMN therapy (also known as SMN corrector therapy or SMN-directed therapy) and 2) muscle-targeted therapy. Despite progress in the development of SMN therapies, a high unmet medical need to improve motor function remains. We believe that the advancement of muscle-targeted therapy will be necessary to address this important gap.

SMN therapies are aimed at addressing the SMN deficiency to prevent further motor neuron deterioration thus modifying the course of disease. This category includes antisense oligonucleotide and small molecule approaches to increase SMN2 expression as well as gene therapy to deliver the SMN1 gene. Early intervention at a very young age is therefore thought to be essential to prevent significant motor functional deterioration. However, for the vast majority of SMA patients living today, this early intervention window has been missed, and such individuals suffer from severe functional impairment. Thus, regardless of the precise nature or mechanism of action for any given SMN therapy, we believe that most SMA patients will continue to experience clinically significant functional deficits.

To address this need, apitegromab is being developed as a potential first muscle-targeted therapy for SMA. We envision the potential for apitegromab to be standard use with any SMN therapy in patients with Type 2 and 3 SMA in order to drive absolute increases in functional performance over baseline.

4. Clinical Development Overview

We are currently conducting SAPPHIRE, a pivotal Phase 3 clinical trial to evaluate the efficacy and safety of apitegromab in patients with nonambulatory Type 2 and Type 3 SMA being treated with SMN therapy.

Beyond Type 2 and Type 3 SMA, we believe that apitegromab has the potential to contribute an important for therapeutic benefit to in patients with either more or less severe forms of SMA, as well as pre-symptomatic patients receiving early intervention with a SMN therapy.

Our aim is to develop apitegromab for the broadest group of patients suffering from SMA. The FDA granted fast track designation, rare pediatric disease designation and orphan drug designation to apitegromab for the treatment of SMA in May 2021, August 2020 and March 2018, respectively. The EMA granted PRIME designation in March 2021 and the EC granted orphan medicinal product designation in December 2018 to apitegromab for the treatment of SMA.

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5. Phase 3 SAPPHIRE Pivotal Trial Design

SAPPHIRE is a randomized, double-blind, placebo-controlled, Phase 3 clinical trial. Approximately 156 A total of 188 patients aged 2-12 2-21 years old with nonambulatory Type 2 or Type 3 SMA who are receiving an SMN therapy, either nusinersen or risdiplam, are anticipated to be enrolled in the study, including 156 patients aged 2-12 years old in the main efficacy population. population and 32 patients aged 13-21 years old in the exploratory subpopulation. Patients will be in the main efficacy population were randomized 1:1:1 to receive for 12 months either apitegromab 10 mg/kg, apitegromab 20 mg/kg, or placebo by intravenous (IV) infusion every 4 weeks. Patients receiving in the SMN therapies exploratory subpopulation were randomized 2:1 to receive either apitegromab 20 mg/kg or placebo.

Table of nusinersen as well as risdiplam are both eligible for enrollment. Contents

Additional key elements of the study design include the following:

- At baseline, all patients will be required to be in the chronic maintenance phase of SMN therapy, corresponding to either at least 6 months of prior treatment in the case of risdiplam or at least 10 months of prior treatment in the case of nusinersen.
- Randomization of patients will be stratified by both the SMN therapy (nusinersen vs. risdiplam) as well as the age at which SMN therapy had been initiated (< 5 years vs. ≥ 5 years).
- The primary efficacy endpoint will evaluate the mean change from baseline in the HFMSE total score after 12 months of treatment.
- Additional endpoints will evaluate safety, proportion of patients with ≥3-point HFMSE increase, Revised Upper Limb Module ("RULM"), World Health Organization ("WHO") motor developmental milestones, PK, PD, anti-drug antibody, and other outcome measures.

In addition, this clinical trial provides the opportunity for an interim analysis when at least 50% of patients in the main efficacy population (age 2-12 years old) have completed 12 months of treatment.

Separately from the main efficacy population, an exploratory population of 48 patients aged 13-21 years old with nonambulatory Type 2 or Type 3 SMA who are receiving an SMN therapy (nusinersen or risdiplam) will be evaluated. These patients will be randomized 2:1 to receive either apitegromab 20 mg/kg or placebo. In this subpopulation of older individuals with SMA, the safety and tolerability of apitegromab will be characterized, and efficacy will also be evaluated in an exploratory, nonpowered manner.

6. Phase 2 TOPAZ Proof-of-Concept Trial

We completed enrollment of 58 patients in our Phase 2 TOPAZ proof-of-concept trial of apitegromab in SMA in January 2020. One patient discontinued from the 12-month treatment period for reasons that were determined to be unrelated to apitegromab treatment. All remaining 57 patients completed the 12-month treatment period and opted into the extension period. Of the 55 More than 90 percent of nonambulatory patients who completed the 24-month TOPAZ extension period, 54 opted to continue remained on treatment in the 36-month extension period. study As of December 31, 2022, 51 of the patients remain enrolled. .

The clinical trial consisted of three distinct cohorts of patients with Type 2 or Type 3 SMA and evaluated the safety and efficacy of apitegromab over a 12-month treatment period. All patients in the clinical trial received apitegromab dosed every four weeks (Q4W) either as a monotherapy or in conjunction with an approved SMN therapy.

In our view, this approach of having evaluated multiple distinct cohorts offers a greater number of opportunities to discern the effects of apitegromab on clinically meaningful motor function measures across multiple patient subpopulations. It is estimated that patients with Type 2 or Type 3 SMA represent over 85% of the overall patient population. We view each of the cohorts evaluated in the TOPAZ trial as representing a significant proportion of patients suffering from SMA.

The primary efficacy objectives evaluated in the TOPAZ trial, HFMSE and Revised Hammersmith Scale ("RHS"), are clinically meaningful outcome measures validated for SMA. These endpoints assess The HFMSE is a validated measure for the assessment of gross motor function in SMA, while the RULM is validated to evaluate upper limb motor performance by evaluating tasks involving short-term bursts of strength which correspond to the ability to perform various everyday activities with their hands and thus involve fast-twitch fiber

function. As the hypothesized effect of myostatin blockade under investigation is to drive increases in fast-twitch fiber function, we believe these endpoints are of direct relevance in assessing the clinical effect of apitegromab. arms.

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Our overall approach to the efficacy analysis is informed by SMA disease biology, the anticipated mechanism of action of apitegromab, the effects of SMN therapy, and available clinical data on SMA. The primary effect of SMN therapy appears to be to address the SMN deficiency and to modify the disease course; thus, the key in preventing significant resulting motor functional deterioration is intervening at a very young age. For most patients with SMA, however, this window for early intervention is no longer available. As a result, these individuals have already suffered considerable atrophy and motor function impairment. neuron degeneration Natural history data indicate that most patients with Types 2 or 3 SMA, other than very young individuals, generally have a stable functional baseline over a 12-month period as evidenced by their HFMSE scores. Long-term data on patients treated with SMN therapy showed that motor function generally plateaus after an initial increase. A one-point improvement on the Hammersmith scale may be considered meaningful on an individual level and a spontaneous an improvement of 3 or more points from baseline would be a notable divergence from the otherwise expected course of disease for most patients. considered meaningful.

7. TOPAZ 24-Month 36-Month Analysis

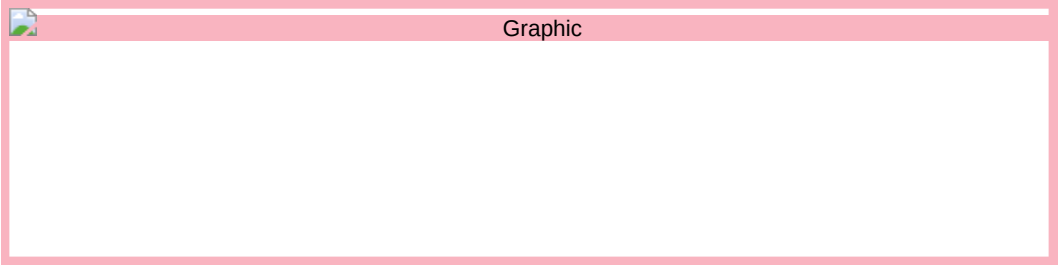
In June 2022, July 2023, at the Cure SMA Research & Clinical Care Meeting, we presented 24-month 36-month efficacy and safety extension data of apitegromab from TOPAZ. These data showed sustained and that continued improvement treatment with apitegromab for nonambulatory over the extended period was associated with substantial and sustained improvement in motor function (shown in the table below), and patient-reported outcomes in patients with nonambulatory Types 2 and 3 SMA receiving an SMN therapy.

TOPAZ evaluated apitegromab across a broad age range (2-21 years) of patients with Types 2 and 3 SMA. All 35 nonambulatory patients (Cohorts 2 and 3) and 12 of 23 ambulatory patients (Cohort 1) were receiving nusinersen maintenance therapy. The primary efficacy endpoint for the nonambulatory population was mean change from baseline in HFMSE. Additional endpoints included mean change from baseline in Revised Upper Limb Module (“RULM”), an assessment specifically designed for upper limb function in patients with SMA. The HFMSE is a validated measure for the assessment of gross motor function in SMA, while the RULM is validated to evaluate upper limb motor performance by evaluating tasks which correspond to the ability to perform various everyday activities with their hands and arms.

For this 24-month evaluation, an observed case analysis was conducted, which pooled all the nonambulatory patients (Cohorts 2 and 3) and was based upon the available data for given timepoints. This analysis population

included patients receiving either low dose (2 mg/kg) or high dose (20 mg/kg) apitegromab (inclusive of patients in Cohort 3 who switched from 2 mg/kg to 20 mg/kg in Year 2) and did not exclude any patients who had missed apitegromab doses due to study site access restrictions from COVID-19.

Nonambulatory patients (ages 2-21 years old) with valid HFMSE assessments had sizable, sustained gains in HFMSE scores at 24 months from baseline (prior to first dose of apitegromab), while RULM scores continued to increase at 24 months. The mean change from baseline results for nonambulatory patients showed:



* Three patients in the nonambulatory group underwent scoliosis surgery in year 2, which has been reported to negatively impact HFMSE scores for a considerable period afterwards. This analysis excluded post-surgery data of these patients.

Dose response continued to be observed across the 24 months of apitegromab administration based upon HFMSE scores and PD data (target engagement as measured by serum latent myostatin concentrations), with signs that that there may be further HFMSE increases as nonambulatory patients originally receiving the low dose switched to the high dose treatment.

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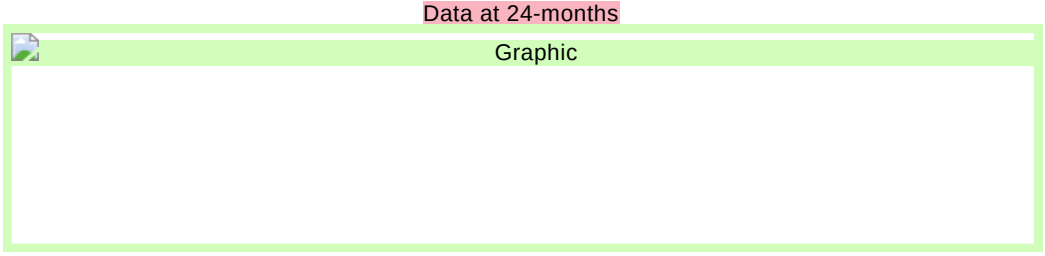
Data at 24-months



For the 36-month data, an observed case analysis was conducted, which pooled data for ambulatory all nonambulatory patients with Type 3 SMA (Cohort 1) suggest stability of RHS scores in ages 2-21 (including those patients receiving on 20 mg/kg of apitegromab for the full duration of the trial, and nusinersen. The those who switched from 2 mg/kg to 20 mg/kg at various time intervals in year 2). As shown in the table above, the

mean RHS change from baseline in HFMSE at 24-months 36 months was -0.7 points (95% CI: -3.1, 1.7) +4.0 and mean change from baseline in RULM (measuring upper limb function) at 36 months was +2.4. These analyses exclude data for the apitegromab patients post scoliosis surgery as such surgery is a known confounding factor for motor function assessment.

Improvement in patient-reported outcomes were consistent with improvements in motor function. Nonambulatory patients (ages 2-21) had improvements in PEDI-CAT (measure of activities of daily living) and nusinersen subgroup (n=10) and -2.8 points (95% CI: -8.4, 2.8) for the apitegromab monotherapy subgroup (n=11). A subset of individuals PROMIS-Fatigue (a patient-reported questionnaire measuring fatigue) that were sustained at 36 months. The mean change in Cohort 1 (n=21) had RHS improvements, as reflected by 42.9% (9/21) and 23.8% (5/21) of patients having ≥1-point and ≥3-point RHS increases PEDI-CAT daily activity domain from baseline at 36 months was 2.2 (95% CI: –0.1, 4.5; N=17), indicating an improvement in the ability to perform daily activities. The mean change in PROMIS-Fatigue from baseline at 36 months was –4.6 (95% CI: –8.7, –0.5; N=14), indicating a decline in fatigue.

Treatment-emergent adverse events ("TEAEs") at 36 months were consistent with previous reports at 12 and 24 months, respectively.

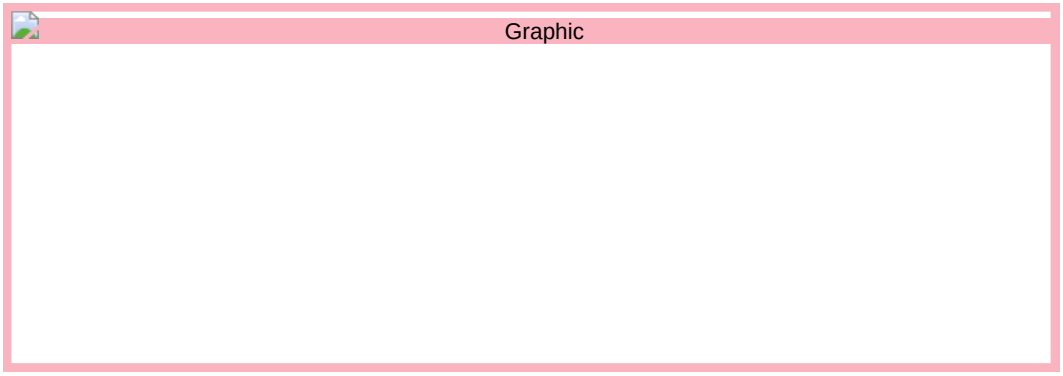
Consistent with the 12-month safety data, no serious safety risks new findings after an aggregate of 198 patient-years of exposure. TEAEs were identified as part of the analysis of the cumulative 24-month data. The incidence mostly mild-to-moderate in severity, and severity of adverse events were generally consistent with the underlying patient population and SMN background therapy. The five most common treatment-emergent adverse events ("TEAEs") TEAEs were headache, pyrexia, COVID-19, nasopharyngitis, and upper respiratory tract infection, cough, and nasopharyngitis. infection. No deaths or suspected unexpected serious adverse reactions have been or hypersensitivity reactions were observed to date with apitegromab. A total of 14 serious TEAEs were reported over the 24-month treatment period, all assessed by the respective trial investigator as unrelated to apitegromab. apitegromab at 36 months. No patients displayed positive titers for apitegromab antibodies ("ADA").

Tertiary endpoint data from the TOPAZ trial was presented at both the 27th International Annual Congress of the World Muscle Society 2022 and the 3rd International Scientific Congress on SMA in October 2022, which showed trends of continuous improvement in quality-of-life measures such as activities of daily living, fatigue and endurance over 24 months.

8. TOPAZ 12-Month Analysis

On April 6, 2021, we announced positive top-line data for the 12-month treatment period of our Phase 2 TOPAZ proof-of-concept trial, which enrolled 58 patients with Type 2 and Type 3 SMA across 16 study sites in the United States and Europe. The clinical trial evaluated the safety and efficacy of intravenous apitegromab dosed every four weeks (Q4W) over a 12-month treatment period. Four patients (one in Cohort 2 and three in Cohort 3) each missed three consecutive doses of apitegromab over the course of the 12-month treatment period due to COVID-19-related site access restrictions and were excluded from the prespecified intent-to-treat primary analysis.

The study participants were enrolled into one of three cohorts. Cohort 1: This open-label, single-arm cohort enrolled 23 patients 1 consisted of individuals aged 5–21 years with ambulatory Type 3 SMA. Patients were treated with 20 mg/kg of SMA; receiving apitegromab either as a monotherapy or in conjunction with an approved SMN therapy (nusinersen). The primary objectives of Cohort 1 were to assess safety and the mean change from baseline in RHS following 12 months of treatment.



Cohort 2: This open-label, single-arm cohort enrolled 15 patients 2 comprised individuals aged 5–21 years with Type 2 or nonambulatory Type 3 SMA and who were already all receiving treatment with an approved SMN nusinersen and had initiated their nusinersen therapy (nusinersen) initiated at age five after reaching 5 years of age. Cohort 3 consisted of nonambulatory individuals aged 2 years or older. One patient missed three consecutive doses older with Type 2 SMA who were receiving nusinersen and had initiated their nusinersen therapy before 5 years of age. All patients received apitegromab due by intravenous infusion every 4 weeks. During the primary treatment period, patients in Cohorts 1 and 2 received open-label apitegromab 20 mg/kg, and patients in Cohort 3 were randomized to COVID-19-related site access restrictions and was excluded from double-blind apitegromab 2 mg/kg or 20 mg/kg. In the prespecified intent-to-treat extension periods, patients who received apitegromab 20 mg/kg in the primary analysis. The primary objectives treatment period continued their dose; patients originally receiving apitegromab 2 mg/kg transitioned to apitegromab 20 mg/kg.

Results of the cohort were to assess safety primary analysis showed that apitegromab treatment was associated with improved motor function as measured by the HFMSE and the mean change from baseline in HFMSE following RULM, and with a favorable safety profile at 12 months (Crawford Neurology 2024 and table below). An ITT sensitivity analysis of treatment.

One patient in Cohort 2 was identified as having received concomitant treatment with an acetylcholinesterase inhibitor before and during the trial, which was not permitted by the trial protocol. This patient experienced a 7-point decline in efficacy including data from all 58 patients enrolled showed consistent findings.

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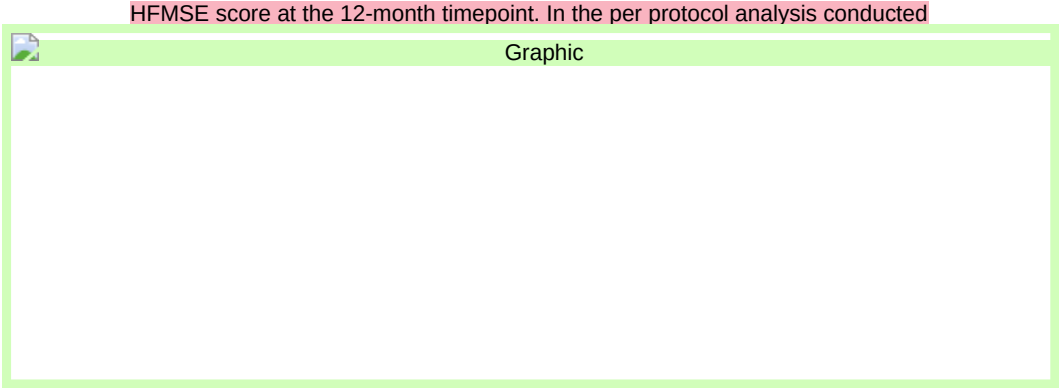
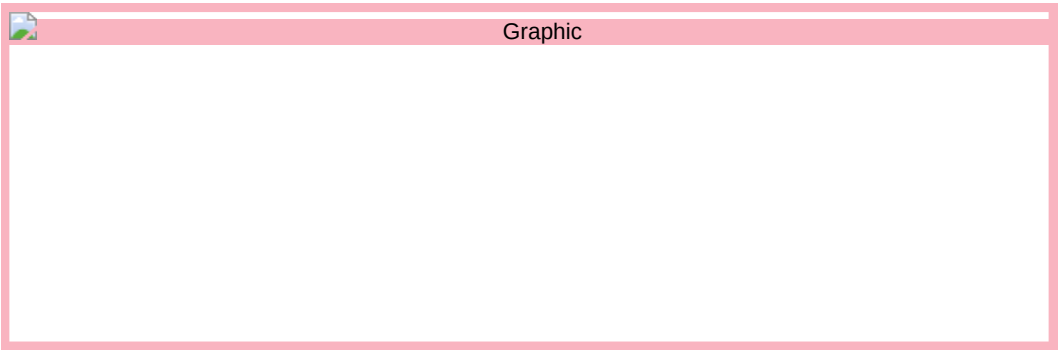
HFMSE score at the 12-month timepoint. In the per protocol analysis conducted

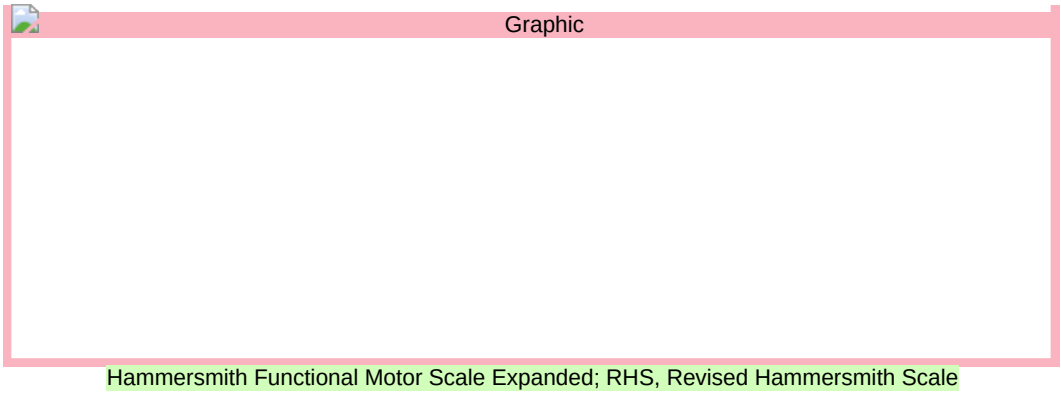


[a]Four participants in accordance with the prespecified approach, which excludes this patient as well as the patient who missed three consecutive doses due to COVID-19-related site access restrictions, the mean change from baseline in HFMSE score for Cohort 3 (n=3) and Cohort 2 was a 1.2-point improvement.



Cohort 3: This randomized, double-blind, parallel arm portion of the clinical trial enrolled patients with Type 2 SMA who had initiated treatment with an approved SMN therapy (nusinersen) before five years of age. Twenty patients were randomized in a 1:1 ratio to receive the low dose (apitegromab 2 mg /kg Q4W) or high dose (apitegromab 20 mg/kg Q4W); patients in both of these treatment arms were also receiving an approved SMN therapy (nusinersen). Three patients (two in high-dose arm and one in low-dose arm) (n=1) each missed three consecutive doses of apitegromab during the 12-month treatment period due to COVID-19-related site access restrictions and were not included in the primary analysis. One subject among the older (5-21 years) non-ambulatory participants received concomitant treatment with an acetylcholinesterase inhibitor before and during the trial and was excluded from the prespecified intent-to-treat primary analysis. The primary objectives of the cohort were per-protocol analysis due to assess safety and the mean change from baseline in this protocol violation.

HFMSE, following 12 months of treatment.



Hammersmith Functional Motor Scale Expanded; RHS, Revised Hammersmith Scale

Dose response was observed; the 20 mg/kg dose achieved numerically greater mean improvements from baseline in HFMSE scores than the 2 mg/kg dose across all assessed timepoints in the 12-month treatment period. The clinically observed dose response was consistent with the PD (target engagement) results. Both the 20 mg/kg and 2 mg/kg doses yielded high levels of target engagement (>100-fold increase from baseline), but the 20 mg/kg dose led to a relatively higher absolute level of target engagement.

Overall safety and tolerability profile:

- Incidence and severity of adverse events were consistent with the underlying patient population and SMN therapy.
- Five most frequently reported treatment-emergent adverse events: headache (24%), pyrexia (22%), upper respiratory tract infection (22%), cough (22%), and nasopharyngitis (21%).

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- Five patients experienced a serious treatment-emergent adverse event, all assessed by the respective trial investigator as unrelated to apitegromab:
    - One patient treated with 2 mg/kg dose (Cohort 3) hospitalized due to adenoidal hypertrophy and tonsillar hypertrophy to perform scheduled adenotonsillectomy (Grade 2). Event resolved without sequelae.
    - Two patients treated with 20 mg/kg dose (both Cohort 1) with gait inability considered a significant disability (both Grade 3). Events remain ongoing.
    - One patient treated with 20 mg/kg dose (Cohort 1) hospitalized with post lumbar puncture syndrome (Grade 2). Event resolved without sequelae.
    - One patient treated with 20 mg/kg dose (Cohort 1) hospitalized due to viral upper respiratory tract infection (Grade 2). Event resolved without sequelae.

- One patient (Cohort 1) presented with a non-serious Grade 3 post lumbar puncture syndrome; assessed by trial investigator as unrelated to apitegromab. Event resolved without sequelae.

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- One patient (Cohort 1) discontinued from the clinical trial due to Grade 2 muscle fatigue that started prior to initiation of dosing with study drug; assessed by the clinical trial investigator as unrelated to apitegromab.

9. Phase 1 Healthy Volunteer Clinical Trial Results

The randomized, double-blind, placebo-controlled, first-in-human, Phase 1 clinical trial was designed to evaluate the safety and tolerability, immunogenicity, PK, and PD of IV administered apitegromab in adult healthy volunteers. A total of 66 subjects were enrolled, including 40 subjects in the single ascending dose ("SAD") and 26 subjects in the multiple ascending dose portions of the study. Full results from the Phase 1 clinical trial were presented at the Cure SMA Annual Conference in June 2019.

Safety and immunogenicity results. Apitegromab was shown to be well-tolerated with no apparent safety signals. There were no dose-limiting toxicities identified up to the highest tested dose of 30 mg/kg, treatment-related serious adverse events ("SAEs") or hypersensitivity reactions. Immunogenicity was assessed by anti-drug antibody testing, and all subjects tested negative.

Pharmacokinetics and pharmacodynamics results. Apitegromab displayed a PK profile generally consistent with that commonly observed with monoclonal antibodies. Drug exposure was dose proportional, and the serum half-life was approximately 23 to 33 days across the apitegromab dose groups. The findings supported the investigation of a once every 4-week dosing regimen in the Phase 2 TOPAZ clinical trial.

Mean serum concentrations of latent myostatin in the SAD were < 20 ng/ml in the pre-treatment baselines for apitegromab treated subjects as well as in placebo subjects throughout the study. Following placebo treatment, there was no meaningful change in the latent myostatin biomarker concentrations. Following single doses of apitegromab at dose levels of 3 mg/kg or greater, marked increases in latent myostatin biomarker concentrations in the serum, by at least an order of magnitude, were observed following apitegromab treatment. This finding demonstrates successful target engagement and provides initial proof-of-mechanism in humans of our therapeutic approach of targeting the latent form of growth factors. The observation also corroborates our biological understanding that the vast majority of drug target (pro and latent forms of myostatin) resides within skeletal muscle rather than within the systemic circulation.

Graphic

Apitegromab engages latent myostatin in Phase 1 clinical trial subjects

10. Apitegromab in Other Disorders Where the Inhibition of Myostatin May Be Beneficial

We see potential for apitegromab broadly across SMA (i.e., Type 1 (such as patients under the age of two with SMA and ambulatory patients with SMA) and our intention is to further investigate this potential. We also believe that the role of apitegromab as a muscle-targeted therapy has broad potential beyond SMA, spanning a number of muscle disorders in which fast-twitch fibers may play an important role in motor function. In some settings, we believe that disease-stabilizing therapy may be necessary to address the underlying defect, which can then be complemented by the potential motor function-building benefit of apitegromab. In settings in which the defect may be less severe and/or the disease may have a slower rate of progression, apitegromab may have the potential to serve as a monotherapy.

There Based on this evidence, we believe a wide range of potential therapeutic applications may be envisioned for apitegromab. We are considering the investigation of apitegromab in multiple indications beyond SMA and have efforts underway to evaluate these opportunities (including preclinical and translational research, clinical development and regulatory path assessments, and commercial assessments).

iv. Cardiometabolic Disorders – SRK-439 (inhibitor of latent myostatin)

1. The Current State of Obesity and Obesity Treatment

Obesity is also now recognized as a top global public health issue, representing a large market with growing numbers: By the year 2030, it's estimated that obesity will affect over 1 billion adults and over 250 million children and adolescents. This is a costly chronic disease, associated with more than $170 billion in excess costs annually in the US given serious

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comorbidities associated with obesity primarily cardiometabolic including cardiovascular disease and type 2 diabetes. The GLP-1 receptor agonists, and other incretin therapies, have been highly effective in reducing overall weight, but that weight loss includes a significant amount—an estimated 25-40%—of lean muscle mass loss as well. Importantly, there is rebound weight gain upon discontinuation of treatment that is primarily fat with lean muscle mass lagging behind. In addition to the weight gain rebound, patients taking GLP-1 RA therapies have experienced issues with tolerability that influence the duration of treatment and can lead to high rates of discontinuation for these therapies.

2. The Role of Muscle and The Opportunity for Myostatin Inhibition

Muscle plays a key role in metabolic functions and energy homeostasis, and given that important role, we believe that maintaining lean muscle mass is essential for healthy and sustainable weight loss management. The preservation of lean mass has many benefits for overall health above and beyond maintaining strength, especially in the setting of obesity with associated co-morbidities. Specifically, muscle is a metabolic organ and increases basal metabolic rate, enhances glucose uptake, enhances insulin sensitivity, and given the cross talk between adipose tissue and muscle, reduces visceral body fat. All of these functions are important for healthy weight loss management.

The increasing recognition of the important role of skeletal muscle in modulating metabolic physiology highlighting highlights a potential therapeutic opportunity for myostatin blockade. For example, data emerging from our preclinical experiments support the hypothesis that blockade of the myostatin pathway has the potential to reduce the mass of visceral fat, a significant driver of cardiometabolic pathophysiology. Excessive fat mass and metabolic abnormalities have been observed in many muscle atrophy states, such as SMA and spinal cord injury. More broadly, reducing visceral fat mass, or improving body compositions (e.g., enhanced muscle-to-fat ratios), may be a potential therapeutic strategy to address a wide range of disorders, such as non-alcoholic steatohepatitis ("NASH"), diabetes, and obesity.

Based*3. SRK-439: A Novel Anti-myostatin Antibody for the Treatment of Obesity*

In addition to our work to advance apitegromab in SMA, we have leveraged our expertise in anti-myostatin and its effect on this evidence, increasing muscle mass to develop myostatin-selective inhibitors for cardiometabolic

disorders, including obesity.

SRK-439, a novel anti-myostatin antibody developed by Scholar Rock, has attractive properties that we believe make it specifically suited for the patient population with obesity. These properties include high in vitro affinity for pro- and latent myostatin, maintenance of myostatin specificity (i.e., no GDF11 or Activin-A binding), and a wide range developability profile, including suitability for subcutaneous dosing and a low dosing volume. We believe the selectivity of potential therapeutic applications these antibodies enables a favorable risk-benefit profile for patients with cardiometabolic disorders.

In addition to these properties, SRK-439 has shown robust preclinical efficacy. In two models of DIO mice, SRK-439 maintained lean mass when combined with a GLP-1 RA therapy, either semaglutide or liraglutide. In both cases, adding SRK-439 to semaglutide or liraglutide alone demonstrated dose dependent increase and reversal of lean muscle mass loss with improvement in fat mass loss as well compared to a GLP-1 RA alone (results for SRK-439 used in combination with semaglutide shown below). These results provide the scientific rationale and support the hypothesis that inhibition of myostatin in combination with GLP-1 RA-driven weight loss may be envisioned for apitegromab. lead to retention of lean muscle.

We are considering the investigation of apitegromab advancing this preclinical program and plan to submit an IND in multiple indications beyond SMA and have efforts underway to evaluate these opportunities (including preclinical and translational research, clinical development and regulatory path assessments, and commercial assessments). mid-2025.

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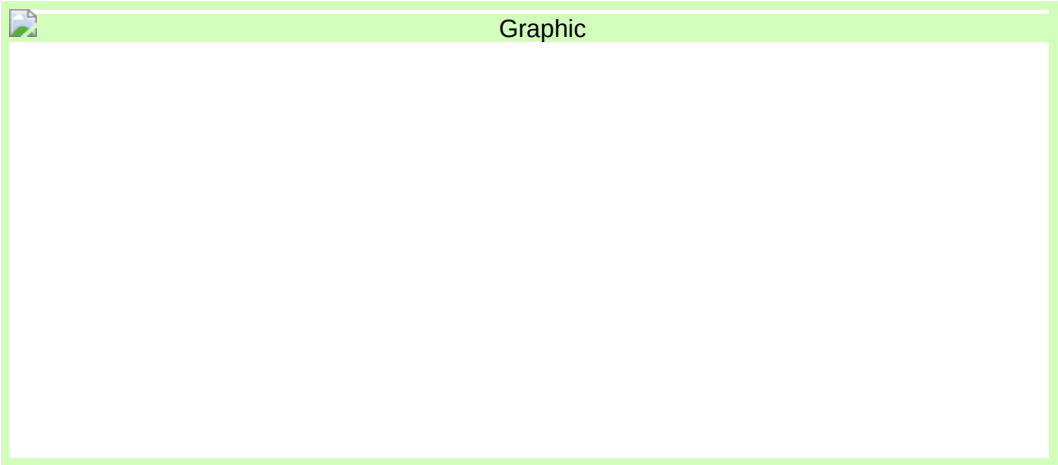

SRK-439 Reversed Lean Mass Loss and Enhanced Fat Mass Loss Induced by Semaglutide Treatment. Shown in the plot on the left is the percent change in lean mass from baseline in diet-induced obesity

mice as measured by quantitative nuclear magnetic resonance, and on the right, percent change in fat mass in DIO mice.

4. Apitegromab in Obesity: Proof-of-Concept

We see potential for apitegromab as a muscle-targeted therapy broadly across disorders in which the role of muscle is critical for function. Based on evidence of apitegromab's improvement of muscle function in SMA, and to inform the development of SRK-439, we plan to initiate a Phase 2 proof-of-concept trial of apitegromab in combination with a GLP-RA agonist, while at the same time advancing our cardiometabolic program with SRK-439 toward an IND. Phase 1 healthy volunteer data for apitegromab are summarized in the SMA section above. Data from the clinical trial in subjects with obesity are expected in mid-2025.

b. Inhibiting TGFβ – SRK -181 (latent TGFβ – 1 inhibitor) and LTBP

We have been a pioneer in developing a differentiated approach to harnessing the therapeutic potential of the TGFβ superfamily of growth factors. The foundation of our industry-leading platform is targeting the TGF superfamily of growth factors with the desired selectivity for both the target (i.e., latent- or pro- form) and disease-specific context. While we are building our experience from this approach with our anti-myostatin pipeline, we have also observed promising preclinical and early clinical data that supports targeting other forms of TGFβ, including for oncology and fibrosis.

The TGFβ superfamily plays a central role in a wide range of cellular processes including growth and differentiation, immune regulation and fibrosis. TGFβ1 is produced by cells as a single protein chain and is then enzymatically processed by the cells into two distinct and physically separated domains — the mature, active growth factor and the remaining portion of the original protein, referred to as the prodomain, or latency associated peptide — which remains associated with and keeps the growth factor in an inactive state. This complex is further associated with one of a number of "presenting molecules" which when secreted serve to tether the latent precursor in specific locations in the body. TGFβ1 is produced by a variety of cell types, including fibroblasts, which deposit latent TGFβ1 in connective tissue, as well as regulatory T cells, cancer cells and macrophages, which display latent TGFβ1 on their cell surfaces.

In a seminal peer-reviewed publication in 2011, by solving a high-resolution x-ray crystal structure of the latent form of TGFβ1, our founder, Dr. Springer elucidated a new understanding of the mechanism that underlies the activation of latent precursor forms of members of the TGFβ superfamily of protein growth factors. This research explained at a molecular level why the secreted form of TGFβ1 is inactive. The prodomain, though physically separated from the mature growth factor domain, forms a "cage" around the active form of TGFβ1, blocking the ability of the growth factor

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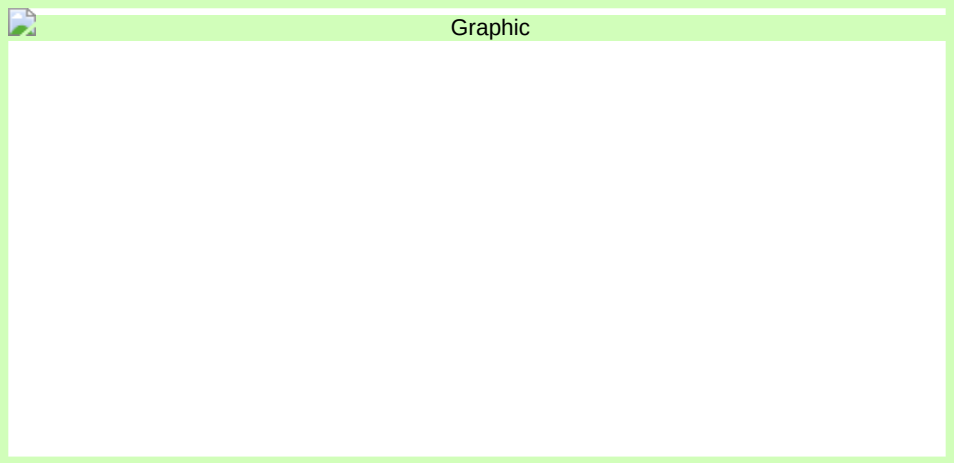
to signal through its receptor. Integrin proteins are able to unlock the “cage” by binding to the prodomain of the latent TGFβ1 complex and applying force to pull the complex open, allowing the mature growth factor to be released and signal in its microenvironment. While mature TGFβ1 shares a high degree of structural similarity with its closely related family members, TGFβ2 and TGFβ3, their respective cages are structurally diverse. By taking advantage of the differences among the prodomains, together with our understanding of the activation mechanism and ability to recapitulate the activation mechanism in vitro, we were able to identify multiple highly selective inhibitors of the activation of latent TGFβ1. By specifically targeting the TGFβ1 isoform, we believe we have the key to unlock the power of checkpoint inhibitors and meaningfully increase response rates across multiple solid tumor types. In March 2019, we selected SRK-181 as a product candidate in our TGFβ1 cancer immunotherapy program based on the strength of preclinical data and human translational insights. In vitro and in vivo studies of SRK-181 showed that it binds to latent TGFβ1 with high affinity and high selectivity, which is evidenced by minimal or no binding to latent TGFβ2 or latent TGFβ3 isoforms. Integrins, such as αVβ6 and αVβ8, can trigger the activation of TGFβ1 and TGFβ3. In addition, biochemical evidence suggests that certain proteases (e.g., Plasmin and Kallikreins) may also induce TGFβ activation. Notably, these integrins and proteases have been implicated in tumor biology in a number of human cancers. SRK-181 is capable of inhibiting both integrin-dependent- and protease-induced activation of TGFβ1.



SRK-181 selectively binds to proTGFβ1complexes with minimal or no binding to proTGFβ2 or proTGFβ3 complexes.

i. TGFβ1 in Cancer Therapy

We believe that specific inhibition of TGFβ1 may have a significant impact on the treatment of patients in certain oncology settings.

Immune checkpoints are cellular mechanisms that act as a brake on the immune system, and expression of these proteins in the tumor microenvironment creates an immunosuppressive environment that allows tumor cells to evade being killed by the immune system. Immune checkpoint proteins, such as PD-1/PD-L1, have therefore become key therapeutic targets in the tumor microenvironment. By inhibiting these proteins, the brakes on the immune system are released, allowing the T cells to kill the cancer cells. There are currently multiple approved checkpoint inhibitor therapies that target the PD-1/PD-L1 pathway.

A significant proportion of patients, in many cases the majority, fail to respond to these checkpoint inhibitor therapies, because they have what appears to be a pre-existing, or primary, resistance to immunotherapy. Other patients' cancers appear to initially respond but subsequently progress. In many human cancers, TGFβ signaling is associated with lack of response to PD(L)-1 blockade, particularly in patients with tumors harboring an immune excluded phenotype (i.e., CD8+ T cells present in nearby stroma but excluded from the tumor parenchyma). Gene expression analysis of pre-treatment

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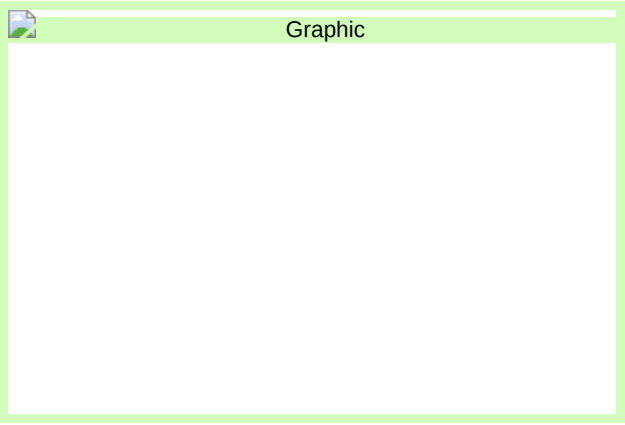
melanoma tumors identified multiple TGFβ-related signaling signatures associated with pre-existing or primary resistance to anti-PD-(L)1 antibody therapy. Similarly, it has also been reported that retrospective pathway analysis of tumor samples from an atezolizumab bladder cancer trial identified the TGFβ pathway as a major determinant of primary resistance to atezolizumab.

Our analysis of publicly available human tumor data has identified TGFβ1 as the predominant TGFβ isoform expressed in many solid tumors.



National Cancer Institute - Cancer Genome Atlas Program RNAseq analysis of >10,000 samples spanning 33 tumor types show high expression of the TGFβ1 isoform in many tumor types

ii. SRK-181 in Cancer Immunotherapy - Inhibitor of Latent TGFβ1 Activation

Our second antibody product candidate, SRK-181, a highly selective inhibitor of the activation of latent TGFβ1, is in clinical development for the treatment of locally advanced or metastatic solid tumors that are resistant to anti-PD-(L)1 therapies. We estimate at least 750,000 cancer patients in the U.S. are eligible for treatment with checkpoint inhibitor therapies every year, of which the majority of patients will develop progression to the treatment.

Increased signaling by TGFβ1 is a key driver of a number of disease-relevant processes, including immune system evasion by cancer cells, bone marrow fibrosis associated with hematological disorders, and tissue and organ fibrosis. Historically, selectively targeting TGFβ1 signaling has been challenging due to the inability of either small molecule inhibitors or antibodies to avoid off-target inhibition of other, closely related growth factors, TGFβ2 and TGFβ3. Treatment of animals with these non-selective TGFβ inhibitors has been associated with a range of toxicities, most notably cardiac toxicity. Furthermore, since each of these growth factors signals through the same TGFβ receptor, ALK5, inhibitors of the TGFβ receptor kinase suffer from similar dose-limiting toxicities. In preclinical studies of our antibodies, we have observed selective inhibition of TGFβ1 activation *in vitro* and immunomodulatory and antifibrotic activity in multiple disease models *in vivo.* vivo. A 28-day pilot nonclinical toxicology study in rats of our leading antibody did not observe any drug-related toxicity up to the highest dose (100 mg/kg weekly) tested in the study. In the same study, we tested non-selective TGFβ inhibitors and observed the published toxicities, including cardiac toxicity as well as death. We have also completed four-week GLP toxicology studies in rats and non-human primates and no SRK-181 related adverse effects were observed up to the highest evaluated dose of 200 mg/kg per week and 300 mg/kg per week, respectively.

In many human cancers, TGFβ signaling is associated with lack of response to PD-(L)1 blockade, particularly in patients with tumors harboring an immune excluded phenotype (i.e., CD8+ T cells present in nearby stroma but excluded from the tumor parenchyma). We have observed multiple mouse models that recapitulate the immune-excluded phenotype and are resistant to PD-1 blockade become responsive to the combination of SRK-181-mIgG1, the murine analog of SRK-181, and an anti- PD-1 antibody. These models, including the MBT-2 bladder cancer model, the Cloudman S91 melanoma model and the EMT6 breast cancer model, were poorly responsive or unresponsive to single agent treatment

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with either anti-PD-1 or SRK-181-mIgG1, with little or no effect on tumor growth. However, in representative experiments, the combination of SRK-181-mIgG1 and anti-PD-1 resulted in tumor regressions of 72%, 57% and 70% in these three mouse models, respectively. Furthermore, the combination treatment led to statistically significant survival benefit in all three models (See “Preclinical Evidence in Overcoming Resistance to Checkpoint Inhibition”).

Our Phase 1 DRAGON clinical trial is intended to initially evaluate our therapeutic hypothesis that SRK-181 in combination with anti-PD-(L)1 therapy may overcome resistance to anti-PD-(L)1 therapy and lead to anti-tumor responses. This clinical trial in patients with locally advanced or metastatic solid tumors is ongoing and investigates the safety, PK and efficacy of SRK-181. The DRAGON trial consists of two parts: Part A (dose escalation of SRK-181 as a single-agent or in combination with an approved anti-PD-(L)1 therapy) and Part B (dose expansion evaluating SRK-181 in combination with an approved anti-PD-(L)1 antibody therapy). Part B encompasses five active cohorts, including urothelial carcinoma, cutaneous melanoma, non-small cell lung

cancer, clear cell renal cell carcinoma and head and neck squamous cell carcinoma, and commenced in 2021. Initial clinical 2021 and completed enrollment in December 2023. Safety, efficacy and biomarker data from Part A was were presented in November 2021 2023 at the SITC 36th 38th Annual Meeting and additional clinical data were Meeting. Data presented at the 2022 SITC Annual Meeting in November 2022. The Phase 1 DRAGON trial continues to advance; we expect support proof-of-concept for SRK-181 in 28 heavily pretreated patients with ccRCC resistant to provide biomarker anti-PD-1. SRK-181 was generally well tolerated and clinical updates showed promising anti-tumor activity in 2023.

Selection of a Potent and Highly Selective Inhibitor of TGFβ1 Activation

TGFβ1 is produced by cells as a single protein chain and is then enzymatically processed by the cells into two distinct and physically separated domains — the mature, active growth factor and the remaining portion of the original protein, referred to as the prodomain, or latency associated peptide — which remains associated with and keeps the growth factor in an inactive state. This complex is further associated with one of a number of "presenting molecules" which when secreted serve to tether the latent precursor in specific locations this patient population. Of 28 evaluable patients in the body. TGFβ1 is produced by ccRCC cohort, six patients treated with SRK-181 in combination with pembrolizumab had confirmed partial responses ("PRs") and achieved a variety best tumor reduction of cell

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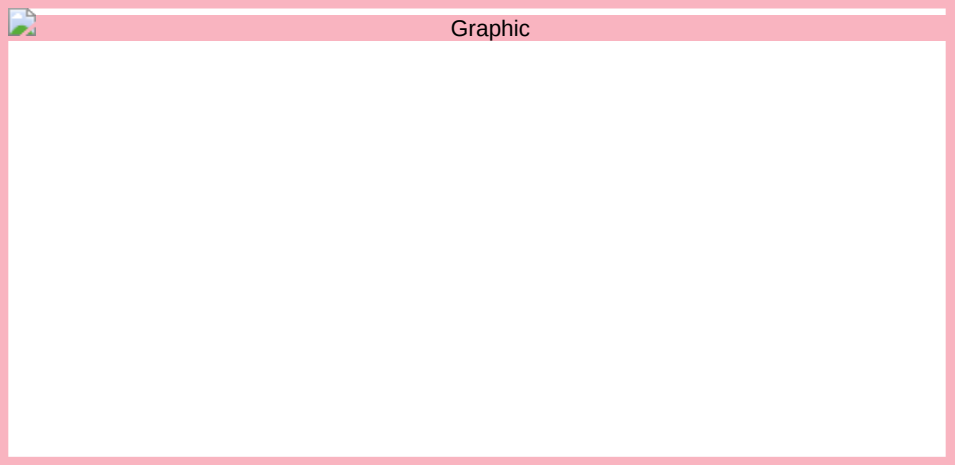
Table 33% to 93%, with an objective response rate of Contents

types, including fibroblasts, which deposit latent TGFβ1 21.4%. In the biomarker analysis for ccRCC, levels of circulating granulocytic myeloid-derived suppressor cells ("gMDSC") correlated with clinical activity in connective tissue, as well as regulatory T cells, cancer cells and macrophages, which display latent TGFβ1 on their cell surfaces.

In a seminal peer-reviewed publication ccRCC patients treated with SRK-181 in 2011, by solving a high-resolution x-ray crystal structure of the latent form of TGFβ1, our founder, Dr. Springer elucidated a new understanding of the mechanism that underlies the activation of latent precursor forms of members of the TGFβ superfamily of protein growth factors. This research explained at a molecular level why the secreted form of TGFβ1 is inactive. The prodomain, though physically separated combination with pembrolizumab. Safety data from the mature growth factor domain, forms a "cage" around the active form of TGFβ1, blocking the ability of the growth factor ccRCC cohort continue to signal through its receptor. Integrin proteins are able to unlock the "cage" by binding to the prodomain of the latent TGFβ1 complex and applying force to pull the complex open, allowing the mature growth factor to be released and signal in its microenvironment. While mature TGFβ1 shares a high degree of structural similarity with its closely related family members, TGFβ2 and TGFβ3, their respective cages are structurally diverse. By taking advantage of the differences among the prodomains,

together with our understanding of the activation mechanism and ability to recapitulate the activation mechanism *in vitro*, we were able to identify multiple highly selective inhibitors of the activation of latent TGFβ1.

By specifically targeting the TGFβ1 isoform, we believe we have the key to unlock the power of checkpoint inhibitors and meaningfully increase response rates across multiple solid tumor types. In March 2019, we selected SRK-181 as a product candidate in our TGFβ1 cancer immunotherapy program based on the strength of preclinical data and human translational insights. *In vitro* and *in vivo* studies of SRK-181 showed that it binds to latent TGFβ1 with high affinity and high selectivity, which is evidenced by minimal or no binding to latent TGFβ2 or latent TGFβ3 isoforms. Integrins, such as αVβ6 and αVβ8, can trigger the activation of TGFβ1 and TGFβ3. In addition, biochemical evidence suggests that certain proteases (e.g., Plasmin and Kallikreins) may also induce TGFβ activation. Notably, these integrins and proteases have been implicated in tumor biology in a number of human cancers. show SRK-181 is capable of inhibiting both integrin-dependent- and protease-induced activation of TGFβ1.



SRK-181 selectively binds to proTGFβ1complexes with minimal or no binding to proTGFβ2 or proTGFβ3 complexes.

TGFβ1 in Cancer Therapygenerally well tolerated. The data cutoff for all analyses was August 29, 2023.

We believe that specific inhibition of TGFβ1 may have a significant impact on the treatment of patients in certain oncology settings.

Immune checkpoints are cellular mechanisms that act as a brake on the immune system, and expression of these proteins in the tumor microenvironment creates an immunosuppressive environment that allows tumor cells to evade being killed

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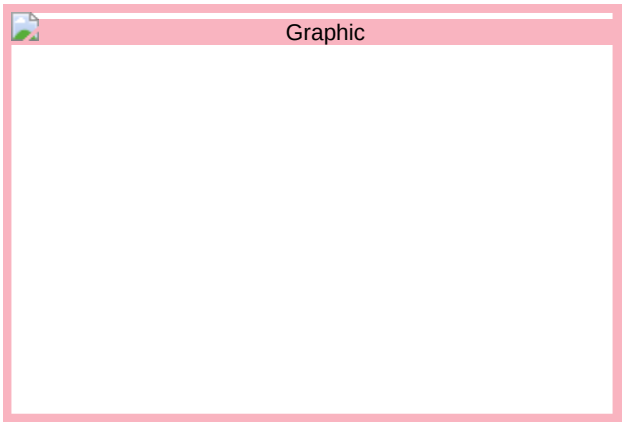
DRAGON trial achieved its study objectives by the immune system. Immune checkpoint proteins, such as PD-1/PD-L1, have therefore become key therapeutic targets in the tumor microenvironment. By inhibiting these proteins, the brakes on the immune system are released, allowing the T cells to kill the cancer cells. There are currently multiple approved checkpoint inhibitor therapies that target the PD-1/PD-L1 pathway.

A significant proportion of patients, in many cases the majority, fail to respond to these checkpoint inhibitor therapies, because they have what appears to be a pre-existing, or primary, resistance to immunotherapy. Other patients' cancers appear to initially respond but subsequently progress. In many human cancers, TGFβ signaling is associated with lack of response to PD(L)-1 blockade, particularly showing objective, durable clinical responses in patients with tumors harboring an immune excluded phenotype (i.e., CD8+ T cells present in nearby stroma but excluded ccRCC resistant to PD-1 therapy beyond what is expected from continuing PD-1 alone. It is anticipated that emerging data from the tumor parenchyma). Gene expression analysis of pre-treatment melanoma tumors identified multiple TGFβ-related signaling signatures associated with pre-existing or primary resistance to anti-PD-(L)1 antibody therapy. Similarly, it has also been reported that retrospective pathway analysis of tumor samples from an atezolizumab bladder cancer DRAGON trial identified the TGFβ pathway as a major determinant of primary resistance to atezolizumab.

Our analysis of publicly available human tumor data has identified TGFβ1 as the predominant TGFβ isoform expressed in many solid tumors.



National Cancer Institute - Cancer Genome Atlas Program RNAseq analysis of >10,000 samples spanning 33 tumor types show high expression of the TGFβ1 isoform in many tumor types

Preclinical Evidence in Overcoming Resistance to Checkpoint Inhibition

Using multiple mouse models that recapitulate the immune-excluded phenotype, we have observed that co-administration of SRK-181-mIgG1, the murine version of SRK-181, with an anti-PD-1 antibody renders these tumor models sensitive to the combination treatment. These models, including the MBT-2 bladder cancer model, the Cloudman S91 melanoma model and the EMT6 breast cancer model, are poorly responsive or unresponsive to single agent treatment with either anti-PD-1 or SRK-181-mIgG1, with little or no effect on tumor

growth. However, the combination of SRK-181-mIgG1 and anti-PD-1 resulted in tumor regressions. Furthermore, the combination treatment led to significant survival benefit in both models.

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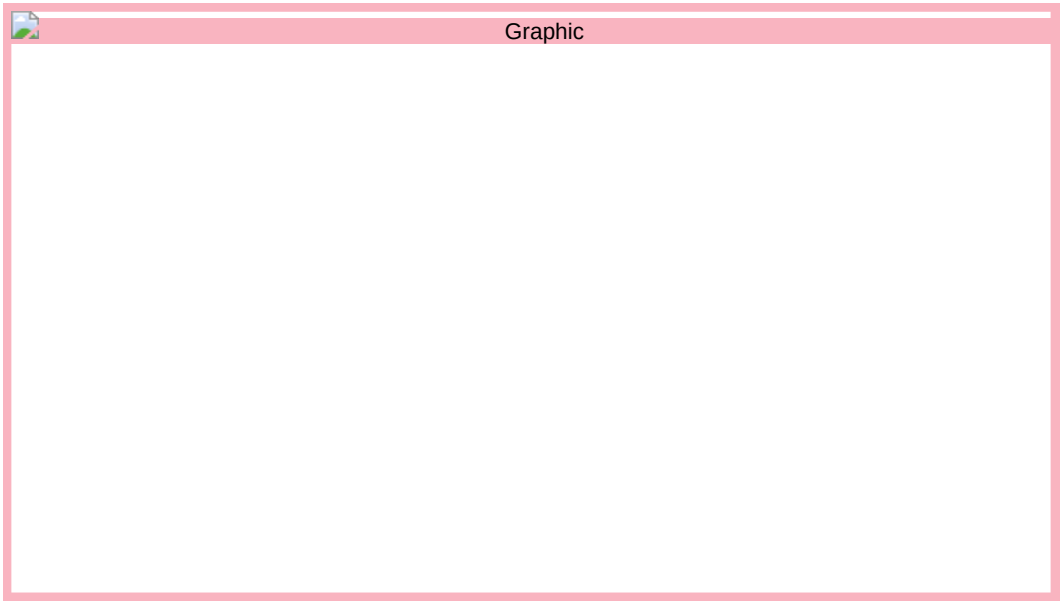

SRK-181-mIgG1 renders the syngeneic Cloudman S91 melanoma model susceptible to anti-PD-1 CPI therapy, as measured by tumor regression and growth control, and survival benefit

This effect on tumor regression and survival benefit was also observed will be presented at medical meetings in the EMT6 breast cancer model, which expresses both TGFβ1 and TGFβ3, suggesting that potently inhibiting TGFβ1 alone is sufficient for enabling a synergistic anti-tumor response in conjunction with anti-PD-1 antibody treatment.

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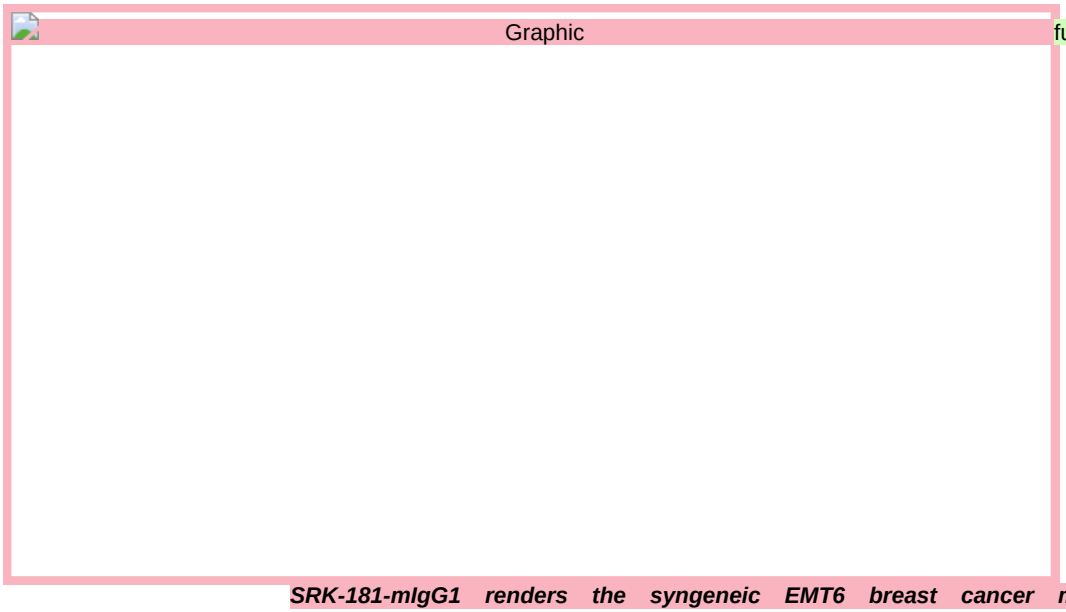
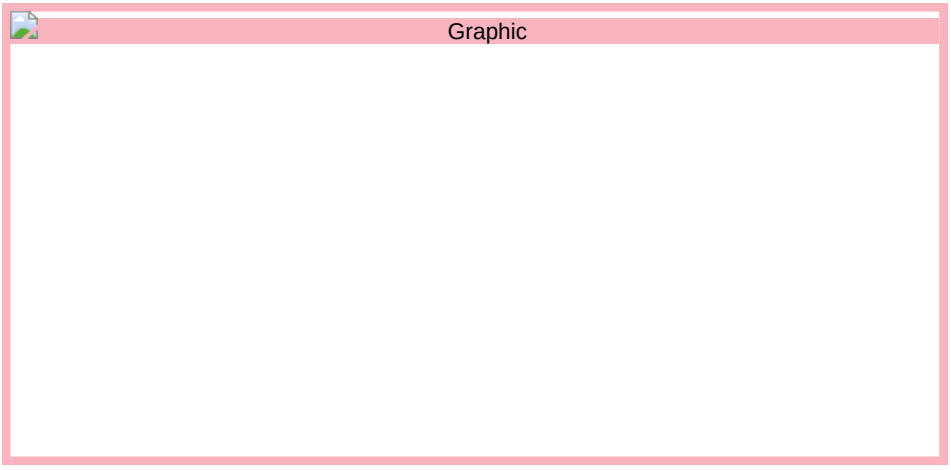
Graphic future.



SRK-181-mIgG1 renders the syngeneic EMT6 breast cancer model susceptible to anti-PD-1 CPI therapy, as measured by tumor regression and growth control, and survival benefit

Furthermore, in *in vivo* mechanistic studies of the same tumor models, we observed an increase in the number of effector T cells in tumors from mice treated with the SRK-181-mIgG1/anti-PD-1 combination versus control or single agent treatment, suggesting that overcoming innate CPI resistance involves enhanced presence and activity of killer T cells. CD8+ population expanded to an average of 34% of the tumor's immune cells from a control average of 3.5%. We also observed a decrease in intratumoral immunosuppressive myeloid cells – a reduction in tumor-associated macrophage ("TAM")/myeloid-derived suppressor cell ("MDSC") population to 14% of the tumor's immune cells from a control average of 47%.

Graphic



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Combination treatment of MBT-2 tumor bearing mice with SRK-181-mIgG1 and an anti-PD-1 antibody causes an increase in intra-tumoral effector T cells and a decrease in intratumoral immunosuppressive myeloid cells

We have demonstrated preclinically the potential of SRK-181 for reduced toxicity that has historically limited drug exposure with non-selective TGFβ inhibition. In a 28-day pilot nonclinical toxicology study in adult rats, we did not observe any drug-related toxicity up to the highest tested dose (100 mg/kg weekly) of SRK-181. In the same study, we tested non-selective TGFβ inhibitors and observed the published toxicities, including cardiac toxicity and death. We have also completed four-week GLP-toxicology studies in rats and non-human primates and no SRK-181 related adverse effects were observed up to the highest evaluated dose of 200 mg/kg per week and 300 mg/kg per week, respectively.

Phase 1 DRAGON Clinical Trial

DRAGON is our Phase 1, open-label, proof-of-concept trial designed to evaluate the safety, tolerability, PK/PD, and efficacy of SRK-181 administered intravenously every 3 weeks (Q3W) in patients with locally advanced or metastatic solid tumors. This clinical trial will investigate if SRK-181 in combination with anti-PD-(L)1 therapy may overcome resistance to anti-PD-(L)1 therapy and lead to anti-tumor responses.

This two-part clinical trial consists of a dose escalation portion (Part A) for SRK-181 as both a single agent and in combination with an approved anti-PD-(L)1 antibody therapy, followed by a dose expansion portion (Part B) evaluating SRK-181 in combination with an approved anti-PD-(L)1 antibody therapy in multiple tumor-specific cohorts. Patients must have locally advanced or metastatic solid tumors that exhibit resistance to anti-PD-(L)1 antibody therapy.

- **Part A**: The dose escalation portion of this clinical trial is assessing SRK-181 as a single agent (Part A1) and in combination with an anti-PD-(L)1 therapy approved for the tumor (Part A2). Parts A1 and A2 are being conducted in a staggered fashion.
    - The primary objectives of Part A are to evaluate safety and tolerability, determine the maximum tolerated dose (“MTD”) or maximum administered dose (“MAD”) and the recommended Phase 2 dose (“RP2D”), and evaluate dose-limiting toxicities. The secondary and exploratory objectives include evaluating PK and anti-drug antibodies (“ADA”), anti-tumor activity and biomarkers.
- **Part B**: The dose expansion portion of the clinical trial is evaluating SRK-181 in combination with an approved anti-PD-(L)1 therapy in multiple solid tumors for which anti-PD-(L)1 therapy is approved, including urothelial carcinoma, cutaneous melanoma, non-small cell lung cancer, clear cell renal cell carcinoma and head and neck squamous cell carcinoma.
    - The primary and secondary objectives of Part B are to evaluate safety and tolerability, anti-tumor activity, PK, and ADA. Biomarkers will also be evaluated as exploratory measures.

Based on the safety and PK data from Part A of the Phase 1 DRAGON trial, we initiated the Part B dose expansion portion of the clinical trial, which is evaluating SRK-181 dosed 1500 mg every three weeks (Q3W) in patients receiving an approved anti-PD-(L)1 therapy dosed Q3W and 1000 mg every two weeks (Q2W) in patients receiving an approved anti-PD-(L)1 therapy dosed Q2W. Part B will enroll and dose patients in multiple proof of concept cohorts conducted in parallel. Each cohort is expected to enroll up to 40 patients with various locally advanced or metastatic solid tumors who have demonstrated resistance to anti-PD-(L)1 therapy.

Initial clinical data from Part A were presented in November 2021 at the SITC 36th Annual Meeting and additional clinical data were presented at the 2022 SITC Annual Meeting in November 2022. Data to date from the Phase 1 DRAGON trial have shown that SRK-181 continues to be well tolerated in general, with early indications of clinical activity and no dose-limiting toxicities. The Phase 1 DRAGON trial continues to advance; we expect to provide biomarker and clinical updates in 2023.

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1. Potential Applications of SRK-181 in Additional Oncology Settings

In addition to cancer immunotherapy, we believe SRK-181 has the potential for use in other oncology settings, such as in immunotherapy-naïve patients, in combination with other therapies beyond checkpoint inhibitors and in myelofibrosis.

Discovery and Preclinical Programs*iii. Fibrosis: LTBP-49247*

Utilizing our proprietary platform, we have multiple early stage and preclinical programs directed against targets that are known to be important in serious diseases. We are discovering and generating highly selective and differentiated monoclonal antibodies against difficult targets by 1) applying our structural insights and antibody discovery expertise, 2) prioritizing human biology, and 3) embedding translational thinking early in the research and development process.

LTBP-49247

Fibrosis is a pathological feature of many diseases and can occur in virtually all organs. It is characterized by excessive accumulation of extracellular matrix in the affected tissue and accounts for substantial morbidity and mortality. TGFβ signaling pathway is a well-established central driver in the pathogenesis of fibrotic diseases and inhibition of this pathway has been shown to improve outcomes in relevant animal models of hepatic, renal, pulmonary, and other fibrotic diseases. In addition, a non-selective inhibitor of TGFβ signaling that inhibits all 3 isoforms (isoform 1, 2, and 3) of TGFβ showed clinical improvement in patients with systemic sclerosis, a

fibrotic connective tissue disease. However, non-selective inhibition of all TGFβ isoforms is known to be associated with serious safety findings, most notably bleeding episodes, and cardiac toxicities. Based on knock out animal models (a model where researchers have inactivated, or "knocked out," an existing gene by replacing it or disrupting it with an artificial piece of DNA), these safety findings are believed to be associated with inhibition of the TGFβ2, and TGFβ3 isoforms. These data suggest that novel approaches to targeting TGFβ signaling may have broad applicability to the treatment of fibrotic disease, where more selective approaches may offer an improved safety profile. Indeed, we have shown in both rats and non-human primates that selective inhibition of the TGFβ1 isoform eliminated the safety liabilities of non-selective targeting approaches and this molecule is being advanced in the clinic in indications where inhibition of immune cell sources of TGFβ1 is needed to potentially achieve maximum efficacy. Given In addition, given that immune cell activation may play a key role in fibrotic disease development, selective targeting of only matrix associated TGFβ1, at the primary site of fibrosis manifestation, while avoiding immune cell associated TGFβ1 is key to maintaining efficacy while avoiding potential long term long-term liabilities of immune cell activation.

Based on this scientific rationale, we utilized our platform to discover and develop antibodies that selectively inhibit the activation of latent TGFβ1 in the context of fibrotic extracellular matrix and that avoid perturbing TGFβ1 presented by cells of the immune system. We selected a highly potent, anti-latent TGFβ1 antibody that selectively inhibits TGFβ1 activation within the extracellular matrix by targeting latent TGFβ1 associated with latent TGFβ-binding proteins

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(LTBPs), thus enabling specific inhibition of TGFβ1 in fibrotic tissue. This antibody demonstrated significant antifibrotic activity in a variety of preclinical rodent models. It also demonstrated robust therapeutic index at all doses tested in a non-GLP mouse safety study. We plan to advance this program to IND-enabling studies.

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Graphic

When latent TGFβ1 is secreted from cells (top center), it is further associated with another protein, referred to as a presenting molecule (examples of which are shown in each image). The presenting molecules are covalently bound to the prodomain and serve to tether the latent TGFβ1 complex in a particular microenvironment. Unlike TGFβ1, a given presenting molecule's expression pattern is restricted to particular cellular and tissue environments. For example, the presenting molecule GARP (right) is found primarily on regulatory T cells, the presenting molecules LTBP1 and LTBP3 (bottom center) are localized to the connective tissue in the extracellular matrix, and the presenting molecule LRRC33 (left) is found primarily on certain myeloid lineage cells such as macrophages.

HJV-35202: A High-Affinity Antibody Demonstrating Selective Inhibition of HJV/RGMc

c. HJV-35202: A High-Affinity Antibody Demonstrating Selective Inhibition of HJV/RGMc

A number of disease states as well as rare genetic mutations can cause disruptions in iron homeostasis and can result in either iron deficiency or overload. These imbalances in iron levels can lead to detrimental complications and are the basis of mortalities and morbidities in many diseases. Hepcidin is a peptide hormone that is produced in the liver and plays a major role in regulating systemic iron homeostasis. Aberrantly increased hepcidin expression is a hallmark of several chronic and devastating diseases where it causes iron-restricted anemia, contributing to the morbidity and mortality of these diseases. Hepcidin expression is controlled via the bone morphogenetic protein (BMP) signaling pathway, with BMP2/6 being the predominant ligands signaling through a large protein receptor complex containing BMP receptors (BMPR) and a BMP co-receptor, repulsive guidance molecule c/ hemojuvelin (RGMc/HJV). The RGM family consists of three members, RGMa, RGMb and RGMc/HJV, and owing to their role as BMP co-receptors, has been shown to be involved in the development and maintenance of many tissues and organs throughout the body. Human

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mutations as well as knockout animal studies have demonstrated the predominant role of RGMc/HJV to be in the regulation of iron homeostasis. These data suggest that novel approaches to specifically target the BMP pathway in the liver may have a broad applicability to the treatment of anemia, especially in chronic diseases where hepcidin is upregulated.

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In contrast to the far-reaching roles of BMP-BMPRs throughout the body, the specific role of RGMc/HJV isoform in iron homeostasis, provided an opportunity to utilize our platform to discover and develop antibodies that selectively bind to and inhibit RGMc. We selected HJV-35202, a highly potent and selective RGMc/HJV inhibitor that has demonstrated significant suppression of hepcidin expression and resultant mobilization of stored iron in vivo in mice, rats, and non-human primates. HJV-35202 may provide a novel approach to treating iron-restricted anemia in patients with chronic diseases driven by hepcidin overexpression. We plan to advance this program to IND-enabling studies.

d. Additional Potential Areas of Exploration

Additional therapeutic areas and targets in which we could potentially apply our scientific platform and expertise include:

- Exploring opportunities to develop other context dependent inhibitors of TGFβ1 to modulate immune cell activation within the context of specific immune diseases.
- Exploring opportunities in modulating metabolic physiology including understanding the important role of skeletal muscle in modulating metabolism. This is highlighted by potential therapeutic opportunity for myostatin blockade. For example, evidence is emerging that blockade of the myostatin pathway can reduce the mass of visceral fat, a significant driver of cardiometabolic pathophysiology. We have efforts underway to evaluate these opportunities, including preclinical and translational research, development path assessments, and commercial evaluations.

We continue to enhance our internal biologics discovery capabilities including the use of humanized transgenic rodents as well as single-domain antibody libraries. These new capabilities allow us to more efficiently discover antibodies and furthers our commitment to building a differentiated portfolio of product candidates.

License Agreements

VII. License Agreements

a. Gilead Collaboration

On December 19, 2018 (the “Effective Date”), we entered into a three-year collaboration with Gilead to discover and develop therapeutics that target TGFβ-driven signaling, a central regulator of fibrosis (“the Collaboration Agreement”). In connection with the Collaboration Agreement, we received an upfront payment of $50 million and an equity investment of $30 million.

In December 2019, we achieved a $25 million preclinical milestone under the Gilead Collaboration Agreement for the successful demonstration of efficacy in preclinical in vivo proof-of-concept studies.

On January 6, 2022, we entered into a letter agreement with Gilead which (i) confirmed that the collaboration period under the Collaboration Agreement had expired as of December 19, 2021, and (ii) agreed the option exercise period for all programs under the Collaboration Agreement had been terminated as of January 6, 2022.

License Agreement with Janssen

On December 17, 2013, we entered into an option and license agreement with Janssen (the “Janssen Agreement”). Pursuant to the Janssen Agreement, Janssen funded our drug discovery research to identify molecules with either one or two pharmacological profiles, over a two-year period beginning on December 17, 2013 (the “collaboration period”).

Janssen exercised its option under this agreement in December 2015 to exclusively license certain collaboration molecules for one pharmacological profile, the selective inhibition of TGFβ1 in the context of regulatory T cells, and our obligations under the program plan for the molecule and related pharmacological profile ceased and Janssen assumed full responsibility for further development of the molecules at its sole cost.

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In July 2022, the Janssen Agreement was terminated and the rights to the molecules were reverted to us.

License Agreement with Children's Medical Corporation

On December 17, 2013, we entered into an exclusive license agreement (the “CMCC Agreement”) with Children's Medical Center Corporation (“CMCC”), to gain exclusive control over co-owned patent rights related to our platform technology. Under the CMCC Agreement, we received an exclusive worldwide license to CMCC's rights in certain patent rights jointly owned by us and CMCC, to develop and commercialize any product or process that but for the licenses granted to us under the CMCC Agreement would infringe such patent rights, a licensed product and licensed process, respectively, for any use. The CMCC Agreement was terminated in June 2022.

Prior to the termination, we paid CMCC annual license maintenance fees of $10,000 and, in 2022, prior to termination, we made a milestone payment of $400,000 upon achievement of a milestone for dosing a patient in a Phase 3 clinical trial.

b. Adimab Agreement

On March 12, 2019, we entered into an amended and restated collaboration agreement (“Adimab Agreement”) with Adimab, LLC (“Adimab”). Under the Adimab Agreement, as amended, we selected a number of biological targets against which Adimab used its proprietary platform technology to discover and/or optimize antibodies based upon mutually agreed upon research plans, and we have the ability to select a specified number of additional biological targets

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against which Adimab will provide additional antibody discovery and optimization services. During the research term and evaluation term for a given research program with Adimab (“Research Program”), we have a non-exclusive worldwide license under Adimab’s technology to perform certain research activities and to evaluate

the program antibodies to determine whether we want to exercise our option to obtain an exclusive license to exploit such antibodies (a “Development and Commercialization Option”).

Pursuant to the Adimab Agreement, we previously paid Adimab a one-time, non-creditable, non-refundable technology access fee. We are also obligated to make certain technical milestone payments to Adimab on a Research Program-by-Research Program basis. Upon exercise of a Development and Commercialization Option, we are obligated to pay to Adimab a non-creditable, nonrefundable option exercise fee of either (i) a low seven-digit dollar amount or (ii) a mid mid- six-digit dollar amount, based on the antibodies in the given Research Program, plus, in either case, an amount equal to any technical milestone payment which was not previously paid with respect to such Research Program and less, in either case, any option extension fees paid with respect to such Research Program. On a Product (as defined in the Adimab Agreement)-by-Product basis, we will pay Adimab upon the achievement of various clinical and regulatory milestone events with total milestone payments not to exceed mid-teen millions in the aggregate for a given Product. For any Product that is commercialized, on a country-by-country and Product-by-Product basis, we are obligated to pay to Adimab a low-to-mid single-digit percentage of annual worldwide net sales of such Product during the applicable royalty period in each country.

SRK-181 is subject to the terms of the Adimab Agreement, and in March 2019, we exercised our Development and Commercialization Option for the Research Program from which SRK-181 was generated. In January 2020 and December 2020, we exercised our Development and Commercialization Option for additional Research Programs.

Intellectual Property

VIII. Intellectual Property

Our commercial success depends in part on our ability to protect intellectual property for our product candidates, including apitegromab and SRK-181, and related methods, as well as our novel approach and proprietary platform for generating monoclonal antibodies; to secure freedom-to-operate to enable commercialization of our product candidates, if approved; and to prevent others from infringing upon our patent rights. Our policy is to seek to protect our intellectual property position by filing patent applications in key jurisdictions, including the U.S., Europe, Canada, Japan and

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Australia, covering our proprietary technology, inventions and improvements that are important to innovate, develop, sustain and implement our business.

We file patent applications directed to compositions comprising our antibodies, classes of antibodies covering our product candidates, use of such antibodies for treating diseases, as well as related manufacturing methods. As of December 31, 2022 December 31, 2023, we have 27 30 pending patent families across multiple programs. Among the pending families, 19 22 have been nationalized, from which 18 20 applications have matured into U.S. issued patents with additional issued patents in multiple jurisdictions globally. Collectively, there are 252 242 national or direct utility applications pending or issued. In addition, there are three four patent family filings which are in the priority year. We continue to review and harvest new inventions for new patent filings.

Two As of December 31, 2023, two granted patents, EP2981822 and EP3368069, are currently the subject of ongoing opposition proceedings before the European Patent Office ("EPO"). We have no other contested proceedings relating to any patents at this time, as of that date, but we cannot provide any assurances that we will not have such proceedings at a later date. For more information regarding the risks related to our intellectual property, please see "Risk factors—Risks Related to Our Intellectual Property."

Ownership and IP Rights

Our earliest patent family, PCT/US2013/068613 (published as WO 2014/074532), is jointly owned by us and CMCC. CMCC is the assignee of the intellectual property rights transferred from two of our co-founders, Drs. Timothy A. Springer and Leonard I. Zon. We are the sole legal owner of all subsequent patent families we have to date.

Brief descriptions of our patent families are provided below, with projected patent terms excluding any possible patent term adjustments or extensions.

a. Platform

Our novel approach to generating selective modulators of supracellular activation of growth factors is broadly embodied in our two earliest "platform" patent families, PCT/US2013/068613 (published as WO 2014/074532) and PCT/US2014/036933 (published as WO 2014/182676). These patent families are directed to methods for modulating the activation of the TGFβ superfamily of growth factors and methods for screening for a monoclonal antibody that

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specifically targets an inactive form of the growth factor, thereby preventing activation (e.g., release) of mature growth factor. The TGFβ superfamily is a group of more than 30 related growth factors/cytokines that mediate diverse biological processes and includes TGFβ1 and myostatin (also known as GDF-8). Issued U.S. patents in the platform families include: U.S. Patents Nos. 9,573,995 (issued 02/21/2017); 9,758,576 (issued 09/12/2017); 9,580,500 (issued 02/28/2017); 9,399,676 (issued 07/26/2016); 9,758,577 (issued 09/12/2017); 10,597,443 (issued 03/24/2020); 10,981,981 (issued 04/20/2021); and 10,981,981 (04/20/2021) 11,827,698 (issued 11/28/2023). There is also a granted European ("EP") platform patent: EP2981822 (granted on 09/02/2020), which was validated in 37 states. These U.S. and EP patents are projected to expire in 2034.

Specifically, EP2981822 has granted composition of matter claims directed to an antibody capable of binding a recombinant antigen comprising pro-TGFβ1 or a growth factor-prodomain complex which comprises the TGFβ1 LAP complex, in addition to claims directed to methods of making such antibodies. EP2981822 is currently the subject of ongoing opposition proceedings before the EPO.

U.S. Patent No. 9,573,995 has issued composition of matter claims directed to an antibody that specifically binds to GARP associated with a human TGFβ1 LAP complex.

U.S. Patent No. 9,758,576 has issued composition of matter claims directed to an isolated monoclonal antibody, or a fragment thereof, that specifically binds the prodomain of a pro/latent GDF-8/myostatin complex, thereby preventing proteolytic cleavage between residues Arg 75 and Asp 76 of GDF-8/myostatin prodomain, so as to inhibit the release of mature GDF-8/myostatin growth factor from the complex.

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U.S. Patent No. 9,580,500 has issued claims directed to phage display library-based antibody production methods for identifying an antibody that binds a GARP/proTGFβ1 complex.

U.S. Patent No. 9,399,676 has issued claims directed to phage display library-based antibody production methods for identifying an antibody that binds a pro/latent GDF-8 complex that has been subjected to enzymatic cleavage. Related product-by-process claims are included in issued U.S. Patent No. 9,758,577.

U.S. Patent No. 10,597,443 has issued claims that broadly cover manufacturing methods for a pharmaceutical composition containing an antibody that binds a large latent complex of TGFβ, thereby modulating TGFβ signaling.

In addition, U.S. Patent No. 10,981,981 has issued claims that broadly cover manufacturing methods for a pharmaceutical composition containing an antibody that binds pro/latent GDF-8, but does not bind to mature

GDF-8, and inhibits GDF-8 signaling.

In addition, U.S. Patent No. 11,827,698 has issued claims that broadly cover manufacturing methods for a pharmaceutical composition containing an antibody that binds pro/latent GDF-8, and inhibits release of mature GDF8 from the pro/latent GDF8 complex.

b. Myostatin Activation Inhibitors

Nine Eleven patent families have been filed to date to cover proprietary myostatin inhibitors and their use in the treatment of various muscle and metabolic diseases. Patent prosecution of these pending patent families is ongoing but relatively early.

Two families are directed to composition of matter claims that cover our proprietary antibodies. PCT/US2015/059468 (published as WO 2016/073853) broadly covers a class of monoclonal antibodies that specifically bind inactive precursors thereby preventing activation of myostatin. This patent family is projected to expire in November 2035. U.S. Patents 10,307,480 and 11,135,291 issued in June 2019 and October 2021, respectively, with issued claims directed to Scholar Rock proprietary antibodies that specifically bind pro/latent myostatin, including 29H4, the parental clone of apitegromab, and variants, as well as methods of making antibodies with pH sensitive binding to pro/latent myostatin. A

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second family, PCT/US2016/052014 (published as WO 2017/049011), discloses the specific amino acid sequence of apitegromab and is projected to expire in September 2036. U.S. Patent 10,751,413 issued in August 2020, with claims directed to antibodies and pharmaceutical compositions comprising the heavy and light chain sequences of apitegromab, while U.S. Patent 11,439,704 issued in September 2022, with claims directed to a method of preventing muscle loss and/or reducing muscle atrophy or treating SMA by administering an antibody having the heavy and light chain sequences of apitegromab. The European counterpart also granted as EP 3350220 B1 in May 2021. The granted claims relate to antibodies comprising the heavy and light chain variable region sequences of apitegromab, and pharmaceutical compositions of the antibodies.

The following patent families are directed to therapeutic uses/methods:

PCT/US2017/012606 (published as WO 2017/120523) broadly covers treatment methods for a number of muscle and neuromuscular disease and disorders using an antibody that specifically blocks the activation step of myostatin. The first U.S. application issued in May 2019 as U.S. Patent 10,287,345 and is projected to expire in September 2036. The issued claims are drawn to methods for inhibiting myostatin activation using our

proprietary activation inhibitors (such as apitegromab) to cause specified pharmacological effects to treat a variety of conditions including, muscle and metabolic disorders. A second U.S. application issued as U.S. Patent 10,882,904 in January 2021. The issued claims recite methods for inhibiting myostatin activation using an antibody comprising the heavy and light chain sequences of apitegromab for various indications.

PCT/US2017/037332 (published as WO 2017/218592) is directed to methods for treating neuromuscular diseases and selecting patient populations that are likely to respond to myostatin inhibition. This filing includes the treatment of SMA in patients who are on SMN therapies (e.g., SMN correctors/upregulators). This patent family is projected to expire in June 2037. The PCT application was nationalized in 11 jurisdictions, and applications in the three key jurisdictions (i.e., U.S., Europe and Japan) have granted. granted, as well as in other countries. Specifically, the U.S. application granted in March of 2021. The granted claims are directed to add-on or combination therapy for treating spinal muscular atrophy with a myostatin inhibitor and a

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neuronal corrector (such as smn upregulator therapy). Similar claims have also granted in other countries including Japan (JP Patent No. 6823167, JP Patent No. 7161554, and JP Patent No. 7161554) 7,344,337). Likewise, the European counterpart granted as EP 3368069B1, and has been validated in 37 states. The granted European claims are directed to add-on therapy and combination therapy for the treatment of SMA using a myostatin-selective inhibitor, in conjunction with an SMN corrector therapy. EP 3368069B1 is currently the subject of ongoing opposition proceedings before the EPO.

PCT/US2018/012686 (published as WO 2018/129395) relates to the treatment of metabolic diseases with a myostatin activation inhibitor and is projected to expire in January 2038. The PCT was nationalized in 2019 and is in the early stages of prosecution. A U.S. patent issued in October of 2021 as U.S. 11,155,611, with claims directed to methods of making a pharmaceutical composition comprising a myostatin-selective inhibitor, comprising screening for an antibody that is capable of decreasing expression of pyruvate dehydrogenase kinase 4 (PDK4) and increasing expression of pyruvate dehydrogenase phosphatase 1 (PDP1). A Japanese patent (JP 7198757) issued in December 2022 with claims directed to a pro/latent myostatin-specific inhibitor for use in treating or preventing obesity or metabolic disorder in a subject on a calorie restriction diet. Similar claims have issued in Europe in 2023 (EP 3565592).

In addition to the five pending patent families listed above, there is also a recently-filed PCT application PCT/US2021/056517 (published as WO2022/093724) directed to inventions deriving from the phase 2 clinical trial of apitegromab. If granted, patents deriving from this PCT would expire in 2041. Another PCT application was filed in 2023, PCT/US2023/020843 (published as WO 2023/215384) with claims directed to therapeutic

methods for treating SMA. If granted, patents from this family would expire in 2043. A further PCT application PCT/US2022/034588 (published as WO2022/2271867) was filed with claims directed to a myostatin pathway inhibitor for use in treating metabolic disorders. If granted, patents deriving from this PCT would expire in 2042. Moreover, issued claims of U.S. Patent 9,758,576 from the platform patents discussed in detail above cover monoclonal antibodies that selectively inhibit myostatin signaling by blocking the proteolytic activation of latent myostatin. These issued composition of matter claims provide protection for our first antibody apitegromab, as well as any other monoclonal antibodies that work by this unique mechanism of action. This patent expires in May 2034, not including any potential patent term extension.

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Finally, two other myostatin-related patent families have been filed and are in the priority year.

c. TGFβ1 Activation Inhibitors

In addition to the patent families discussed above in the "*Intellectual Property-Platform"* section that generically cover certain aspects of the TGFβ1 program, fourteen fifteen patent families have been filed to date, covering various specific aspects of our TGFβ1 programs.

Isoform-specific inhibitors of TGFβ1 which confer improved safety profile and related methods are described in PCT/US2017/021972 (published as WO 2017/156500). A US patent (11,643,459) issued in May 2023, with claims directed to methods for identifying TGFβ1-specific inhibitors. A European patent granted in May of 2023 as EP3365368, with claims to the use of isoform-selective and context-independent anti-TGFβ1 antibodies, defined by CDR sequences or by cross-competition, in the treatment of cancer or myelofibrosis. This family is projected to expire in March 2037.

Among TGFβ1 inhibitors, one of our context-independent antibodies is separately claimed and related preclinical data are described in PCT/US2018/012601 (published as WO 2018/129329). This patent application is projected to expire in January 2038. For this latter family, a Japanese patent (JP Patent No. 7157744) issued in October 2022 with claims covering certain isoform-selective, context-independent antibodies and their use in the treatment of fibrotic diseases.

In addition, high-affinity, isoform-selective TGFβ1 inhibitors are disclosed in PCT/2019/041373 (published as WO US2020/014460). Patents of this family are projected to expire in 2039. Separately, three direct national/regional applications covering related subject matter have been filed, in the U.S., Europe and Hong Kong, and are projected to expire in 2039. A U.S. patent issued in September of 2021 as U.S. 11,130,803, with claims which cover the SRK-181 clinical candidate and pharmaceutical compositions thereof; and a European

patent issued in November of 2021 as EP3677278, with claims that cover the SRK-181 clinical candidate, pharmaceutical compositions, use for treating cancer and myelofibrosis, and methods for manufacturing. Additionally, PCT/US2021/012969 (published as WO 2021/142448) discloses data related to biomarkers for the high-affinity, isoform-selective TGFβ1 inhibitors and, if granted, patents deriving from this PCT application are projected to expire in 2041. Additional biomarkers are disclosed in PCT/US2022/022063 (published as WO2022/204581) and PCT/US2022/032278 (published as WO2022256723). If granted, patents deriving from these PCT applications would expire in 2042. Antibodies claimed in these patent families protect our SRK-181 clinical candidate.

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Separately, other improved isoform-selective, context-independent inhibitors of TGFβ1 are disclosed in PCT/US2019/041390 (published as WO 2020/014473). This family is projected to expire in 2039. PCT/US2021/12930 (published as WO 2021/142427) is directed to optimized isoform-selective, context-independent inhibitors of TGFβ1. This family is projected to expire in 2041.

LTBP complex-specific inhibitors of TGFβ1 are described in three four patent families: PCT/US2018/44216 (published as WO 2019/023661) which is expected to expire in July of 2038; and PCT/US2020/15915 (published as WO2020/160291), which is expected to expire in 2040; and PCT/US2022/73740 (not yet published) (published as WO 2023/288277), which is expected to expire in 2042. 2042; and a fourth patent family which is in the priority year. Two U.S. patents (U.S. Pat. Nos. 11,214,614 and 11,365,245) have been issued in the second patent family with claims directed to antibodies and pharmaceutical compositions.

LRRC33-specific inhibitors are described in a further patent family: PCT/US2018/031759 (published as WO 2018/208888) which is expected to expire in May of 2038. EP3621694 has been allowed, granted in July 2023, with claims directed to therapeutic use of LRRC33 inhibitors for the treatment of various indications. PCT/US2017/042162 (published as WO 2018/013939) was exclusively licensed to Janssen but, as explained above, below, the license agreement was terminated in July 2022. Scholar Rock is now in control of prosecution. This patent family covers antibodies that specifically inhibit GARP-associated TGFβ, and is projected to expire in July 2037.A 2037. A Japanese patent (JP Patent No. 7128801) issued in

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August 2022 with claims directed to antibodies and antigen-binding fragments which specifically bind human pro-TGFβ1 complex, a process for their production and related compositions.

d. RGMc-Selective Inhibitors

PCT/US2019/57687 (published as WO2020/86736) is directed to RGMc-selective inhibitors and will expire in 2039. A second family has been filed and is in the priority year, which is projected to be converted to international patent application (PCT) in October November of 2023. 2024.

e. Intellectual Property Protection

We cannot predict whether the patent applications we pursue will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide any proprietary protection from competitors. Even if our pending patent applications are granted as issued patents, those patents, as well as any patents we license from third parties, may be challenged, circumvented or invalidated by third parties. As mentioned above, two granted patents, EP2981822 and EP3368069, are currently the subject of ongoing opposition proceedings before the EPO. EPO, as of December 31, 2023. While there are currently no contested proceedings or third-party claims relating to any of the other patents described above, as of that date, we cannot provide any assurances that we will not have such proceedings or third-party claims at a later date.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the U.S., the patent term of a patent that covers an FDA-approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during FDA regulatory review process. The Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug or biologic is under regulatory review. 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 one patent applicable to an approved drug or biologic may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug or biologic or provide an additional period of protection for the approved pharmaceutical product following expiry of the patent. In the future, if our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the U.S. Patent and Trademark Office in the U.S. and the national patent offices in Europe, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

In addition to our reliance on patent protection for our inventions, product candidates and research programs, we also rely on trade secret protection for our confidential and proprietary information. For example, certain elements of our proprietary platform may be based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

IX. Manufacturing

We do not own or operate facilities for clinical drug manufacturing, storage, distribution or quality testing. Currently, all of our clinical manufacturing is outsourced to third-party manufacturers. Certain third party manufacturers may require us to enter in manufacturing agreements with them that include substantial milestone payments and royalties. As our development programs expand and we build new process efficiencies, we expect to continually evaluate this our strategy of utilizing third party manufacturers with the objective of satisfying demand for our registration trials and, if approved, the manufacture, sale and distribution of commercial products.

X. Antibody Discovery

We have built and internalized internal antibody display and discovery capability, capabilities, however at times we may continue to rely on third parties to conduct antibody discovery and optimization services for us based on criteria and specifications provided by us. Certain antibody discovery and optimization vendors require us to enter into a license with them for the right to use antibodies discovered by them in humans or for commercial purposes. Such license could include substantial milestone payments and royalties to the extent we choose to use an antibody discovered by such vendor. On March 12, 2019, we exercised an option to receive such a license from Adimab pursuant to our Adimab Agreement. Please see the description above in "License Agreements – Adimab Agreement" for more details on the terms of this agreement.

XI. Competition

The biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies, fierce competition, and strong defense of intellectual property. While Although we believe that our product candidates, discovery programs, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

Any product candidates that we successfully develop and commercialize could compete with currently approved therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products.

Many of the companies against which we may compete have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing commercialization of approved products. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and may compete with us in establishing clinical trial sites and patient registration recruitment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. trials.

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The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

a. Competition for Apitegromab

In the SMA market, there are three approved SMN therapies and no approved muscle-targeted treatments for SMA to date. We believe that it will take several treatment approaches to holistically treat SMA. The SMA drug development pipeline reflects an evolution of the treatment paradigm in SMA and we are pioneering a novel approach to focus on the unmet needs of individuals living with SMA after receiving treatment with an approved SMN therapy. To address the fatal muscle weakness and quality of life impact in SMA. SMA, we are pioneering a novel approach by developing a muscle-targeted therapy.

We are developing apitegromab, a highly selective inhibitor an investigational fully human monoclonal antibody designed to inhibit myostatin activation by selectively binding the pro- and latent forms of myostatin in the activation of latent myostatin, skeletal muscle, for the treatment of patients with SMA. If apitegromab receives marketing approval, we may face competition from other companies conducting clinical trials to develop anti-myostatin inhibitors molecules or other muscle-targeted therapies for SMA, including Roche, Biohaven Ltd, Biogen, and NMD Pharma, and Cytokinetics, Inc. Pharma. Moreover, we may also compete with smaller or earlier-stage companies, and other research institutions that have developed, are developing or may be developing current and future anti-myostatin inhibitors or other muscle-targeted therapies for SMA.

In addition, Novartis, Roche and Biogen are developing alternate formulations of their approved SMN therapies, including Novartis for its gene therapy, onasemnogene abeparvovec, Roche for risdiplam, and Biogen for its antisense

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oligonucleotide (ASO), nusinersen. We do not believe that these therapies are competitive with apitegromab because apitegromab addresses a different aspect of the disease pathology, and that apitegromab is anticipated to be used in patients receiving SMN therapies.

b. Competition for SRK-181

Our competitors for SRK-181 may include other companies developing cancer immunotherapies to be used in combination with CPI therapy. Novartis's NIS793, an anti-TGF-β IgG2 monoclonal antibody licensed from Xoma, is currently in a Phase 3 clinical trial for the treatment of metastatic pancreatic ductal carcinoma (mPDAC) in combination with chemotherapy as well as multiple early-stage clinical studies in a variety of solid tumor types and myelofibrosis.

Other Many companies, including AbbVie Inc, Roche, Bicara Therapeutics, Novartis, Bristol Myers Squibb (acquired Forbius) and Merck KGaA, Merck (acquired Tilos Therapeutics), Roche, Bristol Myers Squibb (acquired Forbius) and AbbVie Inc. are developing therapies for cancer immunotherapy in combination with CPI therapy, that are intended to work, at least in part, through inhibition of the TGFβ signaling pathway.

Our competitors may also include companies that are or will be developing therapies for the same therapeutic areas that we are targeting within our early pipeline, including other neuromuscular disorders, cancer, fibrosis and iron-restricted anemia.

Many of the companies against which we may compete have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

XII. Government Regulation

Government authorities in the U.S. at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, such as apitegromab, SRK-181, SRK-439 and any future product candidates. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be

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obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

a. U.S. Biological Product Development

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (“FDCA”), and its implementing regulations and biologics under the FDCA, the Public Health Service Act (“PHSA”), and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications,

withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Apitegromab, SRK-181, and any future product candidates regulated as biologics must be approved by the FDA through a Biologics License Application ("BLA") process before they may be legally marketed in the U.S. The process generally involves the following:

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice ("GLP") requirements;
- Manufacture of drug substance and drug product in accordance with applicable regulations, including manufacturing activities performed in accordance with current good manufacturing practice ("cGMP") requirements;
- Submission to the FDA of an investigational new drug ("IND") IND application, which must become effective before human clinical trials may begin;

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- Approval by an institutional review board ("IRB") or independent ethics committee at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice ("GCP") requirements and other clinical trial-related trial related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- Submission of a BLA to the FDA;
- A determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;
- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- Potential FDA inspection of Scholar Rock and of the clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the biologic in the U.S.

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The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for apitegromab, SRK-181 and any future product candidates will be granted on a timely basis, or at all.

i. Preclinical Studies and IND

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin. Some long-term long term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

ii. Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all patients provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit

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data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted well conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may be combined or overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected disease affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase 2 clinical trials generally involve studies in disease-affected disease affected patients to evaluate proof of concept proof-of-concept and/or determine the dosing regimen(s) for subsequent investigations. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

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- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended

therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for suspected unexpected serious adverse reactions ("SUSARs"), findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the 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 the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board ("DSMB") or committee. The DSMB provides recommendations for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

iii. FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. Chemistry, manufacturing and control controls ("CMC") information, preclinical studies and clinical trials results, and proposed labeling are submitted to the FDA as part of the BLA. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity and potency for a biologic. The application may include both negative and ambiguous results of preclinical

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studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the U.S.

Under the Prescription Drug User Fee Act ("PDUFA") as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted BLAs before it accepts them for filing, and may request additional information rather than accepting the BLA for filing. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and such decision could include a refusal to file ("RTF") by the FDA. 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 the filing date, in which to complete its initial review of an original BLA and respond to the

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applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will conduct a pre-approval preapproval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. 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. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult 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, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates a BLA, it will issue an Approval Letter or a Complete Response Letter. An Approval Letter authorizes commercial

marketing of the biologic with specific prescribing information for specific indications. The Approval Letter may also include post-marketing requirements or commitments, such as the conduct of additional clinical trials or CMC studies. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming time consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

iv. Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product.

After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

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If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products a product designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may

not be entitled to orphan drug exclusivity. Orphan drug status in the European Union ("EU") has similar, but not identical, requirements and benefits.

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v. Rare Pediatric Disease Designation

The FDA grants Rare Pediatric Disease designation for serious and life-threatening diseases that primarily affect children ages 18 years or younger and fewer than 200,000 individuals in the United States. Eligibility for a priority review voucher may be issued upon approval of a BLA or New Drug Application for therapies developed to treat such rare pediatric diseases. Priority review vouchers may be redeemed to obtain priority review for any subsequent marketing application or be sold or transferred.

vi. Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for Fast Track status any time before receiving BLA approval, but ideally no later than the pre-BLA meeting. Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biologic designated for priority review in an effort to facilitate the review.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. Accelerated approval may also be granted in the case that there are no alternative treatments available. In addition, it must demonstrate 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 ("IMM"), that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials with due diligence and, under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after, the date accelerated approval is granted. In addition, for products being considered for accelerated approval, the FDA currently 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. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a product or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and

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preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as Fast Track designation, plus intensive guidance from the FDA to ensure an efficient drug development program.

Fast Track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

vii. Pediatric Information

Under the Pediatric Research Equity Act (“PREA”), as amended, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the 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 pediatric data or full or partial waivers. Unless otherwise required by regulation,

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PREA does not apply to any biological product for an indication for which orphan designation has been granted. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit submits an initial Pediatric Study Plan ("PSP") within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

viii. Post-marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. Prescription drug and biologic promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy ("REMS") to assure the safe use of the 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 an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, including a REMS or the conduct of post-marketing studies to assess a newly discovered safety issue. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to

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periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws, as well as applicable tracking and tracing requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

ix. Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the U.S. in addition to the FDA, including the Centers for Medicare & Medicaid Services (“CMS”), other divisions of the Department of Health and Human Services (“HHS”), the Department of

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Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

x. Other Healthcare and Privacy Laws

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third-party payors, healthcare providers and physicians 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 market, sell and distribute any drugs for which we obtain marketing approval. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s),

certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. In the U.S., these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

- The Anti-Kickback Statute, which makes it illegal for among other things, any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by individual imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

- The federal civil and criminal false claims laws, including the False Claims Act (“FCA”), which prohibits individuals or entities (including prescription drug manufacturers) from knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off label. Claims which include items or services resulting from a violation of the Anti-Kickback Statute are false or fraudulent claims for purposes of the FCA. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this these laws.

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- The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created additional federal criminal statutes that prohibit among other things, knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. 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, which impose, among other things, specified requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates, which include individuals or entities that perform services for covered entities involving the creation, use, maintenance or disclosure of, individually identifiable health

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information, relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such 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.

- The U.S. Physician Payments Sunshine Act (the “Sunshine Act”), enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “ACA”), which impose new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, for certain payments and “transfers of value” provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), non-physician providers (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

- Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. Such laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures. Some state and local laws require the registration of pharmaceutical sales representatives.

- Many states in which we operate also have laws that protect the privacy and security of sensitive and personal information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. Where state laws are more protective than HIPAA, we must comply with the state laws we are subject to, in addition to HIPAA. In certain cases, it may be necessary to modify our planned operations and procedures to comply with these more stringent state laws. Further, in

- In some cases where we process sensitive and personal information of individuals from numerous states, we may find it necessary to comply with the most stringent state laws applicable to any of the information. For example, the California Consumer Privacy Act (the "CCPA"), which creates new comprehensive 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, went into effect on January 1, 2020. The CCPA 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 went into effect on January 1, 2020 and grants In addition, the California Attorney General Privacy Rights Act, or CPRA, amendment to the power CCPA was passed in November 2020, and as of January 1, 2023 has imposed additional obligations on companies covered

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by the legislation. The CPRA significantly modified the CCPA, including by expanding consumers' rights with respect to bring enforcement actions against violators beginning July 1, 2020. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. certain sensitive personal information. As currently written, the CCPA may impact our business activities and as a result may increase our compliance costs and potential liability.

Similar comprehensive privacy laws have been passed in numerous other states and other states have proposed similar new privacy laws. 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 result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would 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. There are also states that are specifically regulating health information. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving 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 related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, disgorgement, exclusion of drugs from participation in state and federal healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the

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curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource consuming and can divert a company's attention from the business.

xi. Current and Future Healthcare Reform Legislation

In the U.S. and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing 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 marketing approval. We expect that current laws, as well as other healthcare reform measures that may be

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adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

In the U.S., for example, in March 2010, the ACA was enacted. The ACA, among other things:

- subjects biological products to potential competition by lower cost biosimilars;
- addresses 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;
- increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations;
- establishes annual fees and taxes on manufacturers of certain branded prescription drugs;
- expands healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, establishes new government investigative powers and enhanced penalties for non-compliance;
- creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% as of January 1, 2019, pursuant to the Bipartisan Budget Act of 2018)) point of sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expands 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;
- expands the entities eligible for discounts under the PHS Act's pharmaceutical pricing program, also known as the 340B Drug Pricing Program;
- creates new requirements to report financial arrangements with physicians and teaching hospitals, commonly referred to as the Physician Payments Sunshine Act;
- creates a new requirement to annually report the identity and quantity of drug samples that manufacturers and authorized distributors of record provide to physicians;
- creates a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and

- establishes the Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

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Some of the provisions of the ACA have been subject to judicial challenges as well as efforts to repeal, replace or otherwise modify them or to alter their interpretation or implementation. For example:

- The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Selection Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. In concert with subsequent legislation, this includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, with the exception of a temporary suspension that lasted from 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 remained through June 30, 2022. The 2% payment reduction resumed on July 1, 2022. 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American

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Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers may be further reduced by 4% starting in 2025, absent further legislation.

- The American Taxpayer Relief Act of 2012 reduced Medicare payments to several types of health care providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years, among other things.

- The Tax Cuts and Jobs Act of 2017 ("Tax Act"), includes a provision that eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the "individual mandate," effective January 1, 2019.

- The Bipartisan Budget Act of 2018 (“BBA”), among other things, amends the Medicare statute, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole” by raising the manufacturer discount under the Medicare Part D coverage gap discount program to 70% (as of January 1, 2019).

- In 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 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.

- In addition to these legislative efforts, 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, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021, which was subsequently extended through August 15, 2021, during which consumers can enroll in coverage (or adjust existing enrollment) in states with marketplaces served by the HealthCare.gov platform. State-based marketplaces operating their own platform have the option to take similar actions in their states. The executive order also directed certain federal 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. Additional legislative challenges, regulatory changes and judicial challenges related to the ACA remain possible.

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Additionally, there has been increasing legislative, regulatory, and enforcement interest in the United States with respect to 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, address the potential for importation of drugs into the United States, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

- At the federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs the HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply 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 Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. The FDA released such implementing regulations 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. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal 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 these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs.

- In addition, on November 20, 2020, CMS issued an interim final rule to implement a "Most Favored Nation" demonstration project to test Medicare Part B reimbursement of certain separately payable drugs or biologicals identified by CMS as having the highest annual Medicare Part B spending via an alternative payment methodology based on international reference prices. However, on December 29, 2021 CMS rescinded the Most Favored Nations rule.

- Additionally, on December 2, 2020, HHS published 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. The Inflation Reduction Act (the "IRA") of 2022 further delayed implementation of this rule to January 1, 2032.

- The IRA includes several other provisions that may impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries on prescription drugs, impose new requirements for manufacturers of all drugs to offer discounts under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, and require companies to pay rebates to Medicare for drug prices

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that increase faster than inflation. Drugs and biologics that have received orphan designation for one rare disease or condition and the only approved indication is for that disease or condition are exempted from the IRA's price negotiation provisions. A drug or biologic with orphan designations for multiple diseases or conditions or with multiple indications, however, will remain potentially subject to the price negotiation provisions.

Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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In addition, there have been changes related to Medicare Part B reimbursement for drugs purchased under the 340B drug pricing program. In 2018, CMS implemented a reduction in reimbursement for Medicare Part B drugs obtained under the 340B program from Average Sales Price (ASP) +6% to ASP -22.5%. This reduction has been challenged in federal court, and in July 2021 the Supreme Court has agreed to hear this case. On June 15, 2022, the Supreme Court unanimously reversed the Court of Appeals' decision, holding that HHS's 2018 and 2019 reimbursement rates for 340B- hospitals were contrary to the statute and unlawful.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including by imposing price or patient assistance constraints, restrictions on certain product access, marketing cost disclosure and other transparency measures, and, in some cases, measures designed to encourage importation of pharmaceutical products from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included 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.

xii. Packaging and Distribution in the U.S.

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. 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. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

xiii. Other U.S. Environmental, Health and Safety Laws and Regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions. 45

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xiv. U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of apitegromab, SRK-181 our current product candidates and any future product candidates, some 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, commonly referred to as the Hatch Waxman Amendments. The Hatch Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. 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, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

An abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 ("BPCI Act"). This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product 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 biological product without such alternation or switch.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four 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 U.S. 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 a supplement for the biological product or for a subsequent application by 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.

Pediatric exclusivity is another type of regulatory market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods. periods for all formulations, dosage forms, and indications of the biologic. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA issued "Written Request" for such a trial.

b. European Union Drug Development

In the EU, our future products also may be subject to extensive regulatory requirements. As in the U.S., medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

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Similar to the U.S., the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

In April 2014, the EU adopted the Clinical Trials Regulation EU No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022. The main characteristics of the new Clinical Trials Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System ("CTIS"); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for

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clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided into two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation. The transitory provisions of the Clinical Trial Regulation has a transition period of three years from provide that, by January 31, 2025, all ongoing clinical trials must have transitioned to the date it became effective. Clinical Trials Regulation.

In the EU the Paediatric Committee ("PDCO") of the EMA must approve a pediatric investigation plan ("PIP") prior to an applicant filing a marketing authorization application ("MAA"), unless the EMA has granted (1) a product-specific waiver or (2) a class waiver. The PIP outlines the pharmaceutical company's strategy for investigation of the new medicinal product in the pediatric population. Before an MAA can be filed, or an existing marketing authorization can be amended, the EMA determines whether companies actually comply with the agreed studies and measures listed in each relevant PIP. If an applicant obtains a marketing authorization in all EU Member States, or a marketing authorization granted in the centralized procedure by the EC, and the study results for the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of any supplementary protection certificate ("SPC"), provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to 2 years before the SPC expires. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

i. European Union Expedited Review and Development

PRIME or PRIority MEdicine, is a scheme provided by the EMA to enhance support for the development of medicines that target an unmet medical need and provides accelerated assessment of products representing substantial innovation where the MAA will be made through the centralized procedure. To qualify for PRIME, product candidates require early clinical evidence that the therapy has the potential to offer a major therapeutic advantage over existing treatments or benefits patients without treatment options. Products from small-and medium-sized enterprises ("SMEs") may qualify for earlier entry into the PRIME scheme than larger companies. Among the benefits of PRIME are the appointment of a rapporteur to provide continuous support and help build knowledge ahead of an MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process. The receipt of PRIME designation does not change the standards for approval but may expedite the development or approval process. Where, during the course of development, a product no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

ii. European Union Drug Marketing

Much like the Anti-Kickback Statute prohibition in the U.S., the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of

medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians to induce or reward improper performance generally is typically governed by the national anti-bribery laws of European Union Member States, and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the

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practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are

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provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

iii. European Union Drug Review and Approval

In the EU, medicinal products can only be commercialized after obtaining a marketing authorization ("MA"). There are two types of MAs.

Centralized MAs, which are issued by the EC through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP") of the EMA, are valid throughout the EU, and in the

additional Member States (Iceland, Liechtenstein and Norway) of the EEA. European Economic Area ("EEA"). The centralized procedure is mandatory for certain types of products, such as medicinal products produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (i.e., gene therapy, somatic cell therapy or tissue engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

National MAs, which are issued by the competent authorities of the EU Member States and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU Member State, this national MA can be recognized in another Member State through the mutual recognition procedure. If the product has not received a national MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the reference Member State ("RMS"). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics ("SmPC"), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the EU Member States make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

A paediatric-use marketing authorization ("PUMA") is available for medicines which are already authorized, no longer covered by an SPC or patent that qualifies as an SPC and which are to be exclusively development for use in children. A PUMA is a dedicated MA covering the indication and formulation of a medicinal product developed exclusively for use in the paediatric population, where such development has been in accordance with an approved PIP. There are various incentives to apply for a PUMA, including access to the centralized procedure even where the product would otherwise fall outside the mandatory scope of this procedure.

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iv. European Union Data and Market Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity, if granted, prevents applicants for authorization of generics or biosimilars of these innovative products from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU, during a period of eight years from the date on which the reference product was first authorized in the EU. During an additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be placed on the EU market until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if

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such company obtained an MA based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

v. European Union Orphan Designation and Exclusivity

In the EU, after a recommendation from the EMA's Committee for Orphan Medicinal Products ("COMP"), the European Commission may grant orphan designation to a product if (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) it is unlikely that the product, without the benefits derived from orphan status, would generate sufficient return in the EU to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU or, if a method exists, the product would be a significant benefit to those affected by that condition.

In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following medicinal product approval during which time no "similar

medicinal product" may be placed on the market. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. This period may be reduced to six years if the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable so as not to justify maintenance of market exclusivity. Orphan designation must be requested before submitting an application for marketing approval. We will be required to apply for the maintenance of the orphan designation granted to apitegromab for the treatment of SMA at the time of applying for an MA. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The aforementioned EU rules are generally applicable in the European Economic Area, ("EEA"), which consists EEA.

vi. Reform of the Regulatory Framework in the European Union

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU Member States, plus Norway, Liechtenstein for all medicines (including those for rare diseases and Iceland. for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval. In October 2023, the European Parliament published draft reports proposing amendments to the legislative proposals, which will be debated by the European Parliament. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into EU law.

vii. European General Data Protection Regulation

Since we conduct clinical trials in the EEA, we are subject to additional European data privacy laws. The General Data Protection Regulation, (EU) 2016/679 ("GDPR"), became effective on May 25, 2018, and deals with the processing of personal data and on the free movement of such data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal data (such as health and other sensitive data,) relating to identifiable individuals and transferring such information outside the EEA, including to the U.S., providing details to those individuals regarding the processing of their personal information, keeping personal information secure, obtaining consent of the individuals to whom the personal data relates, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total

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worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses, 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. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials

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and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. Compliance with the GDPR will be 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.

National laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. 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. The UK has announced plans to reform the country's data protection legal framework in its Data Reform Bill, but these have been put on hold. 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. Although the UK is regarded as a third country under the EU's GDPR, the EC has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

In the event we continue to conduct clinical trials in the EEA, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the U.S., in compliance with European data protection laws. In the past, companies in the U.S. were able to rely upon the EU-U.S. Privacy Shield framework to legitimize data transfers from the EU the U.S. In July 2020, the Court of Justice of the European Union ("CJEU") in Case C-311/18 (Data Protection Commissioner v Facebook Ireland and Maximillian Schrems ["Schrems II"]) invalidated the EU-U.S. Privacy Shield on the grounds that the Privacy Shield failed to offer adequate protections to EU personal data transferred to the U.S. The CJEU, in the same decision, deemed that the Standard Contractual Clauses ("SCCs") published by the European Commission ("EC") are valid. However, the CJEU ruled that transfers made pursuant to the SCCs need to be assessed on a case-by-case basis to ensure the law in the recipient country provides "essentially equivalent" protections to safeguard the transferred personal data as the EU, and required businesses to adopt supplementary measures if such standard is not met. Subsequent guidance published by the European Data Protection Board in June 2021 described what such supplementary measures must be, and stated that businesses should avoid or cease transfers of personal data if, in the absence of supplementary measures, equivalent protections cannot be afforded. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. The UK is not subject to the EC's new standard contractual clauses but has published a draft version of a UK-specific transfer mechanism, which, once finalized, will enable transfers from the UK. We will be required to implement these new safeguards when conducting restricted data transfers under the EU and UK GDPR and doing so will require significant effort and cost. On March 25, 2022, the EC and the U.S. announced to have reached a political agreement on a new "Trans-Atlantic Data Privacy Framework", which will replace the invalidated Privacy Shield and on December 13, 2022, the EC published a draft adequacy decision on the Trans-Atlantic Data Privacy Framework.

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We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too

burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

c. Regulation in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU, commonly referred to as Brexit, and the UK formally left the EU on January 31, 2020. There was a transition period during which EU pharmaceutical laws continued to apply to the UK, which expired on December 31, 2020. However, the EU and the UK have concluded a trade and cooperation agreement ("TCA"), which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At

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present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply currently still applies in Northern Ireland). The regulatory regime in Great Britain therefore currently aligns in many respects with EU regulations, however it is possible that these regimes will diverge in the future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. Notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under a new international recognition procedure which was put in place by the Medicines and Healthcare products Regulatory Agency ("MHRA"), the UK medicines regulator, on January 1, 2024, the MHRA may take into account decisions on the approval of an MA from the EMA (and certain other regulators) when considering an application for a Great Britain MA.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide MA will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint

Committee on March 24, 2023, so the UK government and the EU will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

i. Clinical Trials

The UK has implemented the now repealed Clinical Trials Directive 2001/20/EC into national law through the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). The extent to which However, the regulation MHRA published details of clinical trials in the UK will mirror the new Clinical Trials Regulation that has now come into effect is not yet known, however the Medicines and Healthcare products Regulatory Agency ("MHRA"), the UK medicines regulator, opened a consultation on a set of its legislative proposals designed to improve and strengthen the UK clinical trials legislation. Such legislation on March 21, 2023. The legislative proposals were published in response to a consultation which ran from January 17, 2022 until March 14, 2022, and the . The MHRA is currently analyzing feedback. will now work with lawyers to draft such new legislation.

ii. Orphan Designation

Since January 1, 2021, a separate process for orphan drug designation to the EU process has been applied to Great Britain. There is now no pre-marketing authorization orphan designation (as there is in the EU) in Great Britain and the application for orphan designation will be reviewed by the MHRA at the time of an application for a UK or Great Britain MA. The criteria for orphan designation remain the same as in the EU, except that they apply to Great Britain only (e.g., there must be no satisfactory method of diagnosis, prevention or treatment of the condition in Great Britain, as opposed to the EU).

d. Rest of the World Regulation

For other countries outside of the UK, the EU and the U.S., such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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e. Additional Laws and Regulations Governing International Operations

If we further expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The U.S. Securities and Exchange Commission ("SEC") also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Coverage and Reimbursement

XIII. Coverage and Reimbursement

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within the U.S. Department of Health and Human Services. 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.

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 product is (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition.

In the U.S. no uniform policy of coverage and reimbursement for drugs or biological products exists, and one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will make a similar determination. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products candidates, if approved, will be made on a payor by payor basis. The level of 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. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products candidates, if approved, will be made on a payor by payor basis. The coverage determination process may be a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. In order to secure coverage and reimbursement for any product

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that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs.

A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. The containment of healthcare costs has become a priority of federal, state and foreign governments and payors, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products.

Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory

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approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product future, which could reduce affect physician usage and patient demand for the product and also have a material adverse effect on sales. demand.

Additional federal programs apply to pharmaceutical companies that affect coverage and reimbursement for drug products. For example, the Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. 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 most branded prescription drugs from 15.1% of average manufacturer price ("AMP") to 23.1% of AMP 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, creating a new method by which rebates owed by are calculated for drugs that are inhaled, infused, instilled, implanted or injected, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA") established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, coverage. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. class must be included. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may

increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to

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receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which 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.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low priced and high priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical

products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries.

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XIV. Human Capital

Our employees are relentlessly focused on the discovery and development of innovative medicines in which signaling by protein growth factors plays a fundamental role. Our people are our most important asset, embodying our values such as discovering the joy in science, in collaboration and in making a difference in the lives of patients, families and our communities. We are guided by our core values to create a collaborative, flexible, agile, empowering, and silo-free culture so that we can move with speed and urgency to deliver high-impact medicines to patients with devastating diseases.

Employees. a. Employees

As of March 1, 2023 March 1, 2024, we had 114 150 full-time employees, of which 83 111 employees are engaged in research and development activities and 31 39 are engaged in general and administrative activities. All of our employees are based in the U.S. and a majority are based in Massachusetts. In May 2022, we experienced a reduction in workforce in which 39 positions were impacted. After the reduction in 2022, we continued to make targeted hires to enhance our capabilities. The new employees were hired to support a variety of functions and key initiatives, including strengthening our clinical development, with hires in various areas of clinical development and operations. We anticipate continuing to add depth and new capabilities in key areas of our business. None of our employees is represented by a labor union or covered by a collective bargaining agreement, and we believe our relationship with our employees is good.

b. Career Development and Growth. Growth

We emphasize employee development and training. To empower employees to unleash their potential individually and as a team, we invest in our employees by providing development opportunities, and the necessary resources to support their success, including coaching, management and leadership training, presentation workshops and paid conference attendance. The diversity of our employees and their skillsets also offers a unique opportunity for us to learn from each other’s experiences.

c. Compensation and Benefits.

Our competitive compensation programs are designed to align the compensation of our employees with our performance and to provide the proper incentives to attract, retain and motivate employees to achieve superior results. The structure of our compensation programs balances incentive earnings for both short-term and long-term performance. We provide employee salaries that are competitive within our industry based on position,

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skill level, experience and knowledge. Additionally, we offer equity to each of our employees to align the interests of our employees with the company's mission.

We are committed to providing comprehensive benefit options and it is our intention to offer benefits that will allow our employees and their families to live healthier and more secure lives. Some examples of the benefits we offer are: medical insurance including prescription drug benefits, dental insurance, vision insurance, accident insurance, life insurance, disability insurance, health savings accounts, flexible spending accounts, wellness programs, access to mental health support and benefits, identity theft insurance and pet insurance.

d. Employee Engagement.

We routinely conduct confidential employee engagement surveys to obtain feedback on a variety of topics, including culture, values, diversity, equity and inclusion, career development, employee satisfaction and tenure, and execution of our company strategy. These survey results are reviewed by our executive team so that we can continue to continue to increase employee satisfaction and improve the well-being of our employees. We value and encourage fostering mechanisms and opportunities for two-way dialogue. We actively strive to operationalize feedback provided by employees in ways that align with our business and culture. We are also committed to communication and transparency, using multiple forums and channels to allow for the sharing of appropriate, timely information to all employees.

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e. Health & Safety.

Ensuring the safety and wellbeing of our employees and communities is of the utmost importance to us, particularly in light of COVID-19. following the COVID-19 pandemic. What we have seen as a result of the pandemic is that flexibility is top of mind and a key consideration. At the start of the pandemic, we immediately formed a task force We continue to keep up to date on federal, state and local mandates as well as the evolving science and communicate with our employees on a regular basis. We've offered offer daily onsite testing and masks at no cost to our employees and visitors and when necessary, conduct internal contract contact tracing.

The need to shift provide the flexibility to working work from home has refocused our work model. We've helped employees set up home offices, provided them access to tools to perform their jobs remotely, provided ergonomic assessments of their working environments, and helped them address IT connectivity. We've also found ways to continue to foster collaboration and community through events like virtual trivia nights, scavenger hunts, coffee chats, charitable giving and lunch-n-learns, that we would normally do in person.

f. Diversity, Equity & Inclusion ("D DE&I"):

We believe that fostering diversity, equity and inclusion is a business imperative which supports and encourages individuals to show up as their whole selves. Investing in meaningful D DE&I work enhances culture and employee experience. We are committed to creating and maintaining a diverse, equitable, inclusive, and safe work environment. As we grow and mature, we look forward to establishing programs that infuse D DE&I within the business, identify barriers that impact recruitment, development, and retention of underrepresented employees, identify educational content, communicate the value and impact of D DE&I on goals and objectives, all while continuing to focus on hiring diverse talent at all levels of the company. Our ability to innovate and meet people's needs is strongest when all voices are heard and valued.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus, or COVID-19, as a pandemic (the "COVID-19 pandemic"). The ultimate extent of the impact of the COVID-19 pandemic or any other epidemic, pandemic, outbreak, or public health crisis on our business, financial condition and results of operations will depend on future developments, including new information that may emerge concerning the severity of such epidemic, pandemic, outbreak, or public health crisis and actions taken to contain or prevent the further spread, including the development of new variants of COVID-19 and development and deployment of vaccines to effectively treat COVID-19 and any new variants. The COVID-19 pandemic has negatively impacted our business, and at various times during the COVID-19 pandemic, we have experienced disruptions or restrictions on our preclinical studies, our ability to access and monitor certain clinical trial sites, restrictions on clinical trial participants' ability to access our clinical trial sites and delays in enrollment. Some clinical trial participants have missed or experienced delays in receiving doses of study drug and completing their clinical trial assessments. While our laboratory operations have resumed to normal capacity, we may continue to experience challenges in procuring materials and supplies, as well as research services from our vendors

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in a consistently timely manner due to COVID-19 related supply chain issues. We continue to monitor developments as we adjust to the disruptions and uncertainties relating to the COVID-19 pandemic.

Facilities

Our corporate headquarters and operations are located in Cambridge, Massachusetts.

In March 2015, we entered into a lease of laboratory and office space at 620 Memorial Drive in Cambridge, Massachusetts. Our amended lease expires expired in September 2023 and we have an option to extend the lease term for five additional years. 2023. In October 2020, we entered into a Sublease agreement with Orna Therapeutics, Inc. to lease this space for the period February 1, 2021 through August 31, 2023, unless terminated earlier. .

In November 2019, we entered into a lease of laboratory and office space at 301 Binney Street in Cambridge, Massachusetts and in 2021 we relocated our corporate headquarters to be used as our new corporate headquarters. this location. The expiration date is in August 2025 and we have the option to extend the term by two years. We relocated our headquarters to 301 Binney Street in 2021.

We believe that our facilities at 301 Binney Street are adequate to meet our current needs, and that suitable additional space will be available as and when needed.

XVL. Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any material legal proceedings.

XVIL. Website Access to Reports

We are subject to the informational requirements of the Exchange Act and are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. We also maintain a website at http://www.scholarrock.com. You may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information that is posted on or is accessible through our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered part of this or any other report that we file with or furnish to the SEC.

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Item 1A. Risk Factors

Careful consideration should be given to the following risk factors, together with all other information set forth in this Annual Report on Form 10-K ("Annual Report"), including our consolidated financial statements and related notes, and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in other documents that we file with the Securities and Exchange Commission (the "SEC"), in evaluating Scholar Rock Holding Corporation and our subsidiaries (collectively, the "Company", "we", or "our") and our business, before investing in our common stock. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The market price of our common stock could decline if one or more of these risks or uncertainties were to occur, which may cause you to lose all or part of the money you paid to buy our common stock. The risk factors described below disclose both material and other risks, and 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 and results of operations. Certain statements below are forward-looking statements. See "Special Note Regarding Forward-Looking Statements" in this Annual Report.

Summary of the Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled "Risk Factors." These risks include, but are not limited to, the following:

Risks Related to Product Development, Regulatory Approval and Commercialization

- Product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of apitegromab, SRK-181, SRK-439, or any future product candidates. Many of the factors that cause, or lead to, a delay in the initiation or completion of clinical trials may also ultimately lead to the denial of regulatory approval or limit market acceptance of our product candidates.
- Our business may be materially and adversely affected by pandemics such as the ongoing COVID-19 pandemic. The COVID-19 pandemic, and the resulting worker shortage, have had, and will likely continue to have, an impact on our business and operations, including clinical trial data and activities.
- The results of preclinical studies and early-stage clinical trials may not be predictive of future results. Success of a product candidate in an early-stage clinical trial may not be replicated in later-stage clinical trials.

- Interim, initial and preliminary results from our clinical trials that we announce or publish from time to time may change (e.g. from positive safety or efficacy results to poor or negative safety or efficacy results) as more patient data become available and are subject to additional audit, validation and verification procedures that could result in material changes in the final data.
- The data from our clinical trials, including from any future clinical trials conducted by us or any of our collaborators, may reveal significant adverse events not seen in our preclinical studies or earlier clinical trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- We rely on third parties to conduct our clinical trials and to conduct certain aspects of our preclinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with legal and regulatory requirements, we may be delayed or unable to receive regulatory approval of or commercialize apitegromab, SRK-181, SRK-439 or any potential future product candidates, and our business could be materially harmed.
- We have never commercialized a product and will need to build and scale our business for potential commercialization of apitegromab, including building our compliance, medical affairs and commercial organizations, which, if we are not able to do so successfully could negatively impact our business, including the potential for a successful commercialization of apitegromab.

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- The regulatory approval process for our product candidates in the U.S., EU UK and other jurisdictions will be lengthy, time-consuming and inherently unpredictable and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.
- The FDA, EMA or regulatory authorities in other jurisdictions may disagree with our development plans and we may fail to receive or be delayed in receiving regulatory approval of our apitegromab, SRK-181, SRK-439 and future product candidates.

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- We have received Orphan Drug designation from the FDA for apitegromab for the treatment of SMA and the EC granted Orphan Medicinal Product designation to apitegromab for the treatment of SMA. We may seek Orphan Drug designation from regulatory authorities in other jurisdictions for apitegromab and Orphan Drug designation from the FDA, EC or regulatory authorities in other jurisdictions for our future other product candidates. In any of these instances, we may not receive the requested designation or we may be unable to realize the benefits associated with Orphan Drug designation, including the potential for market exclusivity.

- Preclinical development is uncertain. Our preclinical programs, such as SRK-439, may experience delays or may never advance to clinical trials, which would adversely affect our ability to develop our product pipeline and receive regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

Risks Related to Manufacturing Our Business and Supply Operations

- Because we rely on a limited number of third-party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials, and, if approved, commercial materials, may become limited or interrupted or may not be of satisfactory quantity or quality.

Risks Related to Our Business and Operations

- Our restructuring reliance on third parties, such as manufacturers, may subject us to risks relating to manufacturing scale-up and the associated workforce reduction announced in May 2022 may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business. cause us to undertake substantial obligations, including financial obligations.

- We will need to continue to grow our organization in certain areas, including our personnel, systems and relationships with third parties, in order to develop our drug candidates. candidates and we may experience difficulties in managing this growth.

- Our executives and highly skilled technical and managerial personnel are critical to our business. If we have transition in management, lose key personnel, or if we fail to recruit additional highly skilled personnel, our ability to further develop apitegromab, SRK-181, SRK-439 and identify and develop new or next generation product candidates may be impaired.

- Failure by us or any of our employees, independent contractors, consultants, commercial partners or vendors to comply with applicable health care privacy and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our business operation results and operations. business.

Risks Related to Intellectual Property

- Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

- We depend Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Third-party claims of intellectual property licensed from third parties. Failure to comply with infringement may prevent or delay our obligations under any of these licenses or termination of any of these licenses could result in the loss of significant rights, which would harm our business. product discovery, development, and commercialization efforts.

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Risks Related to Our Financial Condition and Capital Requirements

- We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.
- We will require additional capital to fund our operations and if we fail to obtain necessary capital, we will not be able to complete the development and commercialization of apitegromab, SRK-181, SRK-439 and any future product candidates.

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Risks Related to Our Common Stock

- Our The price of our stock price is volatile, and various factors you could make our stock less attractive to investors. lose all or part of your investment.

Risks Related to Product Development, and Regulatory Approval and Commercialization

Product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of apitegromab, SRK-181, SRK-439, or any future product candidates. Many of the factors that cause, or lead to, a delay in the initiation or completion of clinical trials may also ultimately lead to the denial of regulatory approval or limit market acceptance of our product candidates.

To receive the requisite Before obtaining regulatory approvals to commercialize for the commercial sale of any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing development is expensive and can take many years to complete, and its outcome is inherently uncertain. uncertain, a clinical trial can fail at any stage of development. We may experience delays in initiating, progressing or completing our clinical trials. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful,

and a clinical trial can meaningful. Clinical trials may fail at any stage of testing. to meet their primary or secondary endpoints, raise safety concerns or generate mixed results. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Clinical data are often susceptible may not be sufficient to varying interpretations apply for and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to receive marketing obtain regulatory approval on the timelines we expect or at all. Other decisions or actions of their products. regulatory agencies may affect our plans, progress or results.

Successful completion of clinical trials is a prerequisite to submitting a Biologics License Application ("BLA") to the FDA, a Marketing Authorisation Application ("MAA") to the EMA, MHRA, and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

We may experience delays in initiating, progressing or completing our clinical trials. We also may experience numerous unforeseen events during, or as a result of, any clinical trials in process or any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize apitegromab, SRK-181, SRK-439, or any future product candidates, including:

- delay or inability to reach agreement with the FDA or comparable foreign regulatory authorities on acceptable clinical trial design, conduct or statistical analysis plan;
- any orders from local, state or federal governments or clinical trial site policies resulting from the COVID-19 pandemic or similar event that determine essential and non-essential functions and staff, which may impact the ability of site staff to conduct assessments, or result in delays to the conduct of the assessments, as part of our clinical trial protocols, or the ability to enter assessment results into clinical trial databases in a timely manner;
- regulators, Institutional Review Boards ("IRBs") or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

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- failure by our collaborators to provide us with an adequate and timely supply of product that complies with the applicable quality and regulatory requirements for a combination trial;

- collaborators may provide insufficient funding for a clinical trial program, delay or stop a clinical trial, abandon a product candidate or clinical trial program, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- clinical trials of any product candidates may fail to show safety and effectiveness, or produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower or more challenging than we anticipate or subjects may drop out of these clinical trials or fail to return for post treatment follow-up at a higher rate than we anticipate;
- challenges in identifying or recruiting sufficient study sites or investigators for clinical trials;

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- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- clinical study sites or clinical investigators may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- limitations on our or our CROs' ability to access and verify clinical trial data captured at clinical study sites through monitoring and source document verification;
- the cost of clinical trials of a product candidate may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials, or reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;
- our product candidates may have undesirable side effects or other unexpected characteristics when used in a new disease indication or with products in a different class which may raise safety, efficacy or other concerns about our product candidate as a potential therapy in that new disease indication or other indications or its use with products in a different class;

- our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate and/or data emerging from other molecules in the same class as our product candidate;

- the FDA, EMA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or change or impose other requirements before permitting us to initiate a clinical trial;

- evolution in the standard of care or changes in applicable governmental regulations or policies during the development of a product candidate that require amendments to ongoing clinical trials and/or the conduct of additional preclinical studies or clinical trials; and

- lack of adequate funding to complete a clinical trial.

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We could also encounter delays if a clinical trial is placed on clinical hold, suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA, the competent authorities and/or ethics committees of the EU Member States or other regulatory authorities, if a clinical trial is recommended for suspension or termination by the data safety monitoring board ("DSMB") or equivalent body for such trial, or on account of changes to federal, state, or local laws. A suspension or termination may be imposed 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, EMA, competent authorities and/or ethics committees of the EU Member States or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Many of the factors that cause, or lead to, a delay in the commencement initiation or completion of clinical trials may also ultimately lead to the denial of regulatory approval or limit market acceptance of our product candidates. Further, the FDA, EMA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. For example, we anticipate some of our future trials to, in part, utilize an open-label trial design, and our ongoing Phase 1 DRAGON clinical trial for SRK-181 in cancer immunotherapy and our ongoing ONYX long-term extension phase of the Phase 2 TOPAZ clinical trial study for apitegromab in Type 2 patients from both the TOPAZ and Type 3 SMA, in part, SAPPHIRE trials, utilize an open-label trial design. An open-label trial is one where both the patient and investigator know whether the patient is receiving the test article or either an existing approved drug or placebo. Open-label trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label studies are aware that they are receiving treatment. Open-label trials may be subject to a patient bias, for example, if

patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Open-label trials also 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. The potential sources of bias in clinical trials as a result of open-label design may not be adequately mitigated and may cause any of our trials that utilize

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such design to fail and additional trials may be necessary to support future marketing applications. In addition, other types of trials (including randomized, double-blind, parallel arm studies), particularly if smaller in size or if limited to one study, are also subject to potential sources of bias and limitations that may exaggerate any therapeutic effect or falsely identify a positive efficacy signal**,** or conversely, fail to detect an efficacy signal when in fact there may actually be a positive therapeutic effect. Further, Furthermore, we are conducting clinical trials with apitegromab in SMA, but by using apitegromab in a Phase 2 obesity clinical trial, we may become aware of safety information associated with apitegromab that we did not observe when we used apitegromab in our clinical trials in SMA. We, the FDA, EMA the competent authorities and/or ethics committees of the EU Member States or other applicable regulatory authorities for their jurisdictions, or an IRB for their site(s) may change the requirements suspend clinical trials of a product candidate at any time for approval even after they have reviewed and commented on the design for our clinical trials. The unpredictability caused by turnover at the FDA, EMA various reasons, including a belief that subjects or other regulatory authorities could increase the risk of patients in such change in the requirements for approval, which could impact our ability trials are being exposed to receive approval, unacceptable health risks or could otherwise delay our clinical development programs and harm our business, financial condition and results of operations. adverse side effects.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. 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. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

Our business may be materially and adversely affected by public health pandemics, epidemics or an outbreak of an infectious disease such as the ongoing COVID-19 pandemic. The COVID-19 pandemic, and the resulting worker shortage, have had, and will likely continue to have, an adverse impact on our business and operations.

The consequences of the COVID-19 pandemic continue to have an impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services have changed significantly. In response to the COVID-19 pandemic, many of our employees continue to work remotely outside of our offices. Additionally, while our laboratory

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operations resumed to normal capacity, we may continue to experience challenges in procuring materials and supplies in a consistently timely manner due to global supply chain issues with third parties.

The pandemic and policies and regulations implemented by governments in response to the pandemic, most of which have been lifted, have had a significant impact, both direct and indirect, on businesses and commerce. Our clinical trials have been affected by the COVID-19 pandemic and many sites instituted policies regarding operations at various times during the COVID-19 pandemic. Even as many clinical trial sites have removed restrictions implemented during the COVID-19 pandemic, they have continued to experience site study staff shortages and turnover, which have resulted in delays. Some factors from the COVID-19 pandemic that could adversely affect enrollment in, as well as initiation, conduct, progress, continuation and completion of our clinical trials include:

- the worker shortage that commenced during the COVID-19 pandemic significantly impacted, and will likely continue to impact, many of the clinical trial sites that we work with for our clinical trials, which has resulted in longer than anticipated contracting, review and site initiation processes for our clinical trials;

- the continued impact from COVID-19 on healthcare providers, patients and personnel, which may vary considerably from jurisdiction to jurisdiction, as well as on local restrictions and practices, including the complexities of having to understand and navigate multiple sets of protocols and the accessibility and rates of vaccinations, and effectiveness of vaccinations in various geographies;

- limitations on travel, quarantine requirements and facility access restrictions that interrupt key trial activities, such as clinical trial site initiations, our ability and the ability of our CROs to access and monitor clinical trial sites, and new clinical trial site policies resulting from the COVID-19 pandemic that determine essential and non-essential functions and staff, which may impact the ability of site staff to conduct assessments, or result in delays to the conduct of the assessments, as part of our clinical trial protocols, or the ability to enter assessment results into clinical trial databases in a timely manner, or that limit the ability of a patient to participate in a clinical trial or delay access to product candidate dosing or assessments;

- patients may have to limit participation in our clinical trials, including missing certain scheduled doses of the investigational product and the skipping or delays in investigational product dosing or assessments as part of a clinical trial that could adversely affect clinical trial data readouts, including efficacy and safety results;

- skipping or delays in the administration of therapies of patients in a clinical trial, such as SMN therapy for SMA or anti-PD-(L)1 therapy for cancer, or other background care that could adversely affect clinical trial data readouts, including efficacy and safety results; and

- interruption in supply of materials necessary for our clinical trials, including delays in global shipping affecting the transport of clinical trial materials used in our trials.

Disruptions and delays resulting from the COVID-19 pandemic could result in additional impacts on our ongoing, as well as future, clinical trials, including delays in or adverse impacts to data readouts (e.g. poor or negative efficacy results, adverse safety signal, reduced amounts of data available or data confounding) from our clinical trials and delays in our ability to identify and enroll patients in current or future clinical trials. The COVID-19 pandemic could result in slower than anticipated enrollment in our Phase 3 SAPPHIRE pivotal clinical trial of apitegromab or Part B of our Phase 1 DRAGON clinical trial of SRK-181, lead to a negative or poor result in these clinical trials, including potential delay or rejection of any product approval by regulatory authorities or the requirement for additional clinical trial(s) beyond the currently planned program (e.g., if the amount of data from our Phase 3 SAPPHIRE clinical trial is deemed by regulatory authorities as insufficient or confounded due to COVID-19 impacts), or other adverse outcomes.

In addition, if a patient participating in one of our clinical trials contracts COVID-19 (which may occur without detection or diagnosis), this could negatively impact the data readouts from these trials; for example, the patient may be unable to participate further (or may have to limit participation) in our clinical trial, the patient may show a different efficacy assessment than if the patient had not been infected, or such patient could experience an adverse event that could be attributed to our drug product. If a patient participating in any of our clinical trials receives COVID-19

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vaccination, it is unknown whether or how the vaccination may impact the data readouts from our clinical trial, such as efficacy and safety.

The extent to which the COVID-19 pandemic, and any associated worker shortages, continues to impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted. The COVID-19 pandemic continues to evolve and the conduct of our trials may be adversely affected, despite efforts to mitigate this impact. Other global health concerns could also result in

social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

Our clinical development strategy depends on the continued use and availability of certain third-party approved drug therapies.

Apitegromab and SRK-181 are our two clinical-stage product candidates. Patients in our Phase 3 SAPPHIRE clinical trial, and certain ONYX, our long-term extension study for patients remaining in from both the open-label extension portion of our Phase 2 TOPAZ clinical trial and SAPPHIRE studies, are receiving apitegromab in conjunction with an approved SMN therapy. These patients are reliant on the continued use and availability of such therapies. If access to an approved SMN therapy such as nusinersen or risdiplam becomes limited or is unavailable, we may be forced to pause or stop our TOPAZ SAPPHIRE or ONYX long-term extension or SAPPHIRE trials, or the medical condition of patients may be affected which could negatively affect the efficacy and safety results for apitegromab in the trial trials or reduce the amount of data or confound the data from these trials. We plan to initiate a Phase 2 proof-of-concept trial of apitegromab in combination with approved GLP-1 RA in obesity. This study will rely upon the continued availability of such GLP-1 RA. Access to approved GLP-1 RAs are limited for use in clinical trials and may continue to be limited for such use. If GLP-1 RAs become more limited or unavailable, we may be unable to enroll, or may be delayed in enrolling patients, or may be forced to stop our Phase 2 study. While we have obtained substantial supply of an approved GLP-1 RA for use in this trial. We have also initiated Phase 2 study, we cannot assure you that we will be able to obtain adequate supply for future studies of our product candidate in obesity. Patients in Part B of the our ongoing Phase 1 DRAGON clinical trial of SRK-181 in patients with locally advanced or metastatic solid tumors that exhibit resistance to anti-PD-(L)1 antibody therapies. Patients in this clinical trial therapies are receiving SRK-181 in conjunction with an approved anti-PD-(L)1 therapy such as pembrolizumab. If access to the approved anti-PD-(L)1 therapy becomes limited or is unavailable, we may not be able to enroll, or may be delayed in enrolling patients or may be forced to pause or stop our Phase 1 DRAGON clinical trial, or the medical condition of patients may be affected which could negatively affect the efficacy and safety results for SRK-181 in the trial. Any delay or suspension of our clinical trials would significantly and adversely affect delay our clinical development programs and harm our business, prospects. financial condition and results of operations.

The results or success of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of future results. Success of a product candidate in an early-stage clinical trial may not be results or replicated in later-stage trials. later preclinical studies or clinical trials of our product candidates in the same indications or other indications.

The results or success of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the future results of future, or replicated in later preclinical studies or later-stage clinical trials. Preclinical studies and early-stage clinical trials are primarily designed to study PK and PD, understand the side effects of product candidates, and evaluate various doses and dosing schedules. Our current or future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later-stages of clinical trials may fail to show desired pharmacological properties or produce positive safety and efficacy results despite having progressed through

preclinical studies and early-stage clinical trials. We completed a Phase 1 clinical trial for apitegromab in healthy adult volunteers and we completed the treatment period of our Phase 2 TOPAZ clinical trial for the treatment of patients with Type 2 and Type 3 SMA. In April 2021, June 2023, we announced positive twelve-month top-line results data from the Phase 2 TOPAZ clinical trial and from June 2021 to June 2022, we announced supportive data from additional exploratory analyses at various medical congresses. In June 2022, we announced 24-month efficacy and safety extension data of apitegromab in patients with Type 2 and Type 3 SMA from the Phase 2 TOPAZ clinical trial, and presented at the Cure SMA Research & Clinical Care Meeting. In October 2022, we announced positive new quality of life data from our Phase 2 TOPAZ trial extension period evaluating patient outcomes after 24 at 36 months of treatment. treatment with apitegromab. These data show that continued treatment with apitegromab over the extended period was associated with substantial and sustained improvement in motor function, and patient-reported outcomes in patients with nonambulatory Types 2 and 3 SMA receiving SMN therapy. Results on safety, efficacy and patient-reported outcomes such as fatigue, mobility and activities of daily living from TOPAZ were presented at the 2023 Cure SMA Research & Clinical Care Meeting. In January 2022, we initiated our Phase 3 SAPPHIRE clinical trial of apitegromab for the treatment of patients with Type 2 and Type 3 SMA. In November 2021 SMA and November 2022, in September 2023, we presented interim clinical announced completion of trial enrollment. We expect the top-line data from Part A, as well as Part B in November 2022, of our Phase 1 DRAGON readout for the SAPPHIRE trial in cancer immunotherapy, at the Society for Immunotherapy fourth quarter of Cancer's Annual Meeting. 2024. We also announced in October 2023 our plans to expand into cardiometabolic disorders based on preclinical data with SRK-439, and our intent to initiate a Phase 2 proof-of-concept trial of apitegromab in combination with a GLP-1 receptor agonist in obesity in mid-2024 with data readout expected in mid-2025. We cannot assure you that the Phase 3 SAPPHIRE clinical trial the Phase 1 DRAGON trial or any other future clinical trials of SRK-181 apitegromab, such as our planned Phase 2 clinical trial in obesity, or apitegromab of SRK-439 will show positive results. Additionally, product candidates evaluated in one disease indication may interact in unforeseen or harmful ways in a patient population with a different disease indication than was previously studied. For example, we are evaluating apitegromab in SMA, and plan to initiate a Phase 2 clinical trial of apitegromab in obesity. Apitegromab may interact in unforeseen or different ways in the obesity population than in the SMA patient population. There can be no assurance that any of our current or planned clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There can also be no assurance that any of our future clinical trials will show similar results to our earlier clinical trials or support further development or registration of any of our product candidates. There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical

development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Interim, initial, or preliminary results from our clinical trials that we announce or publish from time to time may change (e.g. from positive safety or efficacy results to poor or negative safety or efficacy results) as more patient data become available and are subject to additional audit, validation and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, initial, or preliminary data, including interim top-line results or initial or preliminary results from our clinical trials. Any interim, initial or preliminary data and other results from our clinical trials may materially change as more patient data become available. Preliminary, initial, interim or top-line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim, initial or preliminary data we previously published. As a result, interim, initial or preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or considerations may qualify such results, once we have received and fully evaluated additional data. For example, we have presented preliminary and initial clinical data from Part A and Part B of our Phase 1 DRAGON trial in cancer immunotherapy, including preliminary safety and efficacy results, were presented at the European Society for SRK-181 Medical Oncology Targeted Anticancer Therapies Congress in March 2023. Safety, efficacy and biomarker data were presented in November 2023 at the SITC 38th Annual Meeting, and we will continue to present data from our Phase 1 DRAGON trial while the trial is ongoing and tumor ongoing. Tumor response data will be is based on assessments by site investigators. Central reads for the tumor responses are also being conducted, with a comprehensive review of the central reads to be performed once completed within and/or across the cohorts. Differences between preliminary, initial or interim data and final data could adversely affect our business.

The There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical development even after achieving promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Many drugs have failed to replicate efficacy and safety results in larger or more complex later stage trials. Moreover, preclinical and clinical data from our are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials including from any future nonetheless failed to obtain regulatory approval. If we fail to produce positive results in our ongoing and planned preclinical studies and clinical trials conducted by us in apitegromab, SRK-181, SRK-439 or any of our collaborators, may reveal significant adverse events if a regulatory authority interprets and analyzes the results as not seen in our preclinical studies or earlier clinical trials positive, the development timeline and may result in a safety profile or undesirable side effects that could inhibit or limit regulatory approval or market acceptance of any of our product candidates.

If significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the

trials or our development efforts of one or more product candidates altogether. Patients in our clinical trials may develop levels of anti-drug antibodies which could limit the potential efficacy of and commercialization prospects for our product candidates, or trigger hypersensitivity reactions or other adverse effects. We, the FDA, the competent authorities and/or ethics committees of the EU Member States or other applicable regulatory authorities for their jurisdictions, or an IRB for their site(s) and, correspondingly, our business and financial prospects, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. **be materially adversely affected.**

Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. The side effects could result in a number of potentially significant negative consequences, including:

- regulatory authorities may refuse to grant market approval to a product candidate or withdraw approvals of such product;
- we may suspend marketing of such product;
- regulatory authorities may require additional warnings on the label for such product;
- we may be required to develop a Risk Evaluation and Mitigation Strategy ("REMS") for such a product, or if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable foreign regulatory authority;
- we may be required to conduct additional post-market studies;
- we could be sued and held liable for harm caused to subjects or patients; or

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- our reputation may suffer.

Any of these developments could adversely affect our prospects for receiving or maintaining approval for our product candidates and/or inhibit market acceptance of any approved product and could materially harm our business, financial condition and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including due to the impacts of current macroeconomic and geopolitical events, including changing conditions from the COVID-

19 pandemic and the 2022 Russian invasion of Ukraine. reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the willingness or availability of patients to participate in our trials (including due to the COVID-19 pandemic); trials;
- the number and location of participating trial sites;
- the proximity of patients to trial sites and any limitations on travel or access to trial sites (including due to the COVID-19 pandemic); sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other therapies;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop-out of the trials before completion of their involvement in the study.

For example, we are initially developing apitegromab for the treatment of SMA, a rare disease, affecting an estimated 30,000 to 35,000 20,000 patients in the U.S. and Europe. As a result, we may encounter difficulties enrolling patients in our clinical trials for apitegromab due, in part, to the small size of this patient population. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, 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. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Additionally, patients may opt out of participation in clinical trials in favor of treatment with FDA-approved therapies, or therapies approved in the EU or other foreign jurisdictions.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

We rely on third parties to conduct our clinical trials and certain aspects of our preclinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with legal and regulatory requirements, we may be delayed or unable to receive regulatory approval of or commercialize apitegromab, SRK-181, SRK-439, or any future product candidates, and our business could be materially harmed.

We depend upon third parties to conduct certain aspects of our preclinical studies and to conduct our clinical trials, under agreements with universities, medical institutions, CROs, strategic partners and others. We often have to negotiate

budgets and contracts with such third parties, and if we are unsuccessful or if the negotiations take longer than anticipated, this could result in delays to our development timelines and increased costs.

We rely especially heavily on third parties over the course of our clinical trials, and, as a result, have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their individual employment policies or compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with Good Clinical Practice ("GCP") requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in civil monetary penalties, adverse publicity and civil and criminal sanctions. The FDA and

National Institutes of Health recently have signaled the government's willingness to begin enforcing these registration and reporting requirements against non-compliant clinical trial sponsors.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our preclinical studies and clinical trials. The third party CROs and clinical trial sites that conduct our clinical trials have experienced staffing shortages and the inability of a CRO or clinical trial site to maintain appropriate levels of competent staffing to support the demands of our clinical trials could negatively impact the execution of our clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines if they cannot perform their contractual duties or obligations due to the impacts of the COVID-19 pandemic on their operations or at the sites they are overseeing, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, receive regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be

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no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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We have never commercialized a product and will need to build and scale our business for potential commercialization of apitegromab, including building our compliance, medical affairs and commercial organizations, which, if we are not able to do so successfully could negatively impact our business, including the potential for a successful commercialization of apitegromab.

Although we are preparing our commercialization capabilities in anticipation of a potential approval and commercial launch of apitegromab, we have no prior sales or distribution experience and limited capabilities for marketing and market access. We expect to invest significant financial and management resources over time to establish these compliance, medical affairs and commercial organizations for the marketing, sales and distribution of apitegromab, if approved, and other capabilities and infrastructure to support commercial operations. If we are unable to establish these commercial capabilities and infrastructure in a timely manner or to enter into agreements with third parties to market, and sell, our product and/or any future products, distribute apitegromab if apitegromab is approved, we may be unable to complete a successful commercial launch. To the extent we enter into agreements with third parties, the revenue we receive may depend upon the efforts of such third parties, over which we may have limited or no control, and our revenue from product sales may be lower than if we had commercialized the products ourselves. We also face competition in our search for third parties to assist us with the distribution, sales and marketing of our products.

If approved, Furthermore, we intend to commercialize apitegromab globally. We intend to build the compliance, medical affairs and commercial organizations for the marketing, sales and distribution of apitegromab, globally, if approved. In order to commercialize apitegromab for the treatment of SMA, if approved, do so, we must build, on a territory-by-territory basis, marketing, sales, distribution, managerial and other capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so.

The regulatory approval process for our product candidates in the U.S., EU and other jurisdictions will be lengthy, time-consuming and inherently unpredictable and we may experience significant delays fail to receive or be delayed in the clinical development and receiving regulatory approval if any, of our apitegromab, SRK-181, SRK-439 and future product candidates.

The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, promotion and distribution of drug products, including biologics, are subject to extensive regulation by the FDA in the U.S. and other regulatory authorities outside the U.S. We are not permitted to market any biological product in the U.S. until we receive a biologics license from the FDA. We have not previously submitted a BLA to the FDA or similar marketing application to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. FDA approval of a new biologic or drug generally requires dispositive data from two (and in some

cases, one) adequate and well-controlled pivotal Phase 3 clinical trials of the biologic or drug in the relevant patient population. The FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, the results of our clinical trials may not meet the level of statistical significance or amount of data required for approval, we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks, or may disagree with our analysis or interpretation of data from preclinical studies or clinical trials. A BLA must also include significant information regarding the CMC chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection as well as certain key clinical sites conducting our clinical trials. The FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.

The FDA may seek independent advice from a panel of experts, referred to as an Advisory Committee, on complex or novel issues that may be presented in an application, including issues related to the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to receive approval of any product candidates that we develop based on the completed clinical trials.

Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions at which such trials are being conducted, or the FDA, the competent authorities and/or ethics committees of the EU Member States or other regulatory authorities, or recommended for suspension or termination by the DSMB for such trial, 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, EMA, competent authorities of the EU Member States or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or

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administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the prospects for regulatory approval and commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing any clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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The FDA, EMA or regulatory authorities in other jurisdictions may disagree with our development plans and we may fail to receive or be delayed in receiving regulatory approval of apitegromab, SRK-181 and future product candidates.

FDA approval of a new biologic or drug generally requires dispositive data from two (and in some cases, one) adequate and well-controlled pivotal Phase 3 clinical trials of the biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete.

The results of our clinical trials may not support approval. Our product candidates could fail to receive regulatory approval for many reasons, including the following, among other reasons:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance or adequacy in the robustness or amount of data required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to receive regulatory approval in the U.S. or elsewhere;
- the FDA, competent authorities of the EU Member States or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

If we believe the clinical trial data support doing so, we may seek to pursue BLA approval in the United States or marketing authorization in jurisdictions outside the United States for one or more of our product candidates based on results of interim analyses of our pivotal trials, rather than submitting such applications after the relevant pivotal trials have been completed. We cannot assure you that the FDA, EMA or other regulatory authorities will agree with this approach or that these regulatory authorities will find the results from a single

pivotal trial or of an interim analysis (such as that from a single pivotal trial or multiple trials) sufficient to meet the standards for approval or marketing authorization; and if they do not, the prospects for regulatory approval and commercialization of our product candidates may be delayed or harmed.

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We have received Orphan Drug designation from the FDA for apitegromab for the treatment of SMA and the EC granted Orphan Medicinal Product designation to apitegromab for the treatment of SMA. We may seek Orphan Drug designation from regulatory authorities in other jurisdictions for apitegromab and Orphan Drug designation from the FDA, EC or regulatory authorities in other jurisdictions for our future other product candidates. In any of these instances, we may not receive the requested designation or we may be unable to realize the benefits associated with Orphan Drug designation, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if, among other things, it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the EU, after a recommendation from the EMA's Committee for Orphan Medicinal Products ("COMP"), the EC grants orphan designation to promote the development of products that are (a) intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU, or (b) for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the medicinal product in the EU would generate sufficient return to justify the necessary investment in developing the medicinal product. Additionally, the orphan designation requires that there is no satisfactory method of diagnosis, prevention or treatment of the condition authorized for marketing in the EU, or, if such a method exists, the medicinal product must be of significant benefit to those affected by the condition. Any orphan designation that we are granted for our product candidates in the U.S. or in the EU would not assure orphan designation of those product candidates in any other jurisdiction. Orphan designation neither shortens the development time or regulatory review time of a product candidate, nor gives the product candidate any advantage in the regulatory review or approval process (other than as discussed below).

In the U.S., Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity for that indication. Orphan drug exclusivity means the FDA may not approve another application to market the same drug for the same indication for a period of seven years, except in limited

circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the EU, orphan designation entitles a party to scientific assistance regarding necessary tests and trials, financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following grant of marketing authorization for the medicinal product if the criteria for orphan designation continue to be met before the grant of the marketing authorization. This period may be reduced to six years if, at the end of the fifth year, it is determined that the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

We have received Orphan Drug designation from the FDA for apitegromab for the treatment of SMA, and following the EMA's COMP's positive opinion, the EC designated apitegromab as an orphan medicinal product for the treatment of SMA. Even if we receive orphan drug exclusivity, the benefit of that exclusivity may be limited if we seek approval for an indication broader than the orphan-designated indication or could be revoked under certain circumstances, for example if the FDA later determines that the request for designation was materially defective or that we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we receive orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition during the exclusivity period because different drugs with different active moieties can be approved for the same condition, and the same product can be approved for different uses. Also, in the U.S., even after an orphan drug is approved and receives orphan drug exclusivity, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug, including because it has been shown to be clinically superior to the drug with exclusivity because it is safer, more effective or makes a major contribution to patient care. In the EU, a marketing authorization may be granted to a similar medicinal product to an authorized orphan product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior; or

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- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product.
- See the sections of this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 entitled, "Business — Government Regulation — US Biological Product Development — Orphan Drug Designation" and "Business – Government Regulation – European Union Drug Development — European Union Orphan Designation and Exclusivity."

We have received Rare Pediatric Disease designation for apitegromab for the treatment of SMA. However, a marketing application for apitegromab, if approved, may not meet the eligibility criteria for a rare pediatric disease priority review voucher.

We have received Rare Pediatric Disease designation for apitegromab for the treatment of SMA. Designation of a biologic as a product for a rare pediatric disease does not guarantee that a BLA for such biologic will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), we will need to request a rare pediatric disease priority review voucher in our original BLA for apitegromab. The FDA may determine that a BLA for apitegromab, if approved, does not meet the eligibility criteria for a rare pediatric disease priority review voucher, including for the following reasons:

- SMA no longer meets the definition of a rare pediatric disease;

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- apitegromab contains an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in an application;
- the BLA is not deemed eligible for priority review;
- the BLA does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population; or
- the BLA seeks approval for a different adult indication than the rare pediatric disease for which apitegromab is designated.

The authority for the FDA to award rare pediatric disease priority review vouchers for biologics after September 30, 2024 is currently limited to biologics that receive Rare Pediatric Disease designation on or prior to September 30, 2024, and the FDA may only award rare pediatric disease priority review vouchers through September 30, 2026. If the BLA for apitegromab is not approved on or prior to September 30, 2026 for any reason, it will not be eligible for a priority review voucher. However, it is possible the authority for the FDA to award rare pediatric disease priority review vouchers will be further extended by Congress.

We have received Fast Track designation from the FDA and PRIME designation from the EMA for apitegromab for the treatment of SMA. We may seek Breakthrough Therapy designation, or Fast Track designation from the FDA, or Breakthrough Therapy designation or PRIME designation from the EMA for certain of our current and future product candidates, and we may not be successful in receiving such designations, or if received, such designation may not actually lead to a faster development or regulatory review or approval process.

We may seek Fast Track designation, Breakthrough Therapy designation or Fast Track designation or PRIME designation for certain of our product candidates.

A breakthrough therapy In May 2021, the FDA granted Fast Track designation for apitegromab for the treatment of SMA. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life threatening disease or condition, and preliminary clinical evidence indicates eligible for this designation, we cannot assure that the product 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 that have been designated as breakthrough therapies are eligible for more frequent interaction and communication between FDA would decide to grant it. Although the FDA and the sponsor, which can help has granted Fast Track designation for apitegromab in SMA, we may not experience a faster development process, review or approval compared to identify the most efficient path for clinical development. Products designated as breakthrough therapies by the conventional FDA procedures. The FDA may also be eligible for (but are not assured) rolling review, priority review, and/or accelerated approval. withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

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Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification and rescind the breakthrough designation.

If a product is intended See the sections of this Annual Report on Form 10-K for the treatment of a serious or life-threatening condition fiscal year ended December 31, 2023 entitled, “Business — Government Regulation — US Biological Product Development — Expedited Development and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for Fast Track designation. Products receiving a Fast Track designation are eligible for more frequent interaction and communication with FDA and rolling review. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development

process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In May 2021, the FDA granted Fast Track designation for apitegromab for the treatment of SMA. Review Programs."

In March 2021, the EMA granted PRIME designation to apitegromab for the treatment of SMA. PRIME or PRIority MEdicine, is a scheme provided by the EMA to enhance support for the development of medicines that target an unmet medical need. To qualify for PRIME, product candidates require early clinical evidence that the therapy has the potential to offer a major therapeutic advantage over existing treatments or benefit patients without treatment options. Among the benefits of PRIME are the appointment of a rapporteur to provide continuous support and help build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process. The receipt of PRIME designation for apitegromab for the treatment of SMA may not result in a faster development process, review or approval compared to products considered for approval under conventional regulatory agency procedures and does not assure ultimate approval by the EMA.

See the section of this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 entitled, "Business – Government Regulation – European Union Drug Development — European Union Expedited Review and Development."

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Receiving and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in receiving or maintaining regulatory approval of our product candidates in other jurisdictions.

Receiving and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to receive or maintain regulatory approval in any other jurisdiction, but a failure or delay in receiving regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. Even if the FDA grants marketing approval of a product candidate, the EC, the competent authorities of EU Member States or comparable regulatory authorities in foreign jurisdictions may not approve the manufacturing, marketing and promotion of the product candidate in other countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be

approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U.S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Receiving 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. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements, including requirements related to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, import, export, conduct of post-marketing studies and submission of safety, efficacy and other post-marketing information. In addition, we will be subject to continued compliance with current Good Manufacturing Practice ("cGMP") and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EU and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to periodic review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA or other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved uses for which the product may be marketed or contain requirements for potentially costly post-market testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication

plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or 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 trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- permanent injunctions and consent decrees, including the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for their approved indications and in a manner consistent with their FDA-approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of unapproved uses and a company that is found to have improperly promoted unapproved uses may be subject to significant liability.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. 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 face enforcement action and our business may be harmed.

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Even if a product candidate we develop receives marketing approval, it 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 apitegromab, SRK-181, SRK-439 or any future product candidate we develop receives marketing approval, whether as a single agent or in conjunction with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, doctors may deem it sufficient to treat patients with SMA with an SMN therapy such as nusinersen or risdiplam, and therefore will not be willing to utilize apitegromab in conjunction with such SMN therapy. If the product candidates we develop 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 any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the amount, scope and nature of the clinical data (and other forms of data) available;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

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Competing therapies may exist or could emerge that adversely affect the amount of revenue we are able to generate from the sale of apitegromab, if approved, or any of our future product candidates, if successfully developed and approved.

The biopharmaceutical industry is highly competitive. There are many public and private companies, universities, governmental agencies and other research organizations actively engaged in the research and development of products that may be similar to our product candidates or address similar markets. If we are successful in developing apitegromab, it is probable that the number of companies seeking to develop products and therapies similar to our products candidates or targeting similar indications will increase. Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and human resources than we do, and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and the commercialization of those treatments. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. We expect competition in the indications we are pursuing will focus on efficacy, safety, convenience, availability, and price. The commercial opportunity for apitegromab, if approved, could be reduced or eliminated if our competitors develop and commercialize products that are perceived to be safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than apitegromab. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Preclinical development is uncertain. Our preclinical programs, such as SRK-439, may experience delays or may never advance to clinical trials, which would adversely affect our ability to develop our product pipeline and receive regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

We have two product candidates, apitegromab and SRK-181, and may not nominate any other product candidates for any of our programs. Before we can commence clinical trials for any product candidate, we must complete extensive preclinical studies that support our planned INDs in the U.S., or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical studies or of the timing of any planned IND submission to the FDA or similar applications in other jurisdictions, and cannot predict if the FDA, EMA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for the clinical development of our preclinical programs, such as our potential IND for SRK-439, on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA, the competent authorities and/or ethics committees in the EU Member States or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing can be a lengthy, time-consuming and expensive process. The time required for such testing may vary substantially according to the type, complexity and novelty of the program, and can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies such as on account of interruptions or delays in preclinical studies at laboratories or other institutions due to the COVID-19 pandemic, may cause us to incur additional operating expenses. We also may be affected by delays associated with the preclinical testing and studies of certain programs that are the responsibility of our collaborators or our potential future collaborators over which we have limited or no control. The commencement and rate of completion of preclinical studies for a product candidate may be delayed by many factors, including, for example, challenges in reaching consensus with

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regulatory agencies regarding the scope of the necessary preclinical study program and/or appropriate preclinical study designs.

Risk Related to Manufacturing and Supply

Because we rely on third-party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials, and, if approved, commercial materials, may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufacturers to manufacture some of our preclinical product candidate supplies and rely on third-party contract manufacturers to manufacture all of our clinical trial product supplies and, if approved, will rely on third-party contract manufacturers to manufacture all of our commercial product supplies, including all of our drug substance, vialing, labeling, and packaging. We do not own manufacturing facilities for producing any clinical trial or commercial product supplies. There can be no assurance that our preclinical, clinical development, and, if approved, commercial product supplies will not be limited or interrupted, including as a result of impacts of current macroeconomic and geopolitical events, including changing conditions from the COVID-19 pandemic, the 2022 Russian invasion of Ukraine, increasing rates of inflation, rising interest rates, or that our product supplies will be of satisfactory quality or continue to be available at acceptable prices. For example, we rely on a single source supplier for the manufacture of drug substance for apitegromab and SRK-181. In addition, the extent to which current macroeconomic and geopolitical events, including changing conditions from the COVID-19 pandemic, impact our ability to procure sufficient supplies for the development of apitegromab, SRK-181 or future product candidates will depend on the severity and duration of the spread of COVID-19, and the actions undertaken to contain COVID-19 or treat its effects, as well as the changing rates of inflation and interest rates, the 2022 Russian invasion of Ukraine, as well as other factors outside of our control. Any replacement of our current drug substance contract manufacturer would require significant resources, lead time and expertise because there may be a limited number of qualified replacements. If any of our third-party manufacturers divert resources or manufacturing capacity to accommodate the development or manufacture of COVID-19 vaccines, our supply chain may be disrupted, limiting our ability to supply apitegromab or SRK-181 for our clinical trials.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMP. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, such as due to the COVID-19 pandemic, we may be forced to

manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. These factors would increase our reliance on the original manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we must change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will 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 manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for apitegromab, SRK-181 or any future product candidate. To the extent that we have existing, or in the future enter into, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third-

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party's failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials for apitegromab, SRK-181 or of future product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for apitegromab, SRK-181 or future product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of apitegromab, SRK-181 or future product candidates; and

- in the event of approval to market and commercialize apitegromab, SRK-181 or a future product candidate, an inability to meet commercial demands for our products.

In addition, we contract with fill and finishing providers which we believe have the appropriate expertise, facilities and scale to meet our needs. Failure to maintain compliance with cGMP can result in a contractor receiving FDA sanctions, which can impact our ability to operate or lead to delays in any clinical development programs. We believe that our current fill and finish contractors are operating in accordance with cGMP, but we can give no assurance that the FDA, EMA, competent authorities of the EU Member States or other regulatory agencies will not conclude that a lack of compliance exists. In addition, any delay in contracting for fill and finish services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and launches, which could negatively affect our business.

Our reliance on third parties, such as manufacturers and antibody discovery vendors, may subject us to risks relating to manufacturing scale-up and may cause us to undertake substantial obligations, including financial obligations.

In order to continue to conduct later-stage clinical trials with apitegromab, SRK-181 or any of our future product candidates, or, if approved, produce commercial product, we will need to manufacture such product candidate in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality-control issues may arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale-up the manufacture of our product candidates in sufficient quality and quantity, including as a result of the COVID-19 pandemic, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not received, which could significantly harm our business.

In addition, we rely, and intend to continue to rely, on third-party entities to conduct certain antibody discovery work based on criteria and specifications provided by us. Certain of our antibody discovery vendors may require us to enter into a license agreement with them or exercise an option in an existing agreement with them for the right to use antibodies discovered by them in humans or for commercial purposes. Such license or other agreements could include substantial milestone payments and royalties to the extent we choose to use an antibody discovered by such vendors. For example, under our Adimab Agreement, upon exercise of the development and option for the research program from which SRK-181 was generated, we paid to Adimab a non-creditable, nonrefundable option exercise fee; and on a Product (as defined in the Adimab Agreement)-by-Product basis, we will pay Adimab upon the achievement of various clinical and regulatory milestone events with total milestone payments not to exceed mid-teen millions in the aggregate for a given Product; for any Product that is commercialized, on a country-by-country and Product-by-Product basis, we are obligated to pay to Adimab a low-to-mid single-digit percentage of annual worldwide net sales of such Product

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during the applicable royalty period in each country. In addition, if we do not meet our obligations under such license or other agreements, the counterparties may have the ability to terminate the license or other agreements and we could lose the right to use the discovered antibodies, which could significantly and adversely impact our business.

Risks Related to Our Business and Operations

Our restructuring Because we rely on a limited number of third-party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials, and, if approved, commercial materials, may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on a limited number of third-party contract manufacturers to manufacture all of our clinical trial product supplies and, if approved, all of our commercial product supplies, including all of our drug substance, drug product, labeling, and packaging. We do not own our own manufacturing facilities for producing any clinical trial or commercial product supplies. There can be no assurance that our preclinical, clinical development, and, if approved, commercial product supplies will not be limited or interrupted due to impacts to our third-party contract manufacturers. For example, we rely on a single source supplier for the manufacture of apitegromab and SRK-181. Any replacement of our current drug substance contract manufacturer or drug product contract manufacturer would require significant resources, lead time and expertise because there may be a limited number of qualified replacements. In addition, our ability to procure sufficient supplies for the development of apitegromab, SRK-181, SRK-439 or future product candidates could be impacted by factors outside of our control such as current macroeconomic and geopolitical events and the associated workforce reduction announced in May 2022 changing rates of inflation and interest rates. In addition, we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our third-party contract manufacturers supply and/or manufacture materials or products for other companies, which exposes our third-party contract manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt affect the regulatory clearance of our business. contract manufacturers' facilities generally.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMP. In May 2022, we announced a reduction in workforce by approximately 25% in connection with the restructuring event that any of our business manufacturers fails to prioritize and focus on comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our clinical stage assets. We also cannot guarantee that supply of components or other materials becomes limited or interrupted for other reasons, we will may be forced to manufacture the materials ourselves, for which we currently do not have to undertake additional workforce reductions the capabilities or restructuring activities in the future. Furthermore, our strategic restructuring plan may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased

difficulties in our day-to-day operations and reduced employee morale. In addition, if there are unforeseen expenses associated resources, or enter into an agreement with such realignments in our business strategies, and we incur unanticipated charges or liabilities, then another third-party, which we may not be able to effectively realize do on reasonable terms, if at all. In some cases, the expected cost savings technical skills or other benefits technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. These factors would increase our reliance on the original manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we must change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will 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 such actions which a new manufacturer could have an adverse effect negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers for commercial supplies of drug substance, drug product, and packaged and labeled product for apitegromab, if we receive regulatory approval. We will also rely on our business, operating results contract manufacturers to manufacture sufficient quantities of apitegromab to produce validation batches. We do not have long-term supply agreements in place with any of our contract manufacturers, and financial condition. each batch of our product candidates is individually contracted through a purchase order governed by master service and quality agreements. If employees our existing contract manufacturers for our product candidates are not willing to enter into long-term supply agreements, or are not willing or are unable to supply product candidate supplies to us, we could be required to engage new contract manufacturers who were not affected by would need to scale up the workforce reduction seek alternate employment, this manufacturing process before we would be able to use the product candidate supplies they manufacture, which could result in us seeking delays to our clinical trials or future commercialization plans, if we are successful and gain approval.

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To the extent that we have existing, or in the future enter into, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third-party's failure

to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials for apitegromab, SRK-181, SRK-439 or of future product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for apitegromab, SRK-181, SRK-439 or future product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of apitegromab, SRK-181, SRK-439 or future product candidates; and
- in the event of approval to market and commercialize apitegromab, SRK-181, SRK-439 or a future product candidate, an inability to meet commercial demands for our products.

In addition, we contract support at unplanned additional expense or harm with fill and finishing providers which we believe have the appropriate expertise, facilities and scale to meet our productivity. Our workforce reductions could also harm needs. Failure to maintain compliance with cGMP can result in a contractor receiving FDA sanctions, which can impact our ability to attract operate or lead to delays in any clinical development programs. We believe that our current fill and retain qualified management, scientific, finish contractors are operating in accordance with cGMP, but we can give no assurance that the FDA, EMA, competent authorities of the EU Member States or other regulatory agencies will not conclude that a lack of compliance exists. In addition, any delay in contracting for fill and finish services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and manufacturing personnel who are critical to commercial launches, which could negatively affect our business. Any failure

Our reliance on third parties, such as manufacturers, may subject us to attract risks relating to manufacturing scale-up and may cause us to undertake substantial obligations, including financial obligations.

In order to continue to conduct later-stage clinical trials, or, retain qualified personnel could prevent us from if approved, produce commercial product, we will need to manufacture such product candidate in large quantities. In particular, we expect to rely on our contract manufacturers to scale our manufacturing processes for future clinical trials of apitegromab, and if our development efforts are successful and if apitegromab is approved, for commercial supply of apitegromab. We, or any manufacturing partners, may be unable to successfully developing increase the manufacturing capacity for apitegromab in a timely or cost-effective manner to meet our supply requirements. In addition, quality-control issues may arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale-up the manufacture of our product candidates in sufficient quality and quantity, the future. development, testing, clinical trials, and if approved, commercial supply, of that product candidate may be delayed or infeasible, and regulatory approval, commercial launch or commercial supply of any resulting product may be delayed or not received, which could significantly harm our business.

We will need to continue to grow the size of our organization in certain areas, including our personnel, systems and relationships with third parties, in order to develop our product candidates, and we may experience difficulties in managing this growth.

As our clinical development plans and commercialization strategies continue to develop and expand, we expect we will need to hire additional managerial, clinical development, scientific, regulatory, commercial, and administrative

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personnel. Our ability to compete in the highly competitive oncology and immuno-oncology fields biotechnology industry depends upon our ability to attract and retain highly qualified specialized personnel. If As apitegromab and SRK-181 approach approaches commercialization, we will also need to hire sales, marketing and other commercial personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our development efforts effectively, including the clinical and regulatory review process for apitegromab, SRK-181, SRK-439, and any future product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize apitegromab, SRK-181, SRK-439 and future product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on third parties, advisors and consultants to provide certain services, including clinical research organizations, CROs, contract manufacturers and companies focused on antibody development and discovery activities. There can be no assurance that the services of third parties, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may not be able to receive, or may be substantially delayed in receiving, regulatory approval of apitegromab, SRK-181, SRK-439 or future product candidates or otherwise advance our business. There can be no assurance that

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we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel in the biopharmaceutical space, especially those engaged in oncology and immuno-oncology. immuno-oncology and cardiometabolic fields. In this highly competitive market, there may be increased costs to attract and retain qualified personnel. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are not able to offer competitive compensation or appealing opportunities for high quality candidates, we may not be able to attract or retain qualified candidates and personnel. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize apitegromab, SRK-181, SRK-439 or any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our executives and highly skilled technical and managerial personnel are critical to our business. If we have transition in management, lose key personnel, or if we fail to recruit additional highly skilled personnel, our ability to further develop apitegromab, SRK-181 and SRK-439 and identify and develop new or next generation product candidates may be impaired.

Our performance substantially depends on the performance of our management team. We had a Chief Executive Officer transition in October 2022 and a new Chief Medical Officer join in November 2022. Any transition or loss of the services of any of our executives or highly skilled technical and managerial personnel could have a disruptive impact on our ability to implement our strategy and impede the achievement of our research, development and commercialization objectives. In addition, these transitions or departures could, cause us to incur increased operating expenses, divert senior management resources in searching for replacements, or otherwise have a material adverse effect on our business, internal controls, financial condition and results of operations. Management transition inherently causes some loss of institutional knowledge, which can negatively affect strategy and operational execution during this phase. If we have

additional changes to our executives or highly skilled technical and managerial personnel, we may be unable to successfully manage and grow our business, and our results of operations, execution of corporate goals, internal controls and financial condition could suffer as a result. The unplanned loss of the services of our executives or other personnel also could harm our reputation.

Our internal computer systems, or those used by our contract research organizations, or other contractors or consultants, may fail or suffer security breaches.

We have outsourced significant parts of our IT and business infrastructure to third-party providers, and we currently use these providers to perform business critical IT and business services for us. Despite the implementation of security measures, our computer systems, whether they are managed by us directly or by the third parties with whom we contract, and those of our existing and future CROs, and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. 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. Our increased reliance on personnel working from home may increase our cyber security risk, create data accessibility concerns, and make us more susceptible to workforce and communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other agencies and contractors. For example, the loss of preclinical or clinical data 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 apitegromab, SRK-181 and SRK-181 SRK-439 and to conduct preclinical studies and clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of apitegromab, SRK-181, SRK-439 and future product candidates could be delayed.

As a company that uses IT systems, our systems may be subject to cyber-attacks. Due to the nature of some of these attacks, there is a risk that they may remain undetected for a period of time. While we have invested in the protection of data and information technology, our efforts may not prevent service interruptions or security

breaches (e.g., ransomware attacks). We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business, or reputational losses that may result from an interruption or breach of our systems.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws and regulations of the FDA, EU Member States, EMA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA, EMA and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we receive FDA approval of apitegromab, SRK-181, SRK-439 or any future product candidates and begin commercializing those products in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, 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 comply with these laws or regulations. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with

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these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in statutes, regulations or the interpretation of existing statutes or regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; (iv) additional record-keeping requirements; or (v) changes to our pricing arrangements, or coverage of or reimbursement for our products. If any such changes were to be imposed, they could adversely affect the profitability and operation of our business. See the sections of this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 entitled, "Business — Government Regulation — Current and Future Healthcare Reform Legislation" and "Business – Government Regulation – Coverage and Reimbursement."

It is possible that the ACA, as currently enacted or as it may be amended or otherwise modified in the future, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare or other healthcare funding, more rigorous coverage criteria, or new payment methodologies or otherwise affect the prices we may obtain for any of our product candidates for which we may receive regulatory approval. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from commercial payors. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be modified or invalidated. The continuing health care reform initiatives efforts of the government, insurance companies, managed care organizations and other payers of health care services to contain or reduce costs of health care may adversely affect the demand for any product candidates for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and

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reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability; and the level of taxes that we are required to pay.

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

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal

False Claims Act (“FCA”), which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information received in the course of patient recruitment for clinical trials. See the section in this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 entitled “Business – Government Regulation – Other Healthcare Laws.”

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. In addition, there has been a trend of increased state regulation of payments made to physicians for marketing. Some states mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource consuming and can divert a company’s attention from the business.

It is possible that governmental and enforcement 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 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, including the imposition of civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity

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agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Failure to comply with health care privacy and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We, our CROs, and any potential collaborators may be subject to strict and changing federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security) and policies and contractual obligations related to data privacy and security. In the U.S., numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy

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laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our CROs and collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We have conducted our Phase 2 TOPAZ clinical trial of apitegromab in the European Economic Area ("EEA"), are conducting our Phase 3 SAPPHIRE clinical trial and ONYX, our long-term extension clinical trial of apitegromab, in the EEA and the UK, and may conduct future clinical trials in the EEA or the UK and therefore may be subject to additional privacy laws. The EU GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA or the UK, including to the U.S., providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, where required reporting security breaches involving personal data to the competent national data protection authority and affected individuals, where required, appointing data protection officers, where required conducting data protection impact assessments, and record-keeping. The EU GDPR increases substantially the imposes penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. The EU 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 EU GDPR. In addition, the GDPR includes restrictions on cross-border data transfers (see below).

Further to the UK's exit from the EU on January 31, 2020, the EU GDPR ceased to apply in the UK at but the end of UK incorporated the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the EU 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 currently still 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.

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Although the UK is regarded as a third country under the EU's GDPR, the EC has now issued a decision recognizing the UK is recognized as providing adequate protection under the EU GDPR ("UK Adequacy Decision") and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that Likewise, personal data transfers from the UK to the EEA remain free flowing. The UK Government has introduced a Data Protection and Digital Information Bill ("UK Bill") into the UK legislative process. The aim of the UK Bill is to reform the UK's data

protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime and threaten the UK Adequacy Decision from the European Commission. This may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties.

Adequate safeguards must be implemented to enable the transfer of personal data outside of the EEA or the UK in compliance with European and UK data protection laws. On June 4, 2021, the European Commission (EC) issued new forms of standard contractual clauses ("SCCs") for data transfers from controllers or processors in the EEA (or otherwise subject to the EU GDPR) to controllers or processors established outside the EEA (and not subject to the EU GDPR). The new standard contractual clauses SCCs replace the standard contractual clauses SCCs that were adopted previously under the Data

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Protection Directive. The UK is not subject to the EC's new standard contractual clauses SCCs but has published its own standard clauses, the International Data Transfer Agreement, which enables transfers from the UK. We will be required to implement these new safeguards when conducting restricted data transfers under the EU GDPR and UK GDPR and doing so will require significant effort and cost. Where relying on the SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data.

In July 2023, the past, companies in the U.S. were able to rely upon European Commission adopted its adequacy decision for the EU-U.S. and Data Privacy Framework ("Framework"), the Swiss-U.S. successor of the EU-U.S. Privacy Shield frameworks to legitimize data transfers from the EU to the U.S., but in July 2020, framework, which the Court of Justice of the European Union or CJEU, invalidated in Case C-311/18 (Data Protection Commissioner v Facebook Ireland and Maximillian Schrems, or Schrems II) invalidated 2020. On the EU-U.S. Privacy Shield on basis of the grounds that the Privacy Shield failed to offer adequate protections to EU new adequacy decision, personal data transferred can flow safely from the EU to U.S. companies participating in the U.S. On March 25, 2022, Framework, without having to put in place additional data protection safeguards. However, the EC and the U.S. announced to have reached a political agreement on a new "Trans-Atlantic Data Privacy Framework", long term validity of the Framework, which will replace the invalidated Privacy Shield has already been challenged in court, remains uncertain.

The EU GDPR and on December 13, 2022, the European Commission published a draft adequacy decision on the Framework.

The UK GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the EU GDPR and UK GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the EU GDPR and UK GDPR, including as implemented by individual countries. Given the new law, we face uncertainty as to the exact interpretation of the new requirements and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the law. Compliance with the EU GDPR and UK GDPR will be 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.

EU Member States have adopted implementing national laws to implement the EU GDPR which may partially deviate from the EU GDPR and the competent authorities in the EU Member States may interpret EU GDPR obligations slightly differently from country to country, so that we do not expect to operate in a uniform legal landscape in the EU. Also, as it relates to processing and transfer of genetic data, the EU GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. In addition, the UK has announced plans to reform the country's data protection legal framework in its Data Reform Bill, but these have been put on hold.

We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European or UK data protection authority, we may face fines and other penalties. Any such investigation or charges by European or UK data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the EU GDPR and UK GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

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In addition, many states in which we operate have laws that protect the privacy and security of sensitive and personal information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and

such laws may differ from each other, which may complicate compliance efforts. Where state laws are more protective than HIPAA, we must comply with the state laws we are subject to, in addition to HIPAA. In certain cases, it may be necessary to modify our planned operations and procedures to comply with these more stringent state laws. Further, in some cases where we process sensitive and personal information of individuals from numerous states, we may find it necessary to comply with the most stringent state laws applicable to any of the information. For example, California enacted the California's California Consumer Privacy Act ("CCPA"), which creates new comprehensive 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. While there are currently exceptions for protected health information that is subject to HIPAA and clinical trial regulations, as

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currently written, the CCPA, as amended by the California Privacy Rights Act ("CPRA"), and other enacted or proposed comprehensive state consumer privacy legislation may impact our business activities. We continue to monitor the impact that the state consumer privacy and protection laws, like the CCPA, may have on our business activities. See the section in this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 entitled "Business – Government Regulation – European General Data Collection Protection Regulation and State "Business – Government Regulation – Other Healthcare and Privacy Laws."

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

The potential use of new and evolving technologies, such as artificial intelligence, in our offerings to employees may result in additional spending and presents risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, and as a result we may be exposed to reputational harm and liability.

We may build and integrate artificial intelligence into our offerings, and this innovation may present risks and challenges that could affect its adoption, and therefore our business. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act ("AI Act") — the world's first

comprehensive AI law — is anticipated to enter into force in Spring 2024 and, with some exceptions, become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain our service offerings to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate artificial intelligence tools into their own offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

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Additional laws and regulations governing international operations, including certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, could negatively impact or restrict our operations.

If we further expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered

foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and

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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.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not

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provide adequate coverage against potential liabilities, and as a result, may be subject to lengthy and expensive litigation and excessive damages and we may not have, or be able to obtain, sufficient capital to pay such amounts. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of testing apitegromab, SRK-181, SRK-439 and any of our future product candidates in clinical trials and will face an even greater risk if we commercialize any products, if approved. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;

- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate, if approved; and
- decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. We may be unable to obtain, or may obtain on unfavorable terms, additional clinical trial insurance in amounts adequate to

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cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future

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corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could 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 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 other 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.

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold because of the COVID-19 pandemic, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approvals. Should the 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 may defer action on the application until an inspection can be completed. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Additionally, regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption 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. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Our current laboratory operations are concentrated in one location, and we or the third parties upon whom we depend, including our clinical trial sites and the manufacturing facilities of our third-party contract manufacturers, may experience business interruptions and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters.

Our office and laboratory facilities are located in Cambridge, Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, the facilities at any clinical trial site, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of apitegromab, SRK-181, SRK-439 and future product candidates or interruption of our business operations. If a natural disaster, outbreak of disease, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities, our clinical trial sites or the manufacturing facilities of our third-party contract manufacturers, or that otherwise

disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. For example, the COVID-19 pandemic resulted in extended shutdowns of certain businesses and has had ripple effects to businesses around the world. The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services may be slow to return to pre-pandemic levels.

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Global events, including global health concerns like the COVID-19 pandemic, could also result in social, economic, and labor instability in the countries in which we operate or where the third parties with whom we engage, including our clinical trial sites and manufacturing facilities of our third-party contract manufacturers, operate. Unforeseen global events, such as increasing inflation and interest, rates and the related U.S. and global economic impact or the 2022 Russian invasion of Ukraine, could adversely impact our business. For example, we are conducting SAPPHIRE, our Phase 3 clinical trial and, ONYX, our long-term extension clinical trial of apitegromab in the U.S. and EU, and regional instability caused by the 2022 Russian invasion of Ukraine could adversely affect the conduct of our clinical trial. trials. Such conflicts could lead to sanctions, embargoes, supply shortages, regional instability, geopolitical shifts, cyberattacks, other retaliatory actions, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, which could adversely impact our operations and financial results, as well as those of third parties with whom we conduct business.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at our facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy

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any damages and losses. If our facilities, the manufacturing facilities of our third-party contract manufacturers, or the sites where we conduct clinical trials or preclinical studies, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, apitegromab and SRK-181, and future product candidates such as SRK-439, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, apitegromab, SRK-181, SRK-439 or future product candidates or assure that coverage and reimbursement will be available for any product that we may develop. See the sections in this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 entitled "Business–Government Regulation – Coverage and Reimbursement" and "Business–Government Regulation–Current and Future Healthcare Reform Legislation."

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid or national payor bodies (such as in European countries), and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. 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 product is:

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

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In the U.S., no uniform policy of coverage and reimbursement for products exists among third party payors, 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. Coverage and reimbursement for products may vary widely across national payors from country to country.

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. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product

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candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain pharmaceutical products or additional pricing pressures.

Moreover, increasing efforts by governmental and third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the U.S. 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. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European Member States.

We intend to seek approval to market our product candidates in both the U.S. and in selected foreign jurisdictions. If we receive approval in one or more foreign jurisdictions for apitegromab, SRK-181, SRK-439 or future product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of medicinal products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after receiving marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Much like the federal Anti-Kickback Statute prohibition in the U.S., the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the

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national anti-inducement, advertising and anti-bribery laws of EU Member States. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be disclosed publicly. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including several EU Member States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal

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products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced Member States, can further reduce prices. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

We may seek to enter into collaborations in the future with third parties, including for apitegromab, SRK-181, SRK-439 or potential product candidates. If we are unable to enter into such collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to evaluate and, as deemed appropriate, enter into additional collaborations or partnerships in the future when strategically attractive, including potentially with biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet only recently have any capability begun to build our capabilities to prepare for potential commercialization. Accordingly, we may enter into collaborations with other companies to provide us with important technologies, capabilities and funding for our programs and underlying technology.

Any future collaboration we enter into may pose a number of risks, including the following:

- collaborators may have significant discretion or decision-making authority in determining the efforts and resources that they will apply to the collaboration or that we are required to apply to the collaboration;

- collaborators may not perform their obligations as expected or in a manner satisfactory to us;
- we may commit to certain preclinical or clinical development or commercialization efforts as part of the collaboration that we are unable to meet or our collaborators may not be satisfied with our preclinical or clinical development or commercialization efforts;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;

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- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

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- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us;

- collaborations may be terminated by the collaborator, and, if terminated, we may be blocked to advance the program due to collaborator patents that are not licensed to us; and

- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. For example, our collaboration with Gilead Sciences, Inc. that we entered into on December 19, 2018 was terminated on January 6, 2022.

If our future collaborations do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of our potential therapeutic collaborators.

Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the biotechnology or pharmaceutical industry, including within the business and financial communities, could be adversely affected.

We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms

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that we are seeking and other available products for licensing by other companies. Collaborations 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. Our ability to reach a definitive agreement for a collaboration 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 evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its 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 expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations or do not have sufficient funds

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or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. If we are unable

to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. Unforeseen global events, such as the 2022 Russian invasion of Ukraine, and sanctions or actions relating to such events, could affect our ability to file, prosecute, maintain, and/or defend patents and applications in those markets. 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. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the U.S. and/or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. For example, Russia issued a decree in March of 2022, stating that patent owners who reside in a country “unfriendly” to Russia are not entitled to compensation in the event of patent infringement. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property and/or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could

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dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. 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, which may, nonetheless,

ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are

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relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products.

In addition, periodic maintenance fees on any issued patent are due to be paid to the U.S. Patent Office ("USPTO") and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Moreover, complications due to the COVID-19 or other global pandemics may result in inadvertent lapse due to, for example, unexpected closures of the USPTO or foreign patent offices, delays in delivery of notifications relating to deadlines, or failure to timely and/or properly obtain signatures on necessary documents. Additionally, due to the ongoing conflict in Ukraine, there remain uncertainties as a result of to any potential impact on patent protection and/or enforcement in the 2022 Russian invasion of Ukraine, it is unclear whether region, including, for example, payments to the Russian Patent Office and other entities might violate certain sanctions. entities. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others it is possible that our pending patent applications will not result in issued patents;

- we or our licensors, as the case may be, able might not have been the first to make or use compounds or cells that are similar to the biological compositions of our product candidates but that are not covered by file patent applications for these inventions;

- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;

- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;

- the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection owned or in-licensed issued patents may not provide us with any competitive advantages, may be available with regard to formulation narrowed in scope, or method be held invalid or unenforceable as a result of use; legal challenges by third parties;

- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;

- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies;

- it is possible that our pending patent applications will not result in issued patents;

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- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;

- it is possible that others may circumvent our owned or in-licensed patents;

- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;

- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the U.S.;

- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;

- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;

- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;

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- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- others may be able to make or use compounds or cells that are similar to the biological compositions of our product candidates but that are not covered by the claims of our patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that others may circumvent our owned or in-licensed patents;
- the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use;
- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours; and/or
- the patents of others may have an adverse effect on our business.

Our current owned patents and co-owned patents covering our proprietary technologies and our product candidates are expected to expire beginning in 2034, (owned) and November 2033 (co-owned) respectively, without taking into account any possible patent term adjustments or extensions. Our earliest patents may expire before, or soon after, our first product achieves marketing approval in the U.S. or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a material adverse effect on our business, results of operations, financial condition and prospects. We own and co-own pending patent applications covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from November

2033 2034 through 2043, 2045, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of these patent applications.

We depend on intellectual property licensed from third parties. Failure to comply with our obligations under any of these licenses or termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, including intellectual property rights licensed from others. We may be a party to license agreements pursuant to which we in-license key patents and patent applications for our product candidates. These licenses impose various diligence, milestone payment, royalty, insurance and other

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obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license. Any termination of licenses by third parties could result in our loss of significant intellectual property rights and could harm our ability to commercialize our product candidates.

We may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, 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 have been or 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

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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 is licensed to us. It is

possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

Disputes may also arise between us and our 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 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; 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 partners.

If disputes over intellectual property that we have licensed 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.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently, and these rights may be held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we

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may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party third-

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party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

Changes in patent law in the U.S. and in ex-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain.

In addition, recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy-Smith America Invents Act (the “America Invents Act”), enacted in 2013, the U.S. moved from a “first to invent” to a “first to file” system. Under a “first to file” system, assuming the other requirements for patentability

are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act, and many of the substantive changes to

patent law, including the “first to file” provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Recent U.S. Supreme Court rulings have also narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Additionally, some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria which could also make it more difficult to obtain patents.

Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case Amgen Inc. v. Sanofi, the Federal Circuit held that a well characterized antigen is insufficient to satisfy the written description requirement of certain claims directed to a genus of antibodies that are solely defined by function. While the validity of a subset of patents at issue was subsequently upheld by a district court jury, uncertainty remains as to the legal question pertaining to the written description requirement under 35 USC §112 as it relates to functional antibodies. In the case of Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are

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not patentable. We cannot predict how these decisions or any future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other

jurisdictions could have a material adverse effect on our business and financial condition. For example, Russia issued a decree in March of 2022, stating that patent owners who reside in a country “unfriendly” to Russia are not entitled to compensation in the event of patent infringement.

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Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post-grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management’s attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party’s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner’s attorneys’ fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do;

- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the U.S. is protected under the Safe Harbor exemption as set forth in 35 U.S.C. § 271. If and when apitegromab, SRK-181, or another one of our product candidates is approved by the FDA, that certain third-party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we are

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not aware of any claims of such a patent that could otherwise materially adversely affect commercialization of our product candidates, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is “clear and convincing,” a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently

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pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. 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.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, and/or pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may also choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge the grant of a third-party's patent in opposition proceedings in the European Patent Office ("EPO") or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office, then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

Upon completion of the ratification process, Additionally, the Unified Patent/Unified Patent Court system in Europe becomes became fully operational. operational in June 2023.

- The untested new court may be associated with greater degrees of uncertainty in litigation, with respect to both planning and outcome.
- The opt-out selection afforded during the transition may have a direct impact on future litigation and may result in loss of certain flexibility with regard to choice of forum and other litigation strategy considerations.

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We may incur substantial costs as a result of litigation or other proceedings relating to our patents or the patents of our licensors, and we may be unable to protect our rights to our products and technology.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims against a third party(ies), which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, 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. There is also the risk that, even if the validity of our patents or the patents of our licensors is upheld, the court will refuse to stop the third-party on the ground that such third-party's activities do not

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infringe our owned or in-licensed patents. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

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. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In some situations, we or our licensor, may not be able to detect infringement against our owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third-party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third-party. If we, or our licensors, later sue such third-party for patent infringement, the third-party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against such third-party.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include inter parties review, ex parte re-examination, post-grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). For example, EP3368069 and EP2981822 are currently subject to opposition proceedings. Such proceedings are expensive and could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, because patent applications in PCT member jurisdictions are typically not published until 18 months after the earliest filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products, compositions, methods of use, or

technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

For applications filed under pre-AIA, interference proceedings declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the U.S. Filing, prosecuting and defending patents on product candidates 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. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Indeed, Russia issued a decree in March of 2022, stating that patent owners who reside in a country "unfriendly" to Russia are not entitled to compensation in the event of patent infringement. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to

territories where we have patent protection but where enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from 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, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products and/or methods of medical treatment, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

As another example, in Europe, a new unitary patent system becomes became effective in June 2023, which may significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will Subject to current transitional provisions, European patents have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC

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countries. Patents that remain under the jurisdiction of the UPC will be are potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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Patent terms may result in inadequate protection for our product candidates, and we may be unable to obtain patent term extensions and data exclusivity for our product candidates, resulting in material harm to our business.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, 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 Action of 1984, also known as the Hatch Waxman Amendments. The Hatch Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. The patent term restoration period is generally one-half of the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the BLA, plus the time between the date of submission of the BLA and the date of FDA approval of the product. The patent holder must apply for restoration within 60 days of approval. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request.

Given the amount of time required for the development, testing and regulatory review of new product candidates, the patents protecting our product candidates might expire before or shortly after such candidates are commercialized. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could materially harm our business, financial condition, results of operations, and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is

appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third-party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently

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develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

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Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not

disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

Third parties may assert that our employees or consultants have wrongfully used, disclosed, or misappropriated their confidential information or trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants 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 a 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. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Our Financial Condition and Capital Requirements

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

We are a biopharmaceutical company formed in 2012 and our operations to date have been focused on research and development of monoclonal antibodies that selectively inhibit activation of growth factors for therapeutic effect. We

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have not yet demonstrated the ability to progress any of our product candidates through clinical trials, we have no products approved for commercial sale and we have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are

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not profitable and have incurred losses in each period since our inception. For the twelve months ended December 31, 2022 December 31, 2023 and 2021, 2022, we reported a net loss of $134.5 million $165.8 million and $131.8 million $134.5 million, respectively. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $510.6 million $676.4 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, apitegromab, and SRK-181, SRK-439, and any future product candidates.

To become and remain profitable, we or any current or potential future collaborators must develop and eventually commercialize products with significant market potential and favorable pricing. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, receiving marketing approval for product candidates, manufacturing, marketing and selling products for which we may receive marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could decrease the value

of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require additional capital to fund our operations and if we fail to obtain necessary capital, we will not be able to complete the development and commercialization of apitegromab, SRK-181, SRK-439 and any future product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts of cash to conduct further research and development, including clinical trials for apitegromab and SRK-181 and preclinical studies and clinical trials for SRK-439 and any future product candidates, to seek regulatory approvals for our product candidates and to launch and commercialize any products for which we receive regulatory approval. As of December 31, 2022 December 31, 2023, we had approximately $315.4 million $279.9 million in cash, cash equivalents and marketable securities. In June 2022, we sold shares of common stock, pre-funded warrants to purchase shares of our common stock and warrants to purchase shares of our common stock through a registered direct offering for net proceeds of $195.3 million, after deducting placement agent fees and offering expenses. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities as of December 31, 2022 December 31, 2023, will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2025. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Additionally, any program setbacks or delays due to changes in federal or state laws or clinical site or clinical vendor policies as a result of the impacts of current macroeconomic and geopolitical events, including changing conditions from the COVID-19 pandemic, the 2022 Russian invasion of Ukraine, increasing rates of inflation and rising interest rates could impact our programs and increase our expenditures. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, completion, costs and results of clinical trials for apitegromab and SRK-181 and preclinical studies and clinical trials for SRK-439 and any future product candidates;
- the clinical development plans we establish for our product candidates;
- the number and characteristics of product candidates that we identify and develop;

- the terms of any collaboration, strategic alliance, or licensing agreements we are currently party to or may choose to enter into in the future;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA, and other comparable foreign regulatory authorities;

- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of developing research cell lines and development and completion of commercial scale outsourced manufacturing activities;
- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors resulting from pandemics or similar public health crisis or macroeconomic conditions; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be

favorable to us. We also could be required to seek collaborators for apitegromab, SRK-181, SRK-439 or any future product candidate at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. 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 apitegromab, SRK-181, SRK-439 or one or more of our future product candidates or other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

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

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, 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. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

As of December 31, 2022 December 31, 2023, we had net operating loss carryforwards for federal and state income tax purposes of $343.0 million $403.2 million and $339.8 million $402.8 million, respectively, which begin to expire in 2032, except for our post 2017 federal net operating loss carryforwards of $292.5 million $352.7 million which do not expire. As of December 31, 2022 December 31, 2023, we also had available tax credit carryforwards for federal and state income tax purposes of $32.6 million $40.8 million and $5.3 million $6.1 million, respectively, which begin to expire in 2034 and 2023, 2024, respectively. Additionally, for taxable years beginning after December 31, 2017 the deductibility of the indefinite lived federal net operating losses is limited

to 80% of our taxable income in any future taxable year. Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Private placements and other transactions that have occurred since our inception, as well as our Initial Public Offering ("IPO"), IPO, may trigger such an ownership change pursuant to Section 382 of the Code. Any such limitation, whether as the result of our IPO, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years.

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 our current and projected business operations and our financial condition and results of operations.

Actual events 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. Since then, additional financial institutions have experienced similar failures and have been placed into receivership.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although 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 immediate liquidity may exceed the capacity of such program. Additionally, there is no guarantee 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.

Although we assess our banking 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.

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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, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- delayed or lost access to, or reductions in borrowings available under our existing debt facility; or
- potential or actual breach of contractual obligations that require the Company to maintain certain financial accounts at specific financial institutions.

In addition, 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, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any supplier bankruptcy or insolvency, or any breach or default by a supplier, or the loss of any significant supplier relationships, could result in material losses to us and may have a material adverse impact on our business.

Our current investment policy focuses on preservation of capital. However, we could recognize losses on securities held in our investment portfolio, particularly if interest rates increase or economic and

market conditions deteriorate.

As of December 31, 2023, the fair value of our cash equivalents and investments in our marketable debt securities portfolio was approximately $279.9 million and consisted primarily of investments in money market funds and U.S. government securities. Factors beyond our control can significantly influence the fair value of securities in our portfolio and can cause potential adverse changes to the fair value of these securities. For example, fixed-rate securities acquired by us are generally subject to decreases in market value when interest rates rise. Additional factors include, but are not limited to, rating agency downgrades of the securities or our own analysis of the value of the security, defaults by the issuer with respect to the underlying securities, and continued instability in the credit markets. Any of the foregoing factors could cause other-than-temporary impairment in future periods and result in realized losses. The process for determining whether impairment is other-than-temporary usually requires difficult, subjective judgments about the future financial performance of the issuer and any collateral underlying the security in order to assess the probability of receiving all contractual principal and interest payments on the security.

At December 31, 2023, we had one thousand in net unrealized losses in our marketable securities available-for-sale portfolio, and unrealized losses in our securities portfolio may increase in the future due to the aforementioned economic factors. While our goal is to hold each security until maturity, that may not be possible in light of our policy to preserve capital and liquidity and because investment in securities with unrealized losses has a diminished utility as a source of liquidity prior to maturity. Selling securities with an unrealized loss would result in the realization of such losses, which could have an adverse effect on our financial condition and results of operations.

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Risks Related to Our Common Stock

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

Similar to the trading prices of the common stock of other biopharmaceutical companies, the trading price of our common stock is 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 Annual Report on Form 10-K, these factors include:

- announcements of significant acquisitions, strategic collaborations or partnerships, joint ventures or capital commitments by us, our collaborators or our competitors;
- actual or anticipated variations in quarterly operating results or our cash position;

- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- changes in accounting practices; and
- significant lawsuits, including patent or stockholder litigation.

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, operating results or financial condition.

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

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, our ability to pay

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cash dividends is currently restricted by the terms of our debt facility with Oxford and SVB, and future debt or other financing arrangements may contain 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.

Our Board members, management, and their affiliates, own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2022 December 31, 2023, our executive officers, directors and their affiliates beneficially hold, in the aggregate, approximately 22.0% 17.9% of our outstanding voting stock. These stockholders, acting together, are able to significantly influence all matters requiring stockholder approval. For example, these stockholders are able to significantly influence 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.

We As of December 31, 2023, we are no longer an "emerging growth company" and a "smaller reporting company," and we cannot be certain if the reduced reporting disclosure requirements applicable to emerging growth and smaller reporting companies will make our common stock less attractive no longer apply to investors. us.

We As of December 31, 2023, we are no longer an Emerging Growth Company ("EGC"), as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), enacted in April 2012. For as long as we continue . We are now subject to be an emerging growth company, we may take advantage of exemptions from various reporting certain disclosure requirements that are applicable to other public companies that are have not previously been applicable to us as an emerging growth companies. company and may incur

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additional significant legal, accounting and other expenses in relation to our status as a non-EGC. These exemptions requirements include:

- not being to perform system and process evaluation and testing of our internal control over financial reporting to allow our management to report on the effectiveness of our internal control over financial reporting. We will also be required to comply with have our independent registered public accounting firm issue an opinion on the auditor attestation requirements effectiveness of Section 404 our internal control over financial reporting on an annual basis if and when we lose our status as a "smaller reporting company". See Risk Factor titled "We expect to continue to incur increased costs as a result of the Sarbanes-Oxley Act of 2002, operating as amended ("Sarbanes-Oxley Act"); a public company, and our management is required to devote substantial time to new compliance initiatives." for additional information on this requirement;

- reduced additional disclosure obligations regarding executive compensation in our periodic reports and proxy statements;

- exemptions from compliance with the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved; and

- not being required to comply compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; and

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure. statements.

We In addition, we will remain an no longer be able to use the extended transition period for complying with new or revised accounting standards available to emerging growth company until the earlier of (1) December 31, 2023 (2) the last day companies and will be required to adopt new or revised accounting standards as of the fiscal year in which we have total annual gross revenue of at least $1.235 billion or (3) the last day of the fiscal year in which we effective dates for public companies. Such changes may require us to incur additional costs for compliance. See Risk Factor titled "We are deemed and expect to continue to be a large accelerated filer, which requires "smaller reporting company" as defined in the market value Exchange Act, and have elected and expect to continue to elect to take advantage of our common stock that is held by non-affiliates to exceed $700 million as certain of the last business date scaled disclosures available to smaller reporting companies, including reduced disclosure obligations regarding executive compensation" for additional information on scaled disclosure requirements.

We are and expect to continue to be a "smaller reporting company" as defined in the Exchange Act, and have elected and expect to continue to elect to take advantage of certain of the scaled disclosures available to smaller reporting companies, including reduced disclosure obligations regarding executive compensation.

While we are no longer an EGC, we are and expect to continue to be a "smaller reporting company" as defined in the Exchange Act, and have elected and expect to continue to elect to take advantage of certain of the scaled disclosures available to smaller reporting companies, including reduced disclosure obligations regarding executive compensation. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to audit our internal control over financial reporting for so long as we report less than $100 million in annual revenues for the most recently completed second recent fiscal quarter, year and (4) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period. may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. 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 common stock price may be more volatile.

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 irrevocably elected not to avail ourselves of delayed adoption of new or revised accounting standards and, therefore, we will be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

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We are also remain a "smaller reporting company" as defined in the Exchange Act, and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies.**company until our public float exceeds $250 million or our annual revenues exceed $100 million with a public float greater than $700 million.**

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. These rules and regulations have significantly increased our legal and financial

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compliance costs and we anticipate that these activities will become more time-consuming and costly over time. time now that we no longer qualify as an EGC.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are will be required to furnish a report by our management on our internal control over financial reporting, and, once we are no longer an EGC or a "smaller reporting company", we reporting. Our independent registered public accounting firm will not be required to furnish an attestation report on formally attest to the effectiveness of our internal control over financial reporting issued by our independent registered pursuant to Section 404 of the Sarbanes-Oxley Act until the date we report at least $100 million in annual revenues and have a public accounting firm. float of at least $75 million for the most recent fiscal year or have a public float of at least $700 million for the most recent fiscal year. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction to the trading price of our common stock in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an EGC or a "smaller reporting company", our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an EGC for up to five years following the completion of our IPO and will qualify as a "smaller reporting company" if the market value of our common stock held by non-affiliates is below $250 million (or $700 million if our annual revenue is less than $100 million) as of June 30 in any given year. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

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

Our management has broad discretion in the application of our existing cash, cash equivalents and marketable securities. Because of the number and variability of factors that will determine our use of our existing cash and cash equivalents, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash and cash equivalents in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business.

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

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

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

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you 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.

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If securities or industry analysts publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

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

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or

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disproportionate to the operating performance of these companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our amended and restated bylaws contain certain exclusive forum provisions requiring that substantially all disputes between us and our stockholders be resolved in certain judicial forums, which

could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the 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 the Delaware General Corporation Law, our certificate of incorporation or our bylaws, any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. In addition, our amended and restated bylaws contain a provision by virtue of which, unless we consent in writing to the selection of an alternative forum, the U.S. District Court for the District of Massachusetts will be the exclusive forum for any complaint asserting a cause of action arising under the Securities Act. 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, however, stockholders cannot and will not be deemed to have waived compliance with federal securities laws and the rules and regulations thereunder. We have chosen the U.S. District Court for the District of Massachusetts as the exclusive forum for such causes of action because our principal executive offices are located in Cambridge, Massachusetts. Some companies that have adopted similar federal district court forum selection provisions are currently subject to a suit in the Court of Chancery of the State of Delaware brought by stockholders who assert that the federal district court forum selection provision is not enforceable. While the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our federal forum selection provision, and we may incur additional costs of litigation should such enforceability be challenged. If the federal forum selection provision is otherwise found inapplicable to, or unenforceable in respect of, one or more of the specified actions or proceedings, we may incur additional costs, which could have an adverse effect on our business, financial condition or results of operations. We recognize that the federal district court forum selection clause may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general additional litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the Commonwealth of Massachusetts. Additionally, the choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers 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 our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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We have issued a substantial number of warrants and equity awards from our equity plans which are exercisable into shares of our common stock which could result in substantial dilution to the ownership interests of our existing stockholders.

As of December 31, 2022 December 31, 2023, approximately 10,459,181 9,988,156 shares of our common stock were reserved for issuance upon exercise or conversion of outstanding warrants. Additionally, 7,910,306 9,390,505 shares of our common stock were reserved for issuance upon exercise of outstanding stock options and vested restricted stock units. The exercise or conversion of these securities will result in a significant increase in the number of outstanding shares and substantially dilute the ownership interests of our existing stockholders. The shares underlying the equity awards from our equity plans are registered on a Form S-8 registration statement. As a result, upon vesting these shares can be freely exercised and sold in the public market upon issuance, subject to volume limitations applicable to affiliates. The exercise of options and the subsequent sale of the underlying common stock could cause a decline in our stock price. WeAs of December 31, 2023, we also have 27,689,692 19,534,997 shares of our common stock reserved for issuance upon exercise of pre-funded warrants, which are already included in our calculation of our weighted average common shares outstanding.

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Sales of a substantial number of shares of our common stock in the public market after the registered direct offering of June 2022 could cause our stock price to fall.

We sold 16,326,530 shares of common stock and pre-funded warrants to purchase 25,510,205 shares of common stock in our June 2022 registered direct offering. The sales of a substantial number of the shares and/or the exercise and sale of a substantial number of the pre-funded warrants in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. In addition, the sale of substantial amounts of our common stock could adversely impact the price of our common stock. The sale, or the availability for sale, of a large number of shares of our common stock in the public market could cause the price of our common stock to decline.As of December 31, 2023, 8,154,695 of the 27,689,692 pre-funded warrants have been exercised.

The sale or issuance of our common stock to, or through, Jefferies may cause significant dilution and the sale of the shares of common stock acquired by Jefferies, or the perception that such sales may occur, could cause the price of our common stock to fall.

On November 14, 2022, we entered into a sales agreement with Jefferies LLC ("Jefferies"), pursuant to which we may offer and sell our common stock, subject to certain limitations in the sales agreement and compliance with applicable law, at any time throughout the term of the sales agreement. The number of shares that are sold by Jefferies after delivering a placement notice will fluctuate based on the market price of the common stock during the sales period and limits we set with Jefferies. Because the price per share of each share sold will fluctuate based on the market price of our common stock during the sales period, it is not possible at this stage to predict the number of shares that will be ultimately issued. Sales to, or through, Jefferies by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

From November 14, 2022 January 1, 2023 through the date of the consolidated financial statements, December 31, 2022 December 31, 2023, we have not sold 619,290 shares of common stock through the Jeffries Jefferies sales agreement.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cyber Risk Management and Strategy

We have processes for assessing, identifying and managing cybersecurity risks, which are informed by industry standards and built into our overall enterprise risk management function and are designed to help protect our information assets and operations from internal and external cyber threats, and to protect employee, collaborator and patient information from unauthorized access or attack.

We maintain a team of internal and external information technology specialists who are responsible for the design, implementation, and operation of our information technology ecosystem and cybersecurity governance processes. We engage with certain external parties, including consultants, computer security firms and risk management advisors, peer companies, and industry groups in an effort to enhance our cybersecurity oversight and risk management strategy. We also use security technologies, including third-party solutions and monitoring tools that are designed to identify and mitigate cybersecurity risks. Further, we regularly engage third parties to conduct penetration testing, security assessments and tabletop exercises. We also engage a virtual chief information security officer ("vCISO") to support and advise on our cybersecurity program. We have a process to consider the internal risk oversight programs of critical third-party service providers before engagement, including through security questionnaires and contractual requirements, as appropriate. In addition, in an effort to deter and detect cyber threats, we have implemented an annual training program to provide employees with data protection, cybersecurity and incident response and prevention training.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. However, like other companies in our industry, we and our third-party vendors have from time to time experienced threats and security incidents that could affect our information or systems. For more information, please see the section entitled “Risk Factors.”

Governance Related to Cybersecurity Risks

The Audit Committee of our Board of Directors provides direct oversight over cybersecurity risk and provides updates to the Board of Directors regarding such oversight. The Audit Committee receives periodic updates from management, including from our Vice President, Information Technology, or the VP of IT, regarding cybersecurity matters, such as relevant cybersecurity risk assessments, as applicable. We have established a process for the Audit Committee to be notified in the event of significant cybersecurity threats or incidents.

The VP of IT leads the operational oversight of company-wide cybersecurity strategy, policies, processes, and support staff. Additionally, the VP of IT works across all relevant departments to assess and help prepare us and our employees to address cybersecurity risks. The VP of IT reports and provides regular updates to the Chief Operations Officer and Chief Financial Officer on the cybersecurity program as well as periodic updates to executive management, as needed. Our VP of IT has worked in the information technology field for over 19 years at biotechnology companies including publicly-traded organizations.

Item 2. Properties

Our corporate headquarters and operations are located in Cambridge, Massachusetts. In March 2015, we entered into a lease of laboratory and office space at 620 Memorial Drive in Cambridge, Massachusetts. Our amended lease expires expired in

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September 2023 and we have an option to extend the lease term for five additional years. 2023. This space has been was sublet beginning from February 1, 2021 to August 31, 2023.

In November 2019, we entered into a lease of laboratory and office space at 301 Binney Street in Cambridge, Massachusetts to be used as our new corporate headquarters. We were involved in the construction and design of the space. The expiration date is in August 2025 and we have the option to extend the term by two years. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings

From time to time, we are subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this Annual Report, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

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

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol "SRRK". Trading of our common stock commenced on May 24, 2018, following the completion of our IPO. Prior to that time, there was no established public trading market for our common stock.

Stockholders

As of March 2, 2023 March 14, 2024, there were approximately 8 seven stockholders of record of our common stock. This number does not include beneficial owners whose shares are held in street name.

Dividends

We have never declared or paid any dividends to our stockholders since our inception and we do not plan to declare or pay cash dividends in the foreseeable future. We currently anticipate that we will retain all available funds and any future earnings for the operation and expansion of our business. Furthermore, our ability to pay cash dividends is currently restricted by the terms of our debt facility with Oxford and SVB. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend on, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans under this item is incorporated herein by reference to Item 12 of Part III of this Annual Report. Report, such information to be provided in the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2023.

Unregistered Sales of Securities

Not applicable.

Issuer Purchases of Equity Securities

None.

Item 6. Reserved

Not applicable.

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

The information contained in this section has been derived from our consolidated financial statements and should be read together with our consolidated financial statements and related notes included elsewhere in this

Annual Report on Form 10-K. This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, the "Exchange Act" and are subject to the "safe harbor" created by those sections. In particular, statements contained in this Annual Report on Form 10-K that are not historical facts, including, but not limited to statements regarding our future expectations, plans and prospects, including without limitation, our expectations regarding the potential of the TGFβ program, the potential of apitegromab as a therapy in SMA and the timeline for and progress in developing apitegromab, the potential of SRK-181 as a cancer immunotherapy and the timeline for and progress in developing SRK-181, the potential for our anti-myostatin program as a therapy in cardiometabolic disorders, and liquidity, constitute forward-looking statements and are made under these safe harbor provisions. Some of the forward-looking statements can be identified by the use of forward-looking terms such as "believes," "expects," "may," "will," "should," "could," "seek," "intends," "plans," "estimates," "anticipates," or other comparable terms. Forward-looking statements involve inherent risks and uncertainties, which could cause actual results to differ materially from those in the forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. We urge you to consider the risks and uncertainties discussed in greater detail under the heading "Risk Factors" elsewhere in this Annual Report on Form 10-K in evaluating our forward-looking statements. We have no plans to update our forward-looking statements to reflect events or circumstances after the date of this report. As a result of many factors, including those factors set forth under the heading "Risk Factors" elsewhere in this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a late-stage biopharmaceutical company focused on the discovery, development, and development delivery of innovative medicines for the treatment of serious diseases in which signaling by protein growth factors plays a fundamental role. As a global leader in transforming growth factor beta ("TGFβ") superfamily biology, our novel understanding of the molecular mechanisms of growth factor activation enabled us to develop a proprietary platform for the discovery and development of monoclonal antibodies that locally and selectively target the precursor, or latent, forms of growth factors. By targeting the signaling proteins at the cellular level and acting in the disease microenvironment, we believe we may avoid the historical dose-limiting safety challenges associated with inhibiting growth factors for therapeutic effect. We believe our focus on biologically validated growth factors may facilitate a more efficient development path.

Based on this proprietary and scalable technology platform, we are building a growing portfolio of novel product candidates with the aim of transforming the lives of patients suffering from a wide range of serious diseases, including neuromuscular disorders, cardiometabolic disorders, cancer, fibrosis and iron-restricted anemia. We have discovered and progressed the development of:

- Apitegromab, an inhibitor investigational, fully human monoclonal antibody that inhibits myostatin activation by selectively binding the pro- and latent forms of the activation of latent myostatin in skeletal muscle and is being developed for the treatment of SMA. We also believe apitegromab could have potential in the treatment of other neuromuscular disorders where the inhibition of myostatin may be beneficial.

- SRK-439, a novel, preclinical, investigational myostatin inhibitor that has high invitro affinity for pro- and latent myostatin and maintains myostatin specificity and is being developed for the treatment of cardiometabolic disorders.
- SRK-181, an inhibitor of the activation of latent TGFβ1, that is being developed for the treatment of cancers that are resistant to anti-PD-(L)1 antibody therapies.
- Potent and selective inhibitors of the activation of TGFβ for the treatment of fibrotic diseases. We are advancing multiple antibody profiles toward product candidate selection including antibodies that selectively inhibit the activation of latent TGFβ1 in the context of fibrotic extracellular matrix and that avoid perturbing TGFβ1 presented by cells of the immune system.

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- Additional discovery and early preclinical programs related to the selective modulation of growth factor signaling including BMP6 and other growth factors.

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Our first product candidate, apitegromab, is a highly selective, fully human, monoclonal antibody with a unique mechanism of action that results in inhibition of the activation of the growth factor, myostatin, in skeletal muscle. Apitegromab is being developed as a potential first muscle-targeted therapy for the treatment of SMA. We are conducting SAPPHIRE, a pivotal Phase 3 clinical trial to evaluate the efficacy and safety of apitegromab in patients with nonambulatory Type 2 and Type 3 SMA (which is estimated to represent the majority of the current prevalent SMA patient population in the U.S. and Europe). We expect to complete completed enrollment of SAPPHIRE in 2023, with the top-line data readout expected in the fourth quarter of 2024. If successful and if apitegromab is approved, we expect to initiate a commercial product launch in 2025.

Apitegromab was evaluated in the Company's our Phase 2 TOPAZ proof-of-concept clinical trial for the treatment of patients with Type 2 and Type 3 SMA. Positive 12-month top-line results were initially announced in April 2021 2021. The Company has subsequently presented data from the TOPAZ trial over 24-months (June 2022) and presented at the Cure SMA Virtual Conference in June 2021. In June 2022, at the Cure SMA

Research & Clinical Care Meeting, we presented 24-month efficacy and safety extension data of apitegromab from TOPAZ. These data 36-months (July 2023), which showed sustained that continued improvement treatment with apitegromab for nonambulatory over the extended period was associated with substantial and sustained improvement in motor function, and patient-reported outcomes in patients with nonambulatory Types 2 and 3 SMA receiving an SMN therapy (see “Phase 2 TOPAZ Trial Analysis”). We expect to report 36-month extension data from TOPAZ in mid-2023. therapy. The FDA granted Fast Track fast track designation, Rare Pediatric Disease rare pediatric disease designation and Orphan Drug Designation orphan drug designation to apitegromab for the treatment of SMA in May 2021, August 2020 and March 2018, respectively. The EMA European Medicines Agency (“EMA”) granted PRIME designation in March 2021 and the EC European Commission (“EC”) granted Orphan Medicinal Product orphan medicinal product designation in December 2018 to apitegromab for the treatment of SMA.

In October 2023, we announced an expansion of our therapeutic focus into cardiometabolic disorders by advancing our anti-myostatin program with SRK-439, a novel, fully human anti-myostatin monoclonal antibody, for evaluation in cardiometabolic disorders, including obesity. We have identified multiple other diseases for which are developing SRK-039 towards a potential IND submission in 2025. To inform the selective inhibition development of the activation SRK-439, we plan to initiate a Phase 2 proof-of-concept trial of myostatin may offer therapeutic benefit, including additional patient populations apitegromab in SMA (such as Type 1 SMA and ambulatory SMA) and indications outside of SMA. combination with GLP-1 receptor agonist (GLP-1 RA) in 2024 with data expected in mid-2025.

Our second product candidate, SRK-181, a highly selective inhibitor of the activation of latent TGFβ, is being developed for the treatment of cancers that are resistant to CPI therapies, such as anti-PD-1 or anti-PD-L1 antibody therapies. therapies (referred to together as anti-PD-(L)1 antibody therapies). SRK-181 is a highly selective inhibitor of the activation of latent TGFβ1 that is being investigated was evaluated in our Phase 1 DRAGON proof-of-concept clinical trial in patients with locally advanced or metastatic solid tumors that exhibit resistance to anti-PD-(L)1 antibodies. antibody therapies. We completed enrollment of the DRAGON trial in December 2023. This two-part clinical trial consists of a dose escalation portion (Part A) and a dose expansion portion evaluating SRK-181 in combination with an approved anti-PD-(L)1 antibody therapy (Part B). Part B commenced in 2021 and includes the following active cohorts: urothelial carcinoma, cutaneous melanoma, non-small cell lung cancer, clear cell renal cell carcinoma ccRCC, and head HNSCC. Safety, efficacy and neck squamous cell carcinoma. Initial clinical biomarker data from Part A were presented in November 2021 2023 at the SITC 36 38th Annual Meeting and additional Meeting. We believe that the DRAGON trial achieved its study objectives by showing objective, durable clinical responses in patients with ccRCC resistant to PD-1 therapy above what is expected from continuing PD-1 alone. It is anticipated that emerging data were from the DRAGON trial will be presented at medical meetings in the 2022 SITC Annual Meeting in November 2022. future.

Utilizing

Using our innovative approach and proprietary platform, we have multiple early stage are creating a pipeline of novel product candidates that selectively modulate the activation of growth factors implicated in a variety of serious diseases, including neuromuscular disorders, cardiometabolic disorders, cancer, fibrosis, and preclinical programs directed against targets that are known iron-restricted anemia. Our proprietary platform is designed to be important in serious diseases. We are discovering and generating generate highly selective and differentiated monoclonal antibodies against difficult targets by 1) applying our that target the growth factor’s

latent precursor form prior to its activation within the disease microenvironment, or tissue where it is localized. Our structural insights and unique antibody discovery expertise, 2) prioritizing human biology, and 3) embedding translational thinking early in the research and development process. capabilities can also be applied to other protein classes beyond growth factors, with an aim of generating differentiated candidates targeting cell surface receptors such as immune cell receptors or G-protein coupled receptors, where selectivity remains challenging.

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Since inception, we have incurred significant operating losses. Our net losses were $134.5 million $165.8 million for the year ended December 31, 2022 December 31, 2023. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $510.6 million $676.4 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future in performing our ongoing activities, as we:

- continue development activities for apitegromab, including the conduct of the extension phase of our Phase 2 TOPAZ clinical trial, our Phase 3 SAPPHIRE pivotal clinical trial in SMA, ONYX, our open-label long-term extension study of apitegromab for patients from both the TOPAZ and SAPPHIRE studies and the associated drug supply;
- continue research and development activities for SRK-181, including the conduct of our Phase 1 DRAGON proof of concept proof-of-concept clinical trial;
- continue research and development activities for our cardiometabolic program, including the proof-of-concept Phase 2 trial with apitegromab and advancing SRK-439 towards a potential IND submission in 2025;
- continue to discover, validate and develop additional product candidates through the use of our proprietary platform;
- maintain, expand and protect our intellectual property portfolio;
- hire additional research, development, commercial and other business personnel; and
- continue to build the infrastructure to support our operations as a public company.

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To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. sales. If we successfully complete clinical development and obtain regulatory approval for apitegromab, SRK-181, SRK-439 or any of our future product candidates, we may generate revenue in the future from product sales. In addition, if we obtain regulatory approval for apitegromab, SRK-181, SRK-439 or any of our future product candidates, we expect to incur significant expenses related to developing our commercialization capabilities to support product sales, marketing and distribution activities.

Restructuring

In May 2022, we announced a reduction in workforce in connection with the restructuring of our business to prioritize and focus on our clinical stage assets. The restructuring resulted in a reduction of our workforce by 39 positions, or approximately 25%, and occurred during the second quarter of 2022. As a result, we recorded restructuring costs of $1.9 million in the second quarter of 2022, related to severance benefits for the affected employees, including salary continuation, coverage of medical insurance premiums and outplacement services. We also incurred $0.1 million of non-cash expense related to equity modifications associated with the extension of the post-termination option exercise period for the vested portion of the affected employees' outstanding stock options, as well as modifications of certain restricted stock units. All the employees affected by the restructuring plan were notified and provided with their severance benefits offers in the second quarter of 2022, although severance benefits payments associated with the restructuring plan continued through the end of 2022. Each affected employee's eligibility for the severance benefits was contingent upon such employee's execution (without revocation, as applicable) of a separation agreement, which included a general release of claims against us and affiliated persons and entities. All employees impacted by the restructuring plan provided such releases.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus, or COVID-19, as a pandemic (the "COVID-19 pandemic"). The ultimate extent of the impact of the COVID-19 pandemic or any other epidemic, pandemic, outbreak, or public health crisis on our business, financial condition and results of operations will depend on future developments, including new information that may emerge concerning the severity of such epidemic, pandemic, outbreak, or public health crisis and actions taken to contain or prevent the further spread, including the development of new variants of COVID-19 and development and deployment of vaccines to effectively treat COVID-19 and any new variants. The COVID-19 pandemic has negatively impacted our business, and at various times during the COVID-19 pandemic, we have experienced disruptions or restrictions on our preclinical studies, our ability to access and monitor certain clinical trial sites, restrictions on clinical trial participants' ability to access our clinical trial sites and delays in enrollment. Some clinical trial participants have missed or experienced delays in receiving doses of study drug and completing their clinical trial assessments. While our laboratory operations have resumed to normal capacity, we may continue to experience challenges in procuring materials and supplies, as well as research services from our vendors in a consistently timely manner due to COVID-19 related supply chain issues. We continue to monitor developments as we adjust to the disruptions and uncertainties relating to the COVID-19 pandemic.

Financial Operations Overview

Revenue

No revenues have been recorded from the sale of any commercial product. Revenue generation activities have been limited to collaborations, containing research services and the issuance of a license. The Gilead Collaboration Agreement was executed on December 19, 2018 (the “Effective Date”) and we began recognizing associated revenue in

2019. Under the Gilead Collaboration Agreement, Gilead had exclusive options to license worldwide rights to product candidates that emerged from three of our TGFβ programs (each a “Gilead Program”). Each option could have been exercised by Gilead at any time from the Effective Date through a date that was 90 days following the expiration of the Research Collaboration Term for a given Gilead Program (no later than March 19, 2022), or until termination of the Gilead Program, whichever was earlier (the “Option Exercise Period”). On January 6, 2022, Gilead agreed to terminate its option exercise period for all programs. programs and the rights to the respective antibodies reverted to us.

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Revenue associated with the research and development and license performance obligations relating to the Gilead Programs was recognized as revenue using an input method as the research and development services were provided over the research term, which was during the period January 2019 through December 2021. The input method was based on the costs that were incurred on each Gilead Program and the costs that were expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurred over time. In management’s judgment, this input method was the best measure of progress towards satisfying the performance obligations. We evaluated the measure of progress each reporting period and, if necessary, adjusted the measure of performance and related revenue recognition. The estimate of remaining costs was highly subjective, as the research was novel, therefore efforts to be successful may have been significantly different than the estimated costs made at each balance sheet date. The amounts of revenue allocated to the three material rights provided by the options was to be deferred on our consolidated balance sheet until either exercise or termination of the respective options. In January 2022, Gilead agreed that its option exercise period for all programs had been terminated. The remaining $33.2 million of deferred revenue associated with the materials rights provided by the options was recognized as revenue in January 2022. As a result, by January 31, 2022, all revenue related to the Gilead Collaboration Agreement had been recognized.

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Operating Expenses

Research and Development

Research and development expenses consist primarily of costs incurred for our research and development activities, including our product candidate discovery efforts, preclinical studies, manufacturing, and clinical trials under our research programs, which include:

- employee-related expenses, including salaries, benefits and equity-based compensation expense for our research and development personnel;
- expenses incurred under agreements with third parties that conduct research and development and preclinical activities on our behalf;
- expenses incurred under agreements related to our clinical trials, including the costs for investigative sites and CROs, contract research organizations ("CROs"), that conduct our clinical trials;
- manufacturing process-development, manufacturing of clinical supplies and technology-transfer expenses;
- consulting and professional fees related to research and development activities;
- costs of purchasing laboratory supplies and non-capital equipment used in our internal research and development activities;
- costs related to compliance with clinical regulatory requirements; and
- facility costs and other allocated expenses, which include expenses for rent and maintenance of facilities, insurance, depreciation and other supplies.

Research and development costs are expensed as incurred. Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks. Nonrefundable advance payments for research and development goods and services to be received in the future from third parties are deferred and capitalized. The capitalized amounts are expensed as the related services are performed.

A significant portion of our research and development costs have been external costs, which we track on a program-by-program basis after a clinical product candidate has been identified. However, we do not allocate our internal research and development expenses, consisting primarily of employee related employee-related costs, depreciation and other indirect costs, on a program-by-program basis as they are deployed across multiple projects.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, as well as the associated clinical trial material requirements. We expect research and development costs for our product candidates to continue to be substantial for the foreseeable future as the development programs progress. However, we do not believe that it is possible at this time to

accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

The successful development of apitegromab, SRK-181, SRK-439 and any future product candidates is uncertain. Accordingly, at this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of apitegromab, SRK-181, SRK-439 and any future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale

of our product candidates, if approved. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities, if any;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- significant and changing government regulation;
- commercializing the product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of apitegromab, SRK-181, SRK-439 or any of our future product candidates could significantly change the costs and timing associated with the development of that product candidate.

General and Administrative

General and administrative expenses consist primarily of employee-related expenses, including salaries, benefits and equity-based compensation expenses for personnel in executive, finance, business development, investor relations, legal, information technology and human resources functions. Other significant general and administrative expenses include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and fees for accounting, consulting services, and corporate expenses.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on our cash, cash equivalents and marketable securities, partially offset by interest expense incurred on our debt facility, including amortization of debt discount and debt issuance costs partially offset by interest income earned on our cash, cash equivalents and marketable securities.

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Results of Operations

Comparison of the Years Ended December 31, 2022 December 31, 2023 and 2021 2022

The following table summarizes our results of operations for the years ended December 31, 2022 December 31, 2023 and 2021 2022 (in thousands, except percentages):

	Year Ended December 31,		Change		Year Ended December 31,		Change	
	2022	2021	$	%	2023	2022	$	%
Revenue	$ 33,193	$ 18,816	$14,377	76.4 %	$ —	$ 33,193	$(33,193)	(100.0)%
Operating expenses:								
Research and development	124,444	108,468	15,976	14.7 %	121,900	124,444	(2,544)	(2.0)%
General and administrative	43,119	40,269	2,850	7.1 %	49,395	43,119	6,276	14.6 %

Total operating expenses	167,563	148,737	18,826	12.7 %	171,295	167,563	3,732	2.2 %
Loss from operations	(134,370)	(129,921)	(4,449)	3.4 %	(171,295)	(134,370)	(36,925)	27.5 %
Other income (expense), net	(132)	(1,878)	1,746	(93.0)%	5,506	(132)	5,638	(4,271.2)%
Net loss	$(134,502)	$(131,799)	$ (2,703)	2.1 %	$(165,789)	$(134,502)	$(31,287)	23.3 %

Revenue

Revenue was $0 and $33.2 million for the years ended December 31, 2023 and 2022, respectively. The revenue for the year ended December 31, 2022 compared to $18.8 million for the year ended December 31, 2021, an increase of $14.4 million, or 76.4%. The revenue for both periods was related to the Gilead Collaboration Agreement executed in December 2018. Revenue recognized during the year ended December 31, 2022, was attributable to the material rights provided by the options, which was recognized in January 2022 upon Upon Gilead's termination of its option exercise period for all programs. Revenue recognized during the year ended December 31, 2021, was related programs, revenue of $33.2 million attributable to the research and development and license performance obligations, which material rights was recognized using a cost input method as the research and development services were provided. This revenue was fully recognized as of December 31, 2021. in January 2022. All revenue related to the Gilead Collaboration Agreement had been fully recognized by January 31, 2022.

Operating Expenses

Research and Development

Research and development expense was $121.9 million for the year ended December 31, 2023 compared to $124.4 million for the year ended December 31, 2022 compared to $108.5 million for the year ended December 31, 2021, an increase a decrease of $16.0 million $2.5 million, or 14.7% 2.0%. The following table summarizes our research and development expense for the years ended December 31, 2022 December 31, 2023 and 2021 2022 (in thousands, except percentages):

	Year Ended December 31,		Change		Year Ended December 31,		Change	
	2022	2021	$	%	2023	2022	$	%
External costs by program:								
Apitegromab	$ 48,044	$ 38,141	$ 9,903	26.0 %	$ 40,701	$ 48,044	$(7,343)	(15.3)%
SRK-181	12,462	13,999	(1,537)	(11.0)%	14,200	12,462	1,738	13.9 %
Other early programs and unallocated costs	6,175	7,378	(1,203)	(16.3)%	5,818	6,175	(357)	(5.8)%
Total external costs	66,681	59,518	7,163	12.0 %	60,719	66,681	(5,962)	(8.9)%
Internal costs:								

Employee compensation and benefits	41,370	32,487	8,883	27.3 %	44,594	41,370	3,224	7.8 %
Facility and other	16,393	16,463	(70)	(0.4)%	16,587	16,393	194	1.2 %
Total internal costs	57,763	48,950	8,813	18.0 %	61,181	57,763	3,418	5.9 %
Total research and development expense	$124,444	$108,468	$15,976	14.7 %	$121,900	$124,444	$(2,544)	(2.0)%

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The increase decrease in research and development expense was primarily attributable to the following:

- An increase A decrease in our external research and development costs of $7.2 million $6.0 million, which primarily consisted of:
  - $9.9 7.3 million increase decrease in costs associated with apitegromab primarily due to a decrease in clinical drug supply manufacturing driven by timing of clinical supply, partially offset by clinical trial costs,

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particularly the conduct of our Phase 3 SAPPHIRE clinical trial and ONYX, our long-term extension study for patients from both the TOPAZ and SAPPHIRE studies;

- $1.5 1.7 million decrease increase in costs associated with SRK-181, due primarily to greater clinical trial costs and associated purchases of pembrolizumab (to be used in conjunction with SRK-181 in Part B of related to the Phase 1 DRAGON clinical trial) in the prior year; trial, partially offset by lower costs due to timing of clinical drug supply costs; and
- $1.2 0.4 million decrease in costs in other early development candidates and unallocated costs, which is mostly related to prior year expense associated with the purchase of our customized antibody display library from Specifica; costs;

- $8.8 3.4 million increase in internal research and development costs, which was primarily driven by an increase in employee compensation and benefits costs. These costs, include including salaries and bonus, payroll taxes, benefits, and an increase in temporary support, partially offset by decreases in severance expense and non-cash equity-based compensation expense, including for modifications of certain equity awards, as well as severance expense associated with the May 2022 restructuring. awards.

Total research and development expenses are expected to continue to be substantial, driven by employee compensation costs and development costs associated with our clinical stage programs as we continue to advance our product candidates, including apitegromab through our Phase 3 SAPPHIRE clinical trial the extension phase of our Phase 2 TOPAZ clinical trial in SMA and ONYX, our open-label long-term extension study for patients from both the TOPAZ and SAPPHIRE studies and costs associated with supporting our cardiometabolic program, including our planned Phase 2 study of apitegromab and our preclinical program, SRK-439. Additionally, we will continue to invest in our pipeline. We expect costs of our SRK-181 through our program to decrease, as we completed enrollment of the Phase 1 DRAGON clinical trial. trial in December 2023.

General and Administrative

General and administrative expense was $49.4 million for the year ended December 31, 2023 compared to $43.1 million for the year ended December 31, 2022 compared to $40.3 million for the year ended December 31, 2021, an increase of $2.9 million $6.3 million or 7.1% 14.6%. The increase in general and administrative expense was primarily attributable to an increase of $1.9 million in associated with employee compensation and benefits mostly related to costs including salaries, bonus, benefits and non-cash equity-based compensation and expense related to increased headcount, in addition to an increase of $0.9 million in professional fees. services costs. We expect general and administrative expense to increase as we continue to invest in commercial readiness activities. activities.

Other Income (Expense), Net

The change in other income (expense), net was primarily attributable to an increase in interest income earned due to higher average interest rates, and higher balances in our cash, cash equivalents and marketable securities, partially offset by an increase in interest expense related to the Loan and Security Agreement, also due to higher interest rates and a higher principal balance as Tranche 2 was received in December 2021.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any product revenue and have incurred significant operating losses and negative cash flows from our operations. We have funded our operations to date primarily with proceeds from the sale of our convertible preferred stock and units in private placements before our IPO, and sale of our common stock through our IPO in 2018, to Gilead in an exempt private placement, through multiple secondary public offerings and through an at-the-market (“ATM”) sale, sales, as well as payments from our research collaborations and the Loan and Security Agreement entered into in October 2020 and amended in November 2022 and April 2023 (see Note 12) 13).

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The following table provides information regarding our total cash, cash equivalents and marketable securities at December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022 (in thousands):

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 103,275	$ 212,835	$ 101,855	$ 103,275
Marketable securities	212,086	40,159	178,083	212,086
Total cash, cash equivalents and marketable securities	$ 315,361	$ 252,994	$ 279,938	$ 315,361

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During the year ended December 31, 2022 December 31, 2023, our cash, cash equivalents and marketable securities balance increased decreased by $62.4 million $35.4 million. The change was primarily the result of net proceeds from our equity offering completed in June 2022, partially offset by due to cash used to operate our business, including payments related to, among other things, research and development and general and administrative expenses as we continued to invest in our product candidates and supported our internal research and development efforts capital purchases, and made interest payments on our debt. debt, partially offset by proceeds from the sale of common stock (including our equity offering completed in October 2023) and exercises of warrants and stock options.

Our current ATM program, established in November 2022, allows for the sale of shares of our common stock having an aggregate offering price of up to $100 million. During the year ended and as of December 31, 2023, we sold 619,290 shares of our common stock through sales under our ATM program with Jefferies, LLC, and received $5.2 million in net proceeds, after deducting commissions and fees. In October 2021, we sold 500,000

shares of our common stock through a sale in our prior ATM program (in place between March 2021 and June 2022) and received $13.1 million in net proceeds, after deducting commissions and fees.

On October 11, 2023, we entered into the Underwriting Agreement with J.P. Morgan Securities LLC, and Piper Sandler & Co., as representatives of the several underwriters named therein, relating to the issuance and sale of an aggregate of 12,408,760 shares of our common stock at $6.85 per share. Pursuant to the Underwriting Agreement, we also granted the Underwriters a 30-day option to purchase up to 1,861,314 additional shares in an amount equal to 15% of the securities offered in the public offering (the “Option Shares”) of common stock. The Underwriters exercised in full their option to purchase the Option Shares on October 12, 2023. Total proceeds of the transaction, including the Option Shares were approximately $92.4 million, net of underwriting discounts and estimated offering expenses. The offering closed on October 16, 2023.

In June 2022, we entered into a securities purchase agreement relating to the issuance and sale of an aggregate of 16,326,530 shares of our common stock, pre-funded warrants to purchase 25,510,205 shares of our common stock and associated common warrants to purchase 10,459,181 shares of our common stock. The offering price per share and associated common warrant was $4.90 and the offering price per pre-funded warrant and associated common warrant is $4.8999, which equals the per share public offering price for the common shares less the $0.0001 exercise price for each such pre-funded warrant and associated common warrant. Each common warrant has an exercise price per share of $7.35 (150% of the offering price per share of the common stock). Gross proceeds from the transaction were $205.0 million. Upon the offering closing, we received $195.3 million in net proceeds, after deducting placement agent fees and expenses and offering expenses.

In October 2021, we sold 500,000 shares of our common stock through a sale in our ATM program with Jefferies, LLC, and received $13.1 million in net proceeds, after deducting commissions and fees.

In October 2020, we entered into an underwriting agreement relating to the issuance and sale of an aggregate of 3,717,948 shares of our common stock at $39.00 per share and pre-funded warrants to purchase 2,179,487 shares of our common stock. The price of each pre-funded warrant was $38.9999, which equals the per share public offering price for the common shares less the $0.0001 exercise price for each such pre-funded warrant. Gross proceeds of the transaction were $230.0 million. The offering closed in November 2020 and we received $215.9 million in net proceeds, after deducting underwriting discounts and commissions and offering expenses.

In October 2020, we entered into the Loan and Security Agreement with Oxford and SVB, which was amended in November 2022, for $100 million of which $25.0 million from Tranche 1 was received in October 2020 and $25.0 million from Tranche 2 was received in December 2021 (Note 12) 13).

In June and July 2019, we sold 3,450,000 shares of our common stock through an underwritten public offering. As a result of the offering, we received aggregate net proceeds, after underwriting discounts and commissions and other offering expenses, of $48.3 million.

In December 2018, we entered into the Gilead Collaboration Agreement pursuant to which we conducted research and pre-clinical preclinical development activities relating to the diagnosis, treatment, cure, mitigation or prevention of diseases, disorders or conditions, other than in the field of oncology in accordance with a pre-

determined research plan. Pursuant to the Gilead Collaboration Agreement, Gilead made non-refundable payments of $80.0 million, including an upfront payment and an equity investment. In December 2019, we achieved a $25.0 million preclinical milestone for the successful demonstration of efficacy in preclinical *in vivo* proof-of-concept studies, and subsequently received the associated payment in January 2020. Revenue was recognized during the period January 2019 through December 2021, as research and development services were provided. All revenue related to the Gilead Collaboration Agreement had been fully recognized by January 31, 2022, upon the termination of Gilead's option exercise period (Note 14).

During the year ended December 31, 2023, 8,154,695 of the Company's pre-funded warrants were exercised. As of December 31, 2023, the Company had 19,534,997 pre-funded warrants outstanding.

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During the year ended December 31, 2023, 471,025 of the Company's common warrants were exercised. As of December 31, 2023, the Company had 9,998,156 common warrants outstanding.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Net cash used in operating activities	$ (132,694)	$ (126,789)	$(145,226)	$(132,694)
Net cash (used in) provided by investing activities	(171,698)	134,315		
Net cash provided by (used in) investing activities			41,141	(171,698)
Net cash provided by financing activities	194,832	44,951	102,574	194,832
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (109,560)	$ 52,477		
Net decrease in cash, cash equivalents and restricted cash			$ (1,511)	$(109,560)

Net Cash Used in Operating Activities

Net cash used in operating activities was $145.2 million for the year ended December 31, 2023, and consisted of our net loss of $165.8 million, changes in our assets and liabilities of $10.6 million, partially offset by non-cash adjustments of $31.2 million. The non-cash adjustments are primarily from equity-based compensation.

Net cash used in operating activities was $132.7 million for the year ended December 31, 2022, and consisted of our net loss of $134.5 million, changes in our assets and liabilities of $34.4 million, partially offset by non-cash adjustments of $36.2 million. The changes in our assets and liabilities include a $33.2 million change in deferred revenue related to the Gilead collaboration, which relates to the recognition of revenue associated with the material rights provided by the options. The non-cash adjustments are primarily from equity-based compensation.

Net Cash Provided by (Used in) Investing Activities

Net cash used in operating provided by investing activities was $126.8 million $41.1 million for the year ended December 31, 2021 December 31, 2023, and consisted of our compared to net loss of $131.8 million, changes in our assets and liabilities of $28.4 million, partially offset by non-cash adjustments of $33.5 million. The changes in our assets and liabilities include a $18.8 million change in deferred revenue related to the Gilead collaboration. The non-cash adjustments are primarily from equity-based compensation.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was of $171.7 million for the year ended December 31, 2022, compared to net. Net cash provided by investing activities of $134.3 million for the year ended December 31, 2021. Net cash and used in and provided by investing activities for both periods was primarily associated with transactions involved in the routine management of our marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $102.6 million for the year ended December 31, 2023, compared to $194.8 million for the year ended December 31, 2022, compared to $45.0 million. Net cash provided by financing activities for the year ended December 31, 2021 December 31, 2023 was primarily attributable to net proceeds from an equity offering completed in October 2023. Net cash provided by financing activities for the year ended December 31, 2022 was primarily attributable to net proceeds from an equity offering completed in June 2022. Net cash provided by financing activities for the year ended December 31, 2021, consisted primarily of the second $25.0 million drawdown from our Loan and Security Agreement, $13.1 million in net proceeds from the sale of our common stock in an ATM sale completed in October 2021, as well as $6.9 million in proceeds from stock option exercises.

Funding Requirements

We expect our expenses to continue to be substantial as we continue the research and development for, continue and initiate later stage clinical trials for, continue to develop and optimize our manufacturing processes for, and of apitegromab in SMA. In addition, if we seek marketing approval for our product candidates, including apitegromab, and SRK-181, and any of our future product candidates. In addition, if we obtain marketing approval for apitegromab, SRK-181 or any of our future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We expect to continue to incur costs related to SRK-181 as we continue to treat patients who remain on the Phase 1 DRAGON trial. We expect to incur costs to support our cardiometabolic program, including our planned Phase 2 trial of apitegromab and our preclinical program, SRK-439. Additionally, we will support the development of our

pipeline and any other preclinical programs. Furthermore, we expect to continue to incur costs associated with operating as a public company.

We expect that our existing cash, cash equivalents, and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2025. However, we will require additional capital in order

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to complete clinical development and commercialization for each of our current programs. We have based this estimate on

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assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the costs and timing of developing our product candidates and future product candidates, including costs associated with apitegromab and SRK-181, including in our Phase 3 SAPPHIRE clinical in SMA and ONYX, our long-term extension study in SMA for patients from both the TOPAZ and SAPPHIRE studies, our Phase 2 proof-of-concept trial for apitegromab in SMA, the extension phase of our Phase 2 TOPAZ clinical trial for apitegromab in SMA, the open-label extension study for apitegromab and the cardiometabolic program, our Phase 1 DRAGON clinical trial for SRK-181, and the costs and timing of conducting future preclinical studies and clinical trials; trials for SRK-439 or any other product candidates;
- the costs of future manufacturing of apitegromab, SRK-181, SRK-439 and any other future product candidates; including impacts from the COVID-19 pandemic and its impact at our contract manufacturers;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing and clinical trials for other potential product candidates we may develop, if any;
- the costs of identifying and developing, or in-licensing or acquiring, additional product candidates and technologies;

- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements, license agreements, or other agreements we might have at such time;
- the costs of seeking marketing approvals for our product candidates that successfully complete clinical trials, if any;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and research and development activities;
- the costs of supporting our infrastructure and facilities, including equipment and physical infrastructure to support our research and development; and
- the costs of operating as a public company. company; and
- the impact of adverse global economic conditions on our business, which may exacerbate the magnitude of the factors discussed above.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, common stockholder ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of a common stockholder. Additional debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

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If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to

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grant licenses on terms that may not be favorable to us. Market volatility or other factors could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate 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.

Critical Accounting Estimates

This management's discussion and analysis is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgements about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this report, we believe that the following accounting estimates are those most critical to the judgments used in the preparation of our consolidated financial statements. They involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our finance condition or result of operations.

Accrued Research and Development Expenses and related Accruals/Prepaids

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and/or reviewing other third-party sources to identify the

progress of services that have has been performed on our behalf, as well as invoices received and contracted costs. This contributes to 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 cost.

The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. In certain instances, we prepay for services to be provided in the future. These amounts are expensed as the services are performed.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Nonrefundable advance payments for goods and services that will be used in future research and

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development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us

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reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

The accrued research and development expenses at the end of each year are generally paid during the following year and therefore the same estimates and assumptions do not continue to exist each year, although, as described above, the method and procedures to develop those estimates and assumptions are generally consistent.

Revenue Recognition

No revenues have been recorded from the sale of any commercial product. Revenue generation activities have been limited to collaborations, containing research services and the issuance of a license. Prior to January 2022, revenue was being recognized related to the Gilead Collaboration Agreement which was executed in December 2018. We recognized associated revenue between 2019 and 2021 over the period that research was performed under the collaboration and recognized revenue attributable to the material rights provided by the options in January 2022. We account for revenue under ASC Topic 606, Revenue from Contracts with Customers (“ASC 606”).

Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the contract(s) with the customer, (ii) identification of the promised goods or services in the contract and determination of whether the promised goods or services are performance obligations, (iii) measurement of the transaction price, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to our customer.

Identification of the Contract(s) with the Customer

We account for a contract with a customer that is within the scope of ASC 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations, (ii) each party's party’s rights regarding the goods or services to be transferred can be identified, (iii) the payment terms for the goods or services to be transferred can be identified, (iv) the arrangement has commercial substance and (v) collection of substantially all of the consideration to which we will be entitled in exchange for the goods or services that will be transferred to the customer is probable.

Identification of the Performance Obligations

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when: (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual

property, the capabilities of our customer to develop the intellectual property on their own and whether the required expertise is readily available. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. We assess if these options provide a material right to the customer and if so, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying license relative to the option exercise price, including assumptions about technical feasibility and the probability of developing a candidate that would be subject to the option rights.

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Determination of the Transaction Price

We estimate the transaction price based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the amount of the

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potential payments and the likelihood that the payments will be received. We utilize either the most likely amount method or expected value method to estimate the transaction price based on which method better predicts the amount of consideration expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

We evaluate whether development, regulatory, and commercial milestone payments are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of such milestones

and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue and earnings in the period of adjustment.

For sales-based royalties, including milestone payments based on the level of sales, we determine whether the sole or predominant item to which the royalties relate is a license. When the license is the sole or predominant item to which the sales-based royalty relates, we recognize revenue at the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any sales-based royalty revenue resulting from our arrangement.

Allocation of Transaction Price

We allocate the transaction price based on the estimated standalone selling price. We must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Estimating costs for research and development programs is subjective as we estimate the costs anticipated to successfully complete the research performance obligations. As the research is novel, efforts to be successful may be significantly different than the estimated costs at the beginning of the contract. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts we would expect to receive for satisfying each performance obligation.

Recognition of Revenue

We utilize judgment to determine whether the performance obligation is satisfied over time or at a point in time. We determine the appropriate method of measuring progress performance obligations satisfied over time for purposes of recognizing revenue, such as by using an input method based on costs incurred compared to the costs expected to be incurred in the future to satisfy the performance obligation. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. The estimated remaining costs is highly subjective, as the research is novel, therefore efforts to be successful may be significantly different than the estimated costs made at the balance sheet date. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

We receive payments from customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional.

As it relates to the Gilead Collaboration Agreement, the Company recognized the revenue related to the research and development services based on a cost input method over the research term for each respective Gilead Program. We evaluated the measure of progress each reporting period and, if necessary, adjusted the measure of performance and

related revenue recognition. The estimate of remaining costs was highly subjective, as the research was novel, and efforts to be successful may have been significantly different than the estimated costs made at each balance sheet date.

Recent Accounting Pronouncements

We have reviewed all recently issued standards and have determined that, other than Recently Issued Accounting Pronouncements as disclosed in Note 2 to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, such standards will not have a material impact on our financial statements or do not otherwise apply to our operations.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

Our financial statements, together with the report of our independent registered public accounting firm, appear in this Annual Report beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our chief executive officer (principal executive officer) and chief financial officer (principal financial and accounting officer), has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022 December 31, 2023, the end of the period covered by this Annual Report on Form 10-K. Based upon such evaluation, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date. We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a–15(f) and 15d-15(d) under the Exchange Act. Our internal control

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system was designed to provide reasonable assurance to our management and our Board regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance

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with respect to financial statement preparation and presentation. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022 December 31, 2023. In making this assessment, our management used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013 ("COSO criteria"). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2022 December 31, 2023. This Annual Report on Form 10-K does not include an attestation report pursuant to the requirements of our independent registered public accounting firm due to a transition period established by rules Section 404(b) of the SEC for "emerging growth companies". Sarbanes-Oxley Act of as we qualify as a "smaller reporting company" and as such, are exempt from such auditor attestation requirement.

Changes in Internal Controls Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the year ended December 31, 2022 December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2022 December 31, 2023.

Item 11. Executive Compensation

The information required under this item (excluding the information under the heading "Pay Versus Performance") is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2022 December 31, 2023.

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

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2022 December 31, 2023.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2022 December 31, 2023.

Item 14. Principal Accountant Fees and Services

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2022 December 31, 2023.

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PART IV

Item 15. Exhibits, Financial Statements and Schedules

(a)(1) Financial Statements.

Our consolidated financial statements and notes thereto, together with the Reports of Independent Registered Public Accounting Firm are included in Item 8 of this Annual Report on Form 10-K commencing on page F-1.

(a)(2) Financial Statement Schedules.

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements or the notes thereto or is not applicable or required.

(a)(3) Exhibits.

The following exhibits are included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 (and are numbered in accordance with Item 601 of Regulation S-K):

Number	Description	Form	File No.	Exhibit No.	Filing Date	Description	Form	File No.	Exhibit No.	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-224493	3.2	May 8, 2018	Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-224493	3.2	May 8, 2018
3.2	Amendment to Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-224493	3.1.1	May 14, 2018	Amendment to Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-224493	3.1.1	May 14, 2018
3.3	Amended and Restated By-laws of the Registrant	S-1/A	333-224493	3.4	May 8, 2018	Amended and Restated By-laws of the Registrant	S-1/A	333-224493	3.4	May 8, 2018

4.1	Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 22, 2017	S-1	333-224493	4.1	April 27, 2018		Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 22, 2017	S-1	333-224493	4.1	April 27, 2018	
4.2	Specimen Stock Certificate evidencing shares of common stock	S-1/A	333-224493	4.2	May 14, 2018		Specimen Stock Certificate evidencing shares of common stock	S-1/A	333-224493	4.2	May 14, 2018	
4.3	Amended and Restated Warrant to Purchase Stock, by and between Silicon Valley Bank and the Registrant, dated December 22, 2017	S-1	333-224493	4.3	April 27, 2018		Amended and Restated Warrant to Purchase Stock, by and between Silicon Valley Bank and the Registrant, dated December 22, 2017	S-1	333-224493	4.3	April 27, 2018	
4.4	Description of Capital Stock	10-K	001-38501	4.4	March 12, 2020		Description of Capital Stock	10-K	001-38501	4.4	March 12, 2020	
4.5	Form of Pre-Funded Warrant	8-K	001-38501	4.1	June 21, 2022		Form of Pre-Funded Warrant	8-K	001-38501	4.1	June 21, 2022	
4.6	Form of Common Stock Warrant	8-K	001-38501	4.2	June 21, 2022		Form of Common Stock Warrant	8-K	001-38501	4.2	June 21, 2022	

10.1+	2017 Stock Option and Incentive Plan and forms of award agreements thereunder	S-1	333-224493	10.1	April 27, 2018		2017 Stock Option and Incentive Plan and forms of award agreements thereunder	S-1	333-224493	10.1	April 27, 2018	
10.2+	2018 Stock Option and Incentive Plan and forms of award agreements thereunder	S-1/A	333-224493	10.2	May 14, 2018		2018 Stock Option and Incentive Plan and forms of award agreements thereunder	S-1/A	333-224493	10.2	May 14, 2018	
10.3+	Senior Executive Cash Incentive Bonus Plan	S-1/A	333-224493	10.3	May 8, 2018		Senior Executive Cash Incentive Bonus Plan	S-1/A	333-224493	10.3	May 8, 2018	
10.4+	2018 Employee Stock Purchase Plan	S-1/A	333-224493	10.4	May 14, 2018		2018 Employee Stock Purchase Plan	S-1/A	333-224493	10.4	May 14, 2018	
10.5+	Scholar Rock Holding Corporation 2022 Inducement Equity Plan	8.K	001-38501	10.2	June 21, 2022		Scholar Rock Holding Corporation 2022 Inducement Equity Plan	8.K	001-38501	10.2	June 21, 2022	

10.6+	Amendment No. 1 to Scholar Rock Holding Corporation 2022 Inducement Equity Plan, dated September 4, 2022	S-8	333-268327	99.2	November 14, 2022	Amendment No. 1 to Scholar Rock Holding Corporation 2022 Inducement Equity Plan, dated September 4, 2022	S-8	333-268327	99.2	November 14, 2022
10.7*	Amendment No. 2 to Scholar Rock Holding Corporation 2022 Inducement Equity Plan, dated February 3, 2023									
10.8+	Form of Indemnification Agreement	S-1/A	333-224493	10.5	May 14, 2018					
10.7+						Amendment No. 2 to Scholar Rock Holding Corporation 2022 Inducement Equity Plan, dated February 3, 2023	10-K	001-38501	10.7	March 7, 2023

10.9†	Exclusive License Agreement by and between the Registrant, and Children's Medical Center, dated as December 16, 2013	S-1	333-224493	10.6	April 27, 2018	
10.10+	Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement, by Nagesh K. Mahanthappa, dated October 10, 2012	S-1	333-224493	10.10	April 27, 2018	
10.11†	Option and License Agreement by and between the Registrant and Janssen Biotech, Inc., dated as of December 17, 2013	S-1	333-224493	10.13	April 27, 2018	
10.12	Lease Agreement by and between 620 Memorial Leasehold LLC and the Registrant, dated March 5, 2015, as amended by the First Amendment dated February 22, 2016 and the Second Amendment dated February 22, 2018	S-1	333-224493	10.14	April 27, 2018	

10.8+*						Amendment No. 3 to Scholar Rock Holding Corporation 2022 Inducement Equity Plan, dated January 25, 2024				
10.9+						Form of Indemnification Agreement	S-1/A	333-224493	10.5	May 14, 2018
10.10†						Exclusive License Agreement by and between the Registrant, and Children's Medical Center, dated as December 16, 2013	S-1	333-224493	10.6	April 27, 2018
10.13††	Master Collaboration Agreement, dated December 19, 2018, by and between the Registrant and Gilead Sciences, Inc.	8-K/A	001-38501	10.1	December 24, 2018	Master Collaboration Agreement, dated December 19, 2018, by and between the Registrant and Gilead Sciences, Inc.	8-K/A	001-38501	10.1	December 24, 2018
10.14	Letter Agreement by and between Scholar Rock, Inc. and Gilead Sciences, Inc. dated January 6, 2022	10-Q	333-224493	10.1	May 16, 2022	Letter Agreement by and between Scholar Rock, Inc. and Gilead Sciences, Inc. dated January 6, 2022	10-Q	333-224493	10.1	May 16, 2022
10.15††	Form of License Agreement.	8-K/A	001-38501	10.2	December 24, 2018	Form of License Agreement.	8-K/A	001-38501	10.2	December 24, 2018

10.16	Share Purchase Agreement, dated December 19, 2018, by and between Scholar Rock Holding Corporation and Gilead Sciences, Inc.	8-K/A	001-38501	10.3	December 24, 2018	Share Purchase Agreement, dated December 19, 2018, by and between Scholar Rock Holding Corporation and Gilead Sciences, Inc.	8-K/A	001-38501	10.3	December 24, 2018
10.17	Registration Rights Agreement, dated December 19, 2018, by and among the Registrant, Gilead Sciences, Inc. and Scholar Rock Holding Corporation stockholder signatories named therein.	8-K/A	001-38501	10.4	December 24, 2018	Registration Rights Agreement, dated December 19, 2018, by and among the Registrant, Gilead Sciences, Inc. and Scholar Rock Holding Corporation stockholder signatories named therein.	8-K/A	001-38501	10.4	December 24, 2018

10.18	Irrevocable Registration Rights Waiver and Amendment, dated December 19, 2018, by and among the Registrant, Gilead Sciences, Inc. and Scholar Rock Holding Corporation stockholder signatories named therein.	8-K/A	001-38501	10.5	December 24, 2018	Irrevocable Registration Rights Waiver and Amendment, dated December 19, 2018, by and among the Registrant, Gilead Sciences, Inc. and Scholar Rock Holding Corporation stockholder signatories named therein.	8-K/A	001-38501	10.5	December 24, 2018
10.19	Amended and Restated Collaboration Agreement, dated March 12, 2019, by and between Scholar Rock, Inc. and Adimab, LLC	8-K	001-38501	10.1	March 13, 2019	Amended and Restated Collaboration Agreement, dated March 12, 2019, by and between Scholar Rock, Inc. and Adimab, LLC	8-K	001-38501	10.1	March 13, 2019

10.20	Lease Agreement by and between BMR-Rogers Street LLC and Scholar Rock, Inc., dated November 5, 2019. Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedules will be furnished supplementally to the Securities and Exchange Commission upon request.	10-Q	001-38501	10.2	November 12, 2019	Lease Agreement by and between BMR-Rogers Street LLC and Scholar Rock, Inc., dated November 5, 2019. Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedules will be furnished supplementally to the Securities and Exchange Commission upon request.	10-Q	001-38501	10.2	November 12, 2019
10.21+	Employment Agreement, dated July 14, 2020, by and between Scholar Rock, Inc. and Edward H. Myles.	8-K	001-38501	10.2	July 16, 2020	Employment Agreement, dated July 14, 2020, by and between Scholar Rock, Inc. and Edward H. Myles.	8-K	001-38501	10.2	July 16, 2020

10.23	Loan and Security Agreement, dated October 16, 2020, by and among the Registrant, Scholar Rock, Inc., Oxford Finance LLC and Silicon Valley Bank.	10-K	001-38501	10.26	March 9, 2021	
10.25	First Amendment to Loan and Security Agreement, dated November 16, 2021, by and among the Registrant, Scholar Rock, Inc., Oxford Finance LLC and Silicon Valley Bank.	10-K	001-38501	10.27	March 7, 2022	

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10.22+	Consulting Agreement, dated July 16, 2020, by and between Scholar Rock, Inc. and Nagesh K. Mahanthappa.	8-K	001-38501	10.3	July 16, 2020	

10.23	Loan and Security Agreement, dated October 16, 2020, by and among the Registrant, Scholar Rock, Inc., Oxford Finance LLC and Silicon Valley Bank.	10-K	001-38501	10.26	March 9, 2021	
10.24+	Employment Agreement, dated May 23, 2018, by and between Scholar Rock, Inc. and Gregory Carven, as amended.	10-K	001-38501	10.27	March 9, 2021	
10.25	First Amendment to Loan and Security Agreement, dated November 16, 2021, by and among the Registrant, Scholar Rock, Inc., Oxford Finance LLC and Silicon Valley Bank.	10-K	001-38501	10.27	March 7, 2022	
10.26*	Second Amendment to Loan and Security Agreement, dated November 10, 2022, by and among the Registrant, Scholar Rock, Inc., Oxford Finance LLC and Silicon Valley Bank.					
10.27+	Employment Agreement by and between Scholar Rock, Inc. and Nagesh Mahanthappa dated July 30, 2021.	8-K	001-38501	10.1	August 3, 2021	

10.26						Second Amendment to Loan and Security Agreement, dated November 10, 2022, by and among the Registrant, Scholar Rock, Inc., Oxford Finance LLC and Silicon Valley Bank.	10-K	001-38501	10.26	March 7, 2023
10.27						Third Amendment to Loan and Security Agreement, dated April 18, 2023, by and among the Registrant, Scholar Rock, Inc., Oxford Finance LLC and Silicon Valley Bank.	10-Q	001-38501	10.1	August 9, 2023
10.28+	Employment Agreement, by and between Scholar Rock, Inc. and Jay T. Backstrom, dated September 19, 2022.	8-K	001-38501	10.1	September 20, 2022	Employment Agreement, by and between Scholar Rock, Inc. and Jay T. Backstrom, dated September 19, 2022.	8-K	001-38501	10.1	September 20, 2022

10.29+	Employment Agreement, by and between Scholar Rock, Inc. and Jing Marantz, dated November 7, 2022.	8-K	001-38501	10.1	November 9, 2022	Employment Agreement, by and between Scholar Rock, Inc. and Jing Marantz, dated November 7, 2022.	8-K	001-38501	10.1	November 9, 2022
10.30	Form of Securities Purchase Agreement by and among the Registrant and the purchasers dated June 17, 2022	8-K	001-38501	10.1	June 21, 2022	Form of Securities Purchase Agreement by and among the Registrant and the purchasers dated June 17, 2022.	8-K	001-38501	10.1	June 21, 2022
10.31*	Amended and Restated Employment Agreement, by and between Scholar Rock, Inc. and Junlin Ho dated March 1, 2023									
10.31+						Amended and Restated Employment Agreement, by and between Scholar Rock, Inc. and Junlin Ho dated March 1, 2023	10-K	001-38501	10.31	March 7, 2023

10.32+*		Employment Agreement, by and between Scholar Rock, Inc. and Tracey Sacco, dated February 1, 2023.
21.1*	Subsidiaries of the Registrant	Subsidiaries of the Registrant
23.1*	Consent of Independent Registered Public Accounting Firm.	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on the signature page to this report).	Power of Attorney (included on the signature page to this report).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**		Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97#*		Compensation Recovery Policy
101.INS		Inline XBRL Instance Document

101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document

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32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document

104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)	

* Filed herewith.

** Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, the Exchange Act, and shall not be deemed to be incorporated by reference into any filing 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.

+ Indicates a management contract or compensatory plan.

† Confidential treatment has been granted for certain portions of this exhibit. These portions have been omitted and filed separately with the SEC.

†† Portions of this exhibit have been omitted pursuant to a request for confidential treatment that will be separately filed with the SEC.

Item 16. Form 10-K Summary

Not applicable.

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SIGNATURES

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

SCHOLAR ROCK HOLDING CORPORATION

Date: March 7, 2023 March 19, 2024

By: /s/ Jay T. Backstrom
Jay T. Backstrom
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 7, 2023 March 19, 2024

By: /s/ Edward H. Myles

Edward H. Myles

Chief Operating Officer & Chief Financial Officer (Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Jay T. Backstrom and Edward H. Myles, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his true and lawful attorney-in-fact and agent to act in his name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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

Signature	Title	Date
/s/ Jay T. Backstrom Jay T. Backstrom	President and Chief Executive Officer *(Principal Executive Officer)*	March 7, 2023 19, 2024
/s/ Edward H. Myles Edward H. Myles	Chief Operating Officer & Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 7, 2023 19, 2024
/s/ David Hallal David Hallal	Chairman of the Board of Directors	March 7, 2023 19, 2024
/s/ Srinivas Akkaraju Srinivas Akkaraju	Director	March 7, 2023 19, 2024
/s/ Richard Brudnick Richard Brudnick	Director	March 19, 2024
/s/ Kristina Burow	Director	March 7, 2023 19, 2024

Kristina Burow		
/s/ Jeffrey S. Flier Jeffrey S. Flier	Director	March 7, 2023 19, 2024
/s/ Michael Gilman Michael Gilman	Director	March 7, 2023 19, 2024
/s/ Amir Nashat Amir Nashat	Director	March 7, 2023 19, 2024
/s/ Katie Peng Katie Peng	Director	March 19, 2024

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/s/ Joshua Reed Joshua Reed	Director	March 7, 2023 19, 2024
/s/ Akshay Vaishnaw Akshay Vaishnaw	Director	March 7, 2023 19, 2024

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SCHOLAR ROCK HOLDING CORPORATION

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Scholar Rock Holding Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Scholar Rock Holding Corporation (the Company) as of December 31, 2022 December 31, 2023 and 2021, 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years then in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 December 31, 2023 and 2021, 2022, and the results of its operations and its cash flows for each of the two years then in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

External Prepaid and Accrued Research and Development Expenses

Description of the Matter	As shown in Notes 5 and 7 to the financial statements, the Company's external prepaid research and development expenses, long-term prepaid research and development expenses, and accrued research and development expenses totaled $4.1 million, $4.1 million, and $6.8 million, respectively, at December 31, 2023. As discussed in Note 2 to the consolidated financial statements, the Company's accrued and prepaid external research and development expenses are recognized based on various inputs, including an evaluation of the progress achieved to complete specific tasks based on communication with internal and external personnel, open contracts and purchase orders, invoices received, contracted costs, and other information

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provided to the Company by its service providers based on their actual costs incurred. Payments for these activities are due based on the terms of individual arrangements, which may differ from the pattern of costs incurred. Accrued expenses are reflected on the consolidated balance sheet when costs incurred exceed payments made while prepaid expenses are reflected on the consolidated balance sheet when payments made exceed the costs incurred.

Auditing the Company's accrued and prepaid external research and development expenses is especially challenging due to the significant judgement required to estimate the services provided but not yet invoiced. Specifically, the amount of research and development expenses incurred is sensitive to estimates of the progress of the studies, clinical trials or other activities and the associated cost of such services. Additionally, due to the duration of certain of the Company's ongoing research and development activities and the timing of invoicing received from third parties, the actual amounts incurred may not be known at the time the financial statements are issued, further adding to the estimation uncertainty.

How We Addressed the Matter in Our Audit

To test accrued and prepaid external research and development expenses, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used to calculate accrued and prepaid external research and development expenses, as well as evaluating the assumptions and estimates used by management to measure progress of studies, clinical trials or other activities. To assess the extent of services incurred, we assessed the progress of clinical trials with the Company's research and development personnel that oversee the clinical trials and obtained information from service providers regarding costs incurred to date. We also tested subsequent invoices received and inspected the Company's contracts with service providers and any pending change orders to assess the effect on the accrued or prepaid external research and development expenses.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2015.

Boston, Massachusetts

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SCHOLAR ROCK HOLDING CORPORATION
CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Assets				
Current assets:				
Cash and cash equivalents	$ 103,275	$ 212,835	$ 101,855	$ 103,275
Marketable securities	212,086	40,159	178,083	212,086
Prepaid expenses and other current assets	12,663	12,325	8,256	12,663
Total current assets	328,024	265,319	288,194	328,024
Property and equipment, net	7,384	9,564	4,600	7,384
Operating lease right-of-use asset	18,543	25,442	11,417	18,543
Restricted cash	2,498	2,498	2,407	2,498
Other long-term assets	1,719	1,622	4,417	1,719
Total assets	$ 358,168	$ 304,445	$ 311,035	$ 358,168
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	$ 3,994	$ 4,434	$ 3,465	$ 3,994
Accrued expenses	24,321	17,456	20,449	24,321
Operating lease liability	7,852	7,407	7,408	7,852
Short-term debt	—	1,577	1,334	—
Deferred revenue	—	33,193		
Other current liabilities	222	230	85	222
Total current liabilities	36,389	64,297	32,741	36,389
Long-term portion of operating lease liability	11,800	19,652	4,392	11,800
Long-term debt	49,744	48,422	48,684	49,744

Total liabilities	97,933	132,371	85,817	97,933
Commitments and contingencies (Note 11)				
Commitments and contingencies (Note 12)				
Stockholders' equity:				
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2022 and December 31, 2021; no shares issued and outstanding at December 31, 2022 and December 31, 2021	—	—		
Common stock, $0.001 par value; 150,000,000 shares authorized; 51,672,579 and 35,209,099 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	52	35		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2023 and December 31, 2022; no shares issued and outstanding at December 31, 2023 and December 31, 2022			—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 75,979,495 and 51,672,579 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively			76	52
Additional paid-in capital	771,699	548,204	901,471	771,699
Accumulated other comprehensive loss	(884)	(35)		
Accumulated other comprehensive income (loss)			92	(884)
Accumulated deficit	(510,632)	(376,130)	(676,421)	(510,632)
Total stockholders' equity	260,235	172,074	225,218	260,235
Total liabilities and stockholders' equity	$ 358,168	$ 304,445	$ 311,035	$ 358,168

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

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SCHOLAR ROCK HOLDING CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Year Ended December 31,	
	2022	2021
Revenue	$ 33,193	$ 18,816
Operating expenses:		
Research and development	124,444	108,468
General and administrative	43,119	40,269
Total operating expenses	167,563	148,737
Loss from operations	(134,370)	(129,921)
Other income (expense), net	(132)	(1,878)
Net loss	$ (134,502)	$ (131,799)
Net loss per share, basic and diluted	$ (2.26)	$ (3.59)
Weighted average common shares outstanding, basic and diluted	59,611,656	36,711,833
Comprehensive loss:		
Net loss	$ (134,502)	$ (131,799)
Other comprehensive loss:		
Unrealized loss on marketable securities	(849)	(33)
Total other comprehensive loss	(849)	(33)
Comprehensive loss	$ (135,351)	$ (131,832)

	Year Ended December 31,	
	2023	2022
Revenue	$ —	$ 33,193
Operating expenses:		
Research and development	121,900	124,444
General and administrative	49,395	43,119
Total operating expenses	171,295	167,563
Loss from operations	(171,295)	(134,370)
Other income (expense), net	5,506	(132)
Net loss	$ (165,789)	$ (134,502)
Net loss per share, basic and diluted	$ (1.99)	$ (2.26)
Weighted average common shares outstanding, basic and diluted	83,347,086	59,611,656
Comprehensive loss:		
Net loss	$ (165,789)	$ (134,502)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	976	(849)
Total other comprehensive income (loss)	976	(849)
Comprehensive loss	$ (164,813)	$ (135,351)

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

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SCHOLAR ROCK HOLDING CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share data)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance at December 31, 2020	**34,152,470**	**$ 34**	**$ 505,069**	**$ (2)**	**$ (244,331)**	**$ 260,770**
Unrealized loss on marketable securities	—	—	—	(33)	—	(33)
Sale of common shares, net of issuance costs	500,000	—	13,095	—	—	13,095
Exercise of stock options	556,629	1	6,891	—	—	6,892
Equity-based compensation expense	—	—	23,149	—	—	23,149
Net loss	—	—	—	—	(131,799)	(131,799)
Balance at December 31, 2021	**35,209,099**	**$ 35**	**$ 548,204**	**$ (35)**	**$ (376,130)**	**$ 172,074**
Unrealized loss on marketable securities	—	—	—	(849)	—	(849)
Sale of common shares, pre-funded warrants and warrants to purchase common shares, net of issuance costs	16,326,530	16	195,299	—	—	195,315
Exercise of stock options	44,850	1	495	—	—	496
Issuance of common shares upon RSU vesting	92,100	—	—	—	—	—
Equity-based compensation expense	—	—	27,701	—	—	27,701
Net loss	—	—	—	—	(134,502)	(134,502)
Balance at December 31, 2022	**51,672,579**	**$ 52**	**$ 771,699**	**$ (884)**	**$ (510,632)**	**$ 260,235**

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2021	**35,209,099**	**$ 35**	**$ 548,204**	**$ (35)**	**$ (376,130)**	**$ 172,074**
Unrealized loss on marketable securities	—	—	—	(849)	—	(849)

Sale of common shares, pre-funded warrants and warrants to purchase common shares, net of issuance costs	16,326,530	16	195,299	—	—	195,315
Exercise of stock options	44,850	1	495	—	—	496
Issuance of common shares upon RSU vesting	92,100	—	—	—	—	—
Equity-based compensation expense	—	—	27,701	—	—	27,701
Net loss	—	—	—	—	(134,502)	(134,502)
Balance at December 31, 2022	**51,672,579**	**$ 52**	**$ 771,699**	**$ (884)**	**$ (510,632)**	**$ 260,235**
Unrealized gain on marketable securities	—	—	—	976	—	976
Sale of common shares, net of issuance costs	14,889,364	15	97,638	—	—	97,653
Exercise of stock options	258,372	—	1,535	—	—	1,535
Issuance of common shares upon RSU vesting	533,460	—	—	—	—	—
Exercise of pre-funded and common warrants	8,625,720	9	3,454	—	—	3,463
Equity-based compensation expense	—	—	27,142	—	—	27,142
Other	—	—	3	—	—	3
Net loss	—	—	—	—	(165,789)	(165,789)
Balance at December 31, 2023	**75,979,495**	**$ 76**	**$ 901,471**	**$ 92**	**$ (676,421)**	**$ 225,218**

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

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SCHOLAR ROCK HOLDING CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2023**	**2022**
Cash flows from operating activities:				
Net loss	$ (134,502)	$ (131,799)	$ (165,789)	$ (134,502)

Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	2,986	2,627	2,844	2,986
Amortization of debt discount and debt issuance costs	720	335	274	720
Loss on disposal of property and equipment	33	24	11	33
Equity-based compensation	27,701	23,149	27,142	27,701
Amortization/accretion of investment securities	(2,142)	918	(6,220)	(2,142)
Non-cash operating lease expense	6,899	6,397	7,126	6,899
Change in operating assets and liabilities:				
Prepaid expenses and other current assets	(322)	(8,530)	4,530	(322)
Other assets	(97)	(601)	(2,698)	(97)
Accounts payable	(251)	1,016	(529)	(251)
Accrued expenses	6,889	3,663	(3,927)	6,889
Operating lease liabilities	(7,407)	(5,400)	(7,852)	(7,407)
Deferred revenue	(33,193)	(18,816)	—	(33,193)
Other liabilities	(8)	228	(138)	(8)
Net cash used in operating activities	(132,694)	(126,789)	(145,226)	(132,694)
Cash flows from investing activities:				
Purchases of property and equipment	(1,064)	(5,248)	(71)	(1,064)
Proceeds from sale of property and equipment			13	—
Purchases of marketable securities	(300,634)	(60,437)	(290,801)	(300,634)
Maturities of marketable securities	130,000	200,000	332,000	130,000
Net cash (used in) provided by investing activities	(171,698)	134,315		
Net cash provided by (used in) investing activities			41,141	(171,698)
Cash flows from financing activities:				
Proceeds from debt	—	24,984		
Proceeds from sale of common shares, pre-funded warrants and warrants to purchase common shares, net of issuance costs	195,315	13,095	97,709	195,315
Debt modification payment	(975)	—		
Proceeds from pre-funded and common warrant exercises			3,463	—
Proceeds from stock option exercises	492	6,892	1,399	492
Other	—	(20)	3	—
Debt modification payment			—	(975)
Net cash provided by financing activities	194,832	44,951	102,574	194,832
Net (decrease) increase in cash, cash equivalents and restricted cash	(109,560)	52,477		
Net decrease in cash, cash equivalents and restricted cash			(1,511)	(109,560)
Cash, cash equivalents and restricted cash, beginning of period	215,333	162,856	105,773	215,333

Cash, cash equivalents and restricted cash, end of period	$ 105,773	$ 215,333	$ 104,262	$ 105,773
Supplemental disclosure of non-cash items:				
Property and equipment purchases in accounts payable and accrued expenses	$ —	$ 212		
Supplemental cash flow information:				
Cash paid for interest	$ 4,372	$ 2,082	$ 6,399	$ 4,372

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

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SCHOLAR ROCK HOLDING CORPORATION
Notes to Consolidated Financial Statements

1. Nature of the Business and Basis of Presentation

Organization

Scholar Rock Holding Corporation (the "Company") is a late-stage biopharmaceutical company focused on the discovery, development, and development delivery of innovative medicines for the treatment of serious diseases in which signaling by protein growth factors plays a fundamental role. As a global leader in transforming growth factor beta ("TGFβ") superfamily biology, the Company's novel understanding of the molecular mechanisms of growth factor activation enabled the development of a proprietary platform for the discovery and development of monoclonal antibodies that locally and selectively target the precursor, or latent, forms of growth factors.

The Company's first product candidate, apitegromab, is a highly selective, fully human, monoclonal antibody, with a unique mechanism of action that results in inhibition of the activation of the growth factor, myostatin, in skeletal muscle. Apitegromab is being developed as a potential first muscle-targeted therapy for the treatment of spinal muscular atrophy ("SMA"). The Company is conducting SAPPHIRE, a pivotal Phase 3 clinical trial to evaluate the efficacy and safety of apitegromab in patients with nonambulatory Type 2 and Type 3 SMA. In June 2022, 2023, the Company completed enrollment for the Phase 3 SAPPHIRE trial and announced 24-month efficacy and safety extension data of apitegromab in patients with Type 2 and Type 3 SMA from the Phase 2 TOPAZ trial extension period evaluating patient outcomes at 36 months of treatment with apitegromab.

In October 2023, the Company announced plans to expand into cardiometabolic disorders and advance its anti-myostatin program with SRK-439, a novel, fully human anti-myostatin monoclonal antibody, for evaluation in cardiometabolic disorders, including obesity, towards a potential investigational new drug application ("IND") submission in 2025. To inform the development of SRK-439, the Company plans to initiate a Phase 2 proof-of-concept clinical trial. trial of apitegromab in combination with a GLP-1-receptor agonist in 2024.

The Company's second product candidate, SRK-181, a highly selective inhibitor of the activation of latent transforming growth factor beta ("TGFβ"), is being developed for the treatment of cancers that are resistant to checkpoint inhibitor ("CPI") therapies, such as anti-PD-1 or anti-PD-L1 antibody therapies. therapies (referred to together as anti-PD-(L)1 antibody therapies). SRK-181 is a highly selective inhibitor of the activation of latent transforming growth factor beta-1 ("TGFβ1") that is being investigated was evaluated in the Company's Phase 1 DRAGON proof-of-concept clinical trial in patients with locally advanced or metastatic solid tumors that exhibit resistance to anti-PD-(L)1 antibodies. antibody therapies. The Phase 1 DRAGON trial completed enrollment in December 2023. This two-part clinical trial consists of two parts: Part A (dose a dose escalation of SRK-181 as portion (Part A) and a single-agent or in combination with an approved anti-PD-(L)1 therapy) and Part B (dose dose expansion evaluating SRK-181 in combination with an approved anti-PD- (L)1 antibody therapy) therapy (Part B). Part B includes the following active cohorts: urothelial carcinoma, cutaneous melanoma, non-small cell lung cancer, clear cell renal cell carcinoma, and head and neck squamous cell carcinoma. Safety, efficacy and biomarker data were presented in November 2023 at the Society for Immunotherapy of Cancer 38th Annual Meeting.

Additionally, the Company continues to create a pipeline of product candidates to deliver novel therapies to underserved patients suffering from a wide range of serious diseases, including neuromuscular disorders, cardiometabolic disorders, cancer, fibrosis, and iron-restricted anemia. The Company was originally formed in May 2012. Its principal offices are in Cambridge, Massachusetts.

Since its inception, the Company's operations have focused on research and development of monoclonal antibodies that selectively inhibit activation of growth factors for therapeutic effect, as well as establishing the Company's intellectual property portfolio and performing research and development activities. The Company has primarily financed its operations through various equity financings, including in October 2023 (Note 8) 9), as well as research and development collaboration agreements and the Company's debt facility (Note 12) 13).

Revenue generation activities have been limited to two collaborations, both containing research services and the issuance of a license. The first agreement, executed in 2013, was with Janssen Biotech, Inc. ("Janssen"), a subsidiary of Johnson & Johnson and was terminated in July 2022. The second agreement, the Gilead Collaboration Agreement with Gilead

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Sciences, Inc. (“Gilead”), was in effect between December 2018 and January 2022. No revenues have been recorded from the sale of any commercial product.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, successful discovery and development of its drug candidates, raising additional capital, development by its competitors of new technological innovations, protection of proprietary technology and regulatory approval and market acceptance of the Company’s product candidates. The Company anticipates that it will continue to incur significant operating losses for the next several years as it continues to develop its product candidates. The Company believes that its existing cash, cash equivalents, and marketable securities at December 31, 2022 December 31, 2023 will be sufficient to allow the Company to fund its current operations through at least a period of one year after the date these financial statements are issued.

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Basis of Presentation

The consolidated financial statements include the accounts of Scholar Rock Holding Corporation and its wholly owned subsidiaries. All intercompany balances have been eliminated in consolidation.

These consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”).

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and judgments that may affect the reported amounts of assets and liabilities and related disclosures of contingent assets and liabilities at the date of the financial statements and the related reporting of revenues and expenses during the reporting period. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

Concentration of Credit Risk and Off-Balance Sheet Risk

The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts or other foreign-hedging arrangements. The Company follows an investment policy approved by the Board of Directors.

Its primary objectives are the preservation of capital and maintenance of liquidity. The Company invests only in fixed income instruments denominated and payable in U.S. dollars including obligations of the U.S. government and its agencies and money market funds registered according to SEC Rule 2a-7 of the Investment Company Act of 1940. All securities must have a readily ascertainable market value, must be readily marketable and be U.S. dollar denominated.

Cash, Cash Equivalents and Restricted Cash

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents are stated at cost, which approximates market value. At December 31, 2022 December 31, 2023 and 2021, 2022, cash equivalents include money market funds that invest primarily in U.S. government-backed securities and treasuries.

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At December 31, 2022 December 31, 2023 and 2021, 2022, restricted cash consists of letters of credit in the amount of $2.5 million related to its leased facilities. The following table reconciles cash, cash equivalents and restricted cash per the balance sheet to the statement of cash flows (in thousands):

	As of December 31,	
	2023	2022
Cash and cash equivalents	$ 101,855	$ 103,275
Restricted cash	2,407	2,498
	$ 104,262	$ 105,773

	As of December 31,	
	2022	2021
Cash and cash equivalents	$ 103,275	$ 212,835
Restricted cash	2,498	2,498
	$ 105,773	$ 215,333

Marketable Securities

The Company classifies its marketable securities as available-for-sale. Marketable securities with a remaining maturity date greater than one year are classified as non-current. non-current if the Company does not intend to utilize the marketable securities to fund current operations. Marketable securities are maintained by an

investment manager and consist of U.S. treasury obligations and government agency securities. Marketable securities are carried at fair value with the unrealized gains and losses included in accumulated other comprehensive loss income (loss) as a component of stockholders' equity until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense over the life of the underlying marketable security.

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Although available to be sold to meet operating needs or otherwise, securities are generally held through maturity. The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense) within the statement of operations and comprehensive loss. During the years ended December 31, 2022

The Company reviews its portfolio of available-for-sale debt securities, using both quantitative and 2021, no marketable securities were adjusted for other than temporary qualitative factors, to determine if declines in fair value.

The Company evaluates its marketable securities with unrealized losses for other-than-temporary impairment. When assessing marketable securities for other-than-temporary declines in value the Company considers such factors as, among below cost have resulted from a credit loss or other things, how significant factors. If the decline in fair value is as due to credit loss factors, a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery loss is recognized in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that net income. To date, the Company considers has not experienced any credit losses and does not believe it is exposed to be "other than temporary," the Company would reduce the investment to fair value through a charge to the statement of operations and comprehensive loss. No such adjustments were necessary during the periods presented. any significant credit risk on these investments.

Property and Equipment

Property and equipment are recorded at cost. Expenditures for major renewals or betterments that extend the useful lives of property and equipment are capitalized; expenditures for maintenance and repairs are charged to expense as incurred. Depreciation is calculated on a straight-line basis over the estimated useful lives of the related asset. Property and equipment are depreciated as follows:

	Estimated Useful Life

	(in Years)
Laboratory equipment	3 – 5
Computer equipment & software	3
Furniture & fixtures	5
Machinery & equipment	3 – 5
Leasehold improvements	Shorter of the useful life or remaining lease term

Impairment of Long-Lived Assets

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

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an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2022 December 31, 2023 or 2021. 2022.

Leases

The Company accounts for leases using ASC Topic 842, Leases (“ASC 842”). At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its estimated incremental borrowing rates, which are the rates

incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

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In accordance with the guidance in ASC 842, components of a lease should be split into three categories: lease components (e.g. land, building, etc.), non-lease components (e.g. common area maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components. For operating leases, lease expense relating to fixed payments is recognized on a straight-line basis over the term and lease expense relating to variable payments is expensed as incurred.

Fair Value Measurements

ASC Topic 820, Fair Value Measurement ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

Level 1 — Quoted market prices in active markets for identical assets or liabilities.

Level 2 — Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

Level 3 — Unobservable inputs developed using estimates of assumptions developed by the Company, which reflect those that a market participant would use.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Segment Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment operating exclusively in the U.S.

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Revenue Recognition

The Company accounts for revenue using the provisions of ASC Topic 606, Revenue from Contracts with Customers (“ASC 606”). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the contract(s) with the customer, (ii) identification of the promised goods or services in the contract and determination of whether the promised goods or services are performance obligations, (iii) measurement of the transaction price, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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The Company accounts for a contract with a customer that is within the scope of ASC 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations, (ii) each party's rights regarding the goods or services to be transferred can be identified, (iii) the payment terms for the goods or services to be transferred can be identified, (iv) the arrangement has commercial substance and (v) collection of substantially all of the consideration to which the Company will be entitled in exchange for the goods or services that will be transferred to the customer is probable.

The Company first evaluates license and/or collaboration arrangements to determine whether the arrangement (or part of the arrangement) represents a collaborative arrangement pursuant to ASC Topic 808, *Collaborative Arrangements,* based on the risks and rewards and activities of the parties pursuant to the contractual arrangement. The Company accounts for collaborative arrangements (or elements within the contract that are deemed part of a collaborative arrangement), which represent a collaborative relationship and not a customer relationship, outside of the scope of ASC 606. The Company's two collaborations represented revenue arrangements.

For the arrangements or arrangement components that are subject to revenue accounting guidance, in determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: a) the number of performance obligations based on the determination under step (ii) above and whether those performance obligations are distinct from other performance obligations in the contract; b) the transaction price under step (iii) above; and c) the standalone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. In determining the stand-alone selling price of a license to the Company's proprietary technology or a material right provided by a customer option, the Company considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements as well as internally developed estimates that include assumptions related to the market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating its estimated stand-alone selling prices, the Company evaluates whether changes in the key assumptions used to determine its estimated stand-alone selling prices will have a significant effect on the allocation of arrangement consideration between performance obligations.

The Company estimates the transaction price based on the amount of consideration the Company expects to be received for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of the potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate the transaction price based on which method better predicts the amount of consideration expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when: (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own and whether the required expertise is readily available.

The Company allocates the transaction price based on the estimated standalone selling price. The Company must develop assumptions that require judgment to determine the standalone selling price for each performance obligation

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identified in the contract. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Estimating costs for research and development programs is subjective as the Company estimates the costs anticipated to successfully complete the research performance obligations. As the research is novel, efforts to be successful may be significantly different than the estimated costs at the beginning of the contract. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation in order to determine whether the combined performance obligation is satisfied over time or at a point in time. The Company determines the appropriate method of measuring progress of combined performance obligations satisfied over time for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The estimated remaining costs is highly subjective, as the research is novel, therefore efforts to be successful may be significantly different than the estimated costs made at the balance sheet date. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. The Company receives payments from customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as the current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. Amounts recognized as revenue, but not yet received or invoiced, are generally recognized as contract assets.

Exclusive Licenses – If the license granted in the arrangement is determined to be distinct from the other promises or performance obligations identified in the arrangement, which generally include research and development services, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a license is distinct from the other promises, the Company considers relevant facts and circumstances of each arrangement, including the research and development capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from the license for its intended purpose without the receipt of the remaining promise, whether the value of the license is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is

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separately identifiable from the remaining promise. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of

progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the arrangement.

Research and Development Services – The promises under the Company's collaboration and license agreements generally include research and development services to be performed by the Company on behalf of the collaboration partner. For performance obligations that include research and development services, the Company generally recognizes revenue allocated to such performance obligations based on an appropriate measure of progress. The Company utilizes judgment to determine the appropriate method of measuring progress for purposes of recognizing revenue, which is generally an input measure, such as costs incurred. The Company evaluates the measure of progress each reporting period as described under *Exclusive Licenses* above. Reimbursements from the partner that are the result of a collaborative relationship with the partner, instead of a customer relationship, such as co-development activities, are generally recorded as a reduction to research and development expense.

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Customer Options – The Company's arrangements may provide a collaborator with the right to certain optional purchases, such as the right to license a target either at the inception of the arrangement or within a pre-defined option period. Under these agreements, fees may be due to the Company (i) at the inception of the arrangement as an upfront fee or payment or (ii) upon the exercise of an option to acquire a license. If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the inception of the arrangement. The Company allocates the transaction price to material rights based on the relative stand-alone selling price, which is determined based on the identified discount, and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised or expires.

Milestone Payments – At the inception of each arrangement that includes milestone payments based on certain events, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as

regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. If a milestone or other variable consideration relates specifically to the Company's efforts to satisfy a single performance obligation or to a specific outcome from satisfying the performance obligation, the Company generally allocates the milestone amount entirely to that performance obligation once it is probable that a significant revenue reversal would not occur.

Royalties – For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

For a complete discussion of accounting for collaboration revenues, see Note 13, 14, *Agreements.*

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Research and Development Expenses and Accruals Related Accruals/Prepaids

Research and development expenses are expensed as incurred and consist of costs incurred in performing research and development activities, including compensation related expenses for research and development personnel, preclinical and clinical activities including cost of clinical drug supply, overhead expenses including facilities expenses, materials and supplies, amounts paid to consultants and outside service providers, and depreciation of equipment. Upfront license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative future use are also included in research and development expense.

The Company has entered into various research and development service arrangements under which vendors perform various services. The Company records accrued expenses for estimated costs incurred under the arrangements. arrangements in excess of vendor invoices received while cash payments to vendors, including those that are nonrefundable, in excess of estimated costs incurred are recorded as prepaid expenses. Prepaid

expenses are expensed as the related services are performed or goods are received. When evaluating the adequacy and accuracy of the accrued and prepaid expenses, the Company analyzed reviews open contracts and purchase orders, the level of service performed, invoices received, contracted costs, and progress of the studies, clinical trials or other services performed, including invoices received and contracted costs. activities based on communication with internal and/or external personnel. Significant judgments and estimates are made in determining the accrued and prepaid expense balances at the end of each reporting period.

Table period, and payments for these activities are due based on the terms of Contentsindividual arrangements, which may differ from the pattern of costs incurred.

Equity-Based Compensation

The Company accounts for equity awards, including restricted stock awards, restricted stock units, and common stock options, granted as equity award compensation in accordance with ASC Topic 718, Compensation — Stock Compensation ("ASC 718"). ASC 718 requires all stock-based payments to employees, which includes grants of employee equity awards, to be recognized as expense in the statements of operations based on their grant date fair values.

The fair value of each restricted stock award and restricted stock unit is based on the fair value of the Company's common stock less any purchase price, if applicable. The fair value of each stock option award is estimated using the Black-Scholes option-pricing model, which uses as inputs the fair value of the Company's common stock and certain subjective assumptions, including the expected stock price volatility, the expected term of the award, the risk-free rate, and expected dividends. Expected volatility is calculated based on a blend of the Company's reported volatility data for the length of time that market data was available for the Company's stock and the historical data for a representative group of publicly traded companies, for which historical information was available. The historical volatility is generally calculated based on a period of time commensurate with the expected term assumptions. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. The Company uses the simplified method, under which the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to lack of historical exercise data and the plain nature of its stock-based awards. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on common stock.

Compensation expense related to equity awards to employees that are subject to graded vesting is recognized on a straight-line basis, based on the grant date fair value, over the requisite service period of the award, which is generally the vesting term. For awards subject to performance conditions, the Company recognizes equity award compensation expense using an accelerated recognition method over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the

achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date.

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

The Company accounts for forfeitures when they occur.

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Comprehensive Loss

Comprehensive loss is the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss includes net loss and the change in accumulated other comprehensive income (loss) for the period. Accumulated other comprehensive loss income (loss) consisted entirely of unrealized gains and losses on available-for-sale marketable securities during the period ending December 31, 2022 December 31, 2023 and 2021. 2022.

Net Loss per Share

The Company applies the two-class method to compute basic and diluted net loss per share because it has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (losses) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in the earnings as if all income (losses) for the period had been distributed. During periods of loss, there is no allocation required under the two-class method since the participating securities do not have a contractual obligation to fund the losses of the Company.

The Company calculates basic net loss per share by dividing net loss by the weighted average number of common shares outstanding, including pre-funded warrants and excluding restricted common stock. The Company calculates diluted net

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loss per share by dividing net loss by the weighted average number of common shares outstanding, as applicable, after giving consideration to the dilutive effect of restricted stock awards, restricted stock units, warrants, pre-funded warrants, and stock options that are outstanding during the period.

Income Taxes

Income taxes are recorded in accordance with ASC Topic 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Under this method, deferred income tax assets and liabilities are recognized based on future income tax consequences attributable to differences between the financial statement carrying amount of existing assets and liabilities, and their respective income tax basis. Deferred income tax assets and liabilities are measured using enacted income tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions, as necessary. The tax benefits recorded are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is "more likely than not" to be realized following resolution of any uncertainty related to the tax benefit, assuming that the matter in question will be raised by the tax authorities.

The Company is open to examination by the Internal Revenue Service for the tax years ended December 31, 2013 to December 31, 2022 December 31, 2023. Since the Company is in a U.S. loss carryforward position, carryforward tax attributes generated in prior years may still be adjusted upon future examination if they have or will be used in a future period. The Company is currently not under examination by the Internal Revenue Service or any other jurisdictions for any tax years. The Company has not recorded any interest or penalties on any unrecognized tax benefits since its inception.

Recently Issued Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The standard requires that a financial asset or a group of financial assets measured at amortized cost basis to be presented at the net amount expected to be collected. Under current previous GAAP, a company only considered past events and current conditions in measuring an incurred

loss. Under ASU 2016-13, the information that a company must consider is broadened in developing an expected credit loss estimate for assets measured either collectively or individually. The use of forecasted information incorporates more timely information in the estimate of expected credit loss. The guidance is applied using a modified retrospective, or prospective approach, depending on a specific amendment. In November 2019, the FASB deferred the effective date for smaller reporting companies to fiscal years beginning after December 15, 2022. Therefore, the new standard was effective for the Company on January 1, 2023. The Company established processes and internal controls to comply with the new credit loss standard and related disclosure requirements. The Company's investment policy has primary objectives of preservation of capital and maintenance of liquidity. As a result, the Company typically invests in money market funds, U.S. treasury obligations and government agency securities. The Company believes that such funds are subject to minimal credit risk. The Company has not experienced any credit losses and does not believe it is exposed to any significant credit risk on these investments. The adoption of this standard did not have a material impact on the Company's consolidated financial position and results of operations.

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The standard requires disclosure of incremental segment information on an annual and interim basis and allows for multiple measures of a segment's profit or loss provided that one of those measures is consistent with GAAP. The amendments in this update do not change how a public company identifies its operating segments, aggregates those operating segments, or applies the quantitative thresholds to determine its reportable segments, but rather requires public entities to provide in interim periods all disclosures about a reporting segment's profit or loss and assets that are currently required annually. ASU 2023-07 becomes effective for the annual period starting on January 1, 2024, and for interim periods starting on January 1, 2025. The option for early adoption is permitted, however, the Company has decided not to early adopt, does not anticipate a material impact to its net financial position, or and is still evaluating the impact on its disclosures in future years as a result of the adoption of ASU 2016-13. 2023-07.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures,* which enhances the transparency of income tax disclosures to provide information to investors to better assess how a company's operations and related tax risks, tax planning and operational opportunities affect its tax rate and prospects for future cash flows. This requires public entities to disclose additional categories in the rate reconciliation regarding federal and state income taxes, and provide more details surrounding reconciling items if a quantitative threshold is met. The effective date for public companies is for annual periods starting on January 1, 2025. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance, however, the Company has decided not to early adopt, does not anticipate a material impact to its net financial position, and is still evaluating the impact on its disclosures will be in future years as a result of the adoption of ASU 2023-09.

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3. Fair Value of Financial Assets and Liabilities

The following tables summarize the assets and liabilities measured at fair value on a recurring basis at December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	Fair Value Measurements at December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 98,073	$ 98,073	$ —	$ —
Marketable securities:				
U.S. Treasury obligations	212,086	212,086	—	—
Total assets	$310,159	$310,159	$ —	$ —

	Fair Value Measurements at December 31, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 61,764	$ 61,764	$ —	$ —
U.S. treasury obligations, included in cash and cash equivalents	30,765	30,765	—	—
Marketable securities:				
U.S. treasury obligations and government agency securities	178,083	178,083	—	—
Total assets	$270,612	$270,612	$ —	$ —

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	Fair Value Measurements at December 31, 2021				Fair Value Measurements at December 31, 2022			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Assets:								
Money market funds, included in cash and cash equivalents	$188,493	$188,493	$ —	$ —	$ 98,073	$ 98,073	$ —	$ —
Marketable securities:								

U.S. Treasury obligations	40,159	40,159	—	—				
U.S. treasury obligations					212,086	212,086	—	—
Total assets	$228,652	$228,652	$ —	$ —	$310,159	$310,159	$ —	$ —

Cash, cash equivalents and marketable securities are Level 1 assets and include investments in money market funds and U.S. treasury obligations and government agency securities that are valued using quoted market prices. Accordingly, money market funds and government funds are categorized as Level 1 as of December 31, 2022 December 31, 2023 and 2021. 2022. There were no transfers of assets between fair value measurement levels during the years ended December 31, 2022 December 31, 2023 and 2021. 2022.

The carrying amounts reflected in the balance sheets for prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values at December 31, 2022 December 31, 2023 and 2021, 2022, due to their short-term nature.

The Company believes the terms of its debt reflect current market conditions for an instrument with similar terms and maturity, therefore the carrying value of the Company's debt approximates its fair value based on Level 3 of the fair value hierarchy.

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4. Marketable Securities

The following table summarizes the Company's investments as of December 31, 2022 December 31, 2023 (in thousands):

		Gross			Gross		
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Marketable securities available-for-sale:								
U.S. Treasury obligations	$ 212,970	$ —	$ (884)	$212,086				

U.S. treasury obligations and government agency securities					$177,991	$ 93	$ (1)	$178,083
Total available-for-sale securities	$ 212,970	$ —	$ (884)	$212,086	$177,991	$ 93	$ (1)	$178,083

The following table summarizes the Company's investments as of December 31, 2021 December 31, 2022 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Marketable securities available-for-sale:								
U.S. Treasury obligations	$ 40,194	$ —	$ (35)	$40,159				
U.S. treasury obligations					$212,970	$ —	$(884)	$212,086
Total available-for-sale securities	$ 40,194	$ —	$ (35)	$40,159	$212,970	$ —	$(884)	$212,086

The aggregate fair value of marketable securities with unrealized losses was $11.9 million and $212.1 million at December 31, 2023 and $30.2 million at December 31, 2022 and 2021, 2022, respectively. At December 31, 2022 December 31, 2023 and 2021, 23 2022, three investments and three 23 investments, respectively, were in an unrealized loss position. All such investments have been in an unrealized loss position for less than a year and these losses are considered temporary. The Company has the ability and intent to hold these investments until a recovery of their amortized cost, which may not occur until maturity.

The Company believes that U.S. treasury obligations and government agency securities are subject to minimal credit risk. As a result, the Company did not record any charges for credit-related impairments for its available-for-sale securities for the year ended December 31, 2023.

5. Prepaid Expenses and Other Assets

At December 31, 2023 and 2022, prepaid expenses and other current assets consist of the following (in thousands):

	As of December 31, 2023	As of December 31, 2022
Prepaid external research and development expenses	$ 4,059	$ 7,528
Prepaid other	2,486	1,552
Receivables	1,076	2,735
Prepaid insurance	635	848

	$ 8,256	$ 12,663

At December 31, 2023 and 2022, other long-term assets consist of the following (in thousands):

	As of	
	December 31, 2023	December 31, 2022
Prepaid external research and development expenses	$ 4,074	$ 1,422
Prepaid other	312	256
Prepaid insurance	31	41
	$ 4,417	$ 1,719

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5. 6. Property and Equipment, Net

At December 31, 2022 December 31, 2023 and 2021, 2022, property and equipment consists of the following (in thousands):

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Laboratory equipment	$ 10,298	$ 9,497	$ 10,270	$ 10,298
Leasehold improvements	5,160	5,160	3,581	5,160
Computer equipment & software	1,080	1,080	1,029	1,080
Furniture & fixtures	1,002	995	1,002	1,002
Machinery & equipment	75	75	44	75
Construction in progress	—	48		
	17,615	16,855	15,926	17,615
Less: Accumulated depreciation and amortization	(10,231)	(7,291)	(11,326)	(10,231)
	$ 7,384	$ 9,564	$ 4,600	$ 7,384

Depreciation and amortization expense was $3.0 million $2.8 million and $2.6 million $3.0 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

6. 7. Accrued Expenses

At December 31, 2022 December 31, 2023 and 2021, 2022, accrued expenses consist of the following (in thousands):

	As of		As of	
	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Accrued payroll and related expenses			$ 10,591	$ 6,800
Accrued external research and development expense	$ 15,178	$ 8,428	6,825	15,178
Accrued payroll and related expenses	6,800	7,147		
Accrued professional and consulting expense	1,510	1,421	2,267	1,510
Accrued other	833	460	766	833
	$ 24,321	$ 17,456	$ 20,449	$ 24,321

7. 8. Preferred Stock

The Board of Directors or any authorized committee thereof is expressly authorized, to the fullest extent permitted by law, to provide by resolution or resolutions for, out of the unissued shares of Preferred Stock, the issuance of the shares of Preferred Stock in one or more series of such stock, and by filing a certificate of designations pursuant to applicable law of the State of Delaware, to establish or change from time to time the number of shares of each such series, and to fix the designations, powers, including voting powers, full or limited, or no voting powers, preferences and the relative, participating, optional or other special rights of the shares of each series and any qualifications, limitations and restrictions thereof.

8. 9. Common Stock

In June 2022, October 2023, the Company entered into a securities purchase an underwriting agreement (the "Underwriting Agreement") with J.P. Morgan Securities LLC, and Piper Sandler & Co., as representatives of the several underwriters named therein (the "Underwriters"), relating to the issuance and sale of an aggregate of 16,326,530 14,270,074 shares of its the Company's common stock, pre-funded warrants which includes the exercise in full by the underwriters of their option to purchase 25,510,205 an additional 1,861,314 shares of its common stock and associated common warrants to purchase 10,459,181 shares of its common stock. The offering price per share and associated common warrant was $4.90 and the offering price per pre-funded warrant and associated common warrant was $4.8999, which equals the per share (the "Option Shares"), at a public offering price for the common shares less the $0.0001 exercise price for each such pre-funded warrant. The pre-funded warrants are exercisable at any time and only expire when exercised in full. Each common warrant has an exercise price of $6.85 per share of $7.35 (150% share. Total proceeds of the offering price per share transaction, including the Option Shares were $92.4 million, net of the common stock), is immediately exercisable underwriting discounts and will expire on December 31, 2025. The offering was made pursuant to a

registration statement on Form S-3. Gross proceeds from the transaction were $205.0 million and the Company received $195.3 million in net proceeds, after deducting placement agent fees and estimated offering expenses. The pre-funded warrants and warrants meet the

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condition for equity classification and were therefore recorded as a component of stockholders' equity within additional paid-in capital. offering closed on October 16, 2023.

The Company has had a sales agreement in place during various time periods with Jefferies LLC ("Jefferies") with respect to an at-the-market ("ATM") offering program. Under this program, the Company is able to offer and sell, from time to time at its sole discretion, shares of its common stock through Jefferies as its sales agent. In an ATM offering,

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exchange-listed companies incrementally sell newly issued shares into the secondary trading market through a designated broker-dealer at prevailing market prices. The current ATM agreement, established in November 2022, allows for the sale of shares of common stock having an aggregate offering price of up to $100 million. As of December 31, 2022 December 31, 2023, no sales have been transacted under the current agreement. In October 2021, 500,000 Company has sold 619,290 shares, of common stock were sold pursuant to an ATM, resulting in generating net proceeds of approximately $13.1 million. $5.2 million, under the ATM program.

In October 2020, the The Company entered into an underwriting agreement relating to the issuance and sale of an aggregate of 3,717,948 shares has issued pre-funded warrants, as well as warrants as part of its common stock at $39.00 per share and financing activities. Both the pre-funded warrants to purchase 2,179,487 shares of its common stock. The price of each pre-funded warrant was $38.9999, which equals the per share public offering price for the common shares less the $0.0001 exercise price for each such pre-funded warrant. Total gross proceeds of the transaction were $230.0 million and net proceeds were $215.9 million, after deducting

underwriting discounts and commissions and offering expenses. The pre-funded warrants are exercisable at any time, do not expire, and meet the condition conditions for equity classification and were therefore are recorded as a component of stockholders' equity within additional paid-in capital. In June 2022 and November 2020, the Company issued 25,510,205 and 2,179,487 pre-funded warrants, respectively. During the year ending December 31, 2023, 8,154,695 of the Company's pre-funded warrants were exercised. As of December 31, 2023, the Company has 19,534,997 pre-funded warrants outstanding. In June 2022, the Company also issued 10,459,181 warrants with an exercise price of $7.35. During the year ending December 31, 2023, 471,025 of the Company's warrants were exercised. As of December 31, 2023, the Company has 9,988,156 warrants outstanding.

In June and July 2019, the Company sold 3,450,000 shares of its common stock, including the exercise of the overallotment option, through an underwritten public offering at a price of $15.00 per share. The offering was made pursuant to the Company's effective shelf registration statement on Form S-3. The Company received aggregate net proceeds, after underwriting discounts and commissions and other offering expenses, of approximately $48.3 million.

Shares Reserved For Future Issuance

As of December 31, 2022 December 31, 2023, the Company had common shares reserved for issuance as follows:

	As of December 31,	
	2022	2023
Common shares reserved for exercise of pre-funded warrants	27,689,692	19,534,997
Common shares reserved for issuance upon exercise or conversion of outstanding warrants	10,459,181	9,988,156
Common shares reserved for exercise of outstanding stock options and unvested restricted stock units under the 2017 and 2018 Plans		4,992,784
Common shares reserved for unvested restricted stock units under the 2018 Plan	1,667,522	7,191,377
Common shares reserved for exercise of outstanding stock options and unvested restricted stock units under the 2022 Inducement Plan	1,250,000	2,199,128
Common shares reserved for future issuance under the 2018 Plan	1,063,499	1,807,499
Common shares reserved for future issuance under the 2022 Inducement Plan	750,000	800,872
Common shares reserved for future issuance under the 2018 ESPP	1,489,463	1,843,077
	49,362,141	43,365,106

9. 10. Equity-Based Compensation

Equity Plans

As of December 31, 2022 December 31, 2023, the Company has four active equity plans, the 2018 Stock Option and Incentive Plan (the "2018 Plan"), the 2017 Stock Option and Incentive Plan (the "2017 Plan"), the 2018 Employee Stock Purchase Plan (the "2018 ESPP") and the 2022 Inducement Equity Plan (the "2022 Inducement Plan").

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2018 Stock Option and Incentive Plan

The 2018 Plan was adopted by the Board of Directors on May 2, 2018, and approved by the Company's stockholders on May 11, 2018. The 2018 Plan has replaced the 2017 Plan as no additional awards will be granted under that plan following the consummation of the IPO. At December 31, 2022 there were 1,063,499 shares available to grant under the 2018 Plan.

The 2018 Plan provides for the grant of equity-based incentive awards, including incentive stock options, non-qualified stock options, restricted stock awards, unrestricted stock awards and restricted stock units to the Company's officers, employees, directors and other key persons (including consultants). Stock options and restricted stock units granted under the 2018 Plan to employees generally vest over four years. The shares of common stock underlying any awards that are forfeited, cancelled, repurchased or are otherwise terminated by the Company under the 2018 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan.

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The 2018 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2019, by 4% of the outstanding number of shares of common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Board of Directors or compensation committee (the "Annual Increase"). These limits are subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization.

2017 Stock Option and Incentive Plan

The 2017 Plan provides for the grant of incentive stock options, non-qualified stock options, restricted stock awards, unrestricted stock awards and restricted stock units. Stock options granted under the 2017 Plan to employees generally vest over four years. The Company no longer issues grants from the 2017 Plan. The shares of common stock underlying any awards that are forfeited, cancelled, repurchased or are otherwise terminated by the Company under the 2017 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan.

2018 Employee Stock Purchase Plan

On May 2, 2018, the Board of Directors adopted the 2018 ESPP, and it was approved by the stockholders on May 11, 2018. At December 31, 2022 December 31, 2023 there were 1,489,463 1,843,077 shares available to grant under the 2018 ESPP and no shares had been issued. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2019 through January 1, 2028, by the lesser of (i) 353,614 shares of common stock, (ii) 1% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31 or (iii) such lesser number of shares as determined by the 2018 ESPP administrator. The number of shares reserved under the 2018 ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization.

2022 Inducement Equity Plan

The 2022 Inducement Plan was approved by the Board of Directors on June 16, 2022 and provides for the grant of non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards and dividend equivalent rights to individuals that were not previously an employee or director of the Company or individuals returning to employment after a bona fide period of non-employment with the Company. Stock options and restricted stock units granted under the 2022 Inducement Plan to employees generally vest over four years. The shares of common stock underlying any awards that are forfeited, cancelled, repurchased or are otherwise terminated by the Company under the 2022 Inducement Plan will be added back to the shares of common stock available for issuance under the 2022 Inducement Plan. The 2022 Inducement Plan was approved for 1,000,000 shares of common stock in June 2022 and an additional 1,000,000 shares of common stock were added in both September 2022. At December 31, 2022 there were 750,000 shares available to grant under the 2022 Inducement Plan. and February 2023.

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Total Equity-Based Compensation Expense

The Company recorded equity-based compensation expense related to all equity-based awards, which was allocated as follows in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Research and development expense	$ 12,926	$ 10,176	$11,203	$12,926
General and administrative expense	14,775	12,973	15,939	14,775
	$ 27,701	$ 23,149	$27,142	$27,701

Equity-based compensation during the year ended December 31, 2022 includes $2.0 million related to the modification of certain equity awards.

The following table summarizes the Company's unrecognized equity-based compensation expense as of December 31, 2022:

	As of December 31, 2022	
	Unrecognized Expense (in thousands)	Weighted Average Remaining Period of Recognition (years)
Restricted Stock Units	16,533	2.6
Stock Options	35,786	2.6
	$ 52,319	

Restricted Stock Units

The following table summarizes the Company's restricted stock unit activity for the current year:

	Number of Units	Weighted Average Grant Date Fair Value
Restricted stock units as of December 31, 2021	314,901	$ 47.38
Granted	1,745,350	$ 10.97
Vested	(92,100)	$ 43.79
Forfeited	(300,629)	$ 21.31
Restricted stock units as of December 31, 2022	1,667,522	$ 14.17

The total fair value of restricted stock units vested during the year ended December 31, 2022 was $1.3 million.

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The following table summarizes the Company's unrecognized equity-based compensation expense as of December 31, 2023:

	As of December 31, 2023	
	Unrecognized Expense (in thousands)	Weighted Average Remaining Period of Recognition (years)
Restricted Stock Units	$ 18,482	2.6
Stock Options	30,649	2.3
	$ 49,131	

Restricted Stock Units

The following table summarizes the Company's restricted stock unit activity for the current year:

	Number of Units	Weighted Average Grant Date Fair Value
Restricted stock units as of December 31, 2022	1,667,522	$ 14.17
Granted	1,281,245	$ 9.58
Vested	(533,460)	$ 14.18
Forfeited	(325,755)	$ 10.49
Restricted stock units as of December 31, 2023	2,089,552	$ 11.92

The total fair value of restricted stock units vested during the year ended December 31, 2023 was $5.3 million.

Stock Options

The following table summarizes the Company's stock option activity for the current year:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Val (in thousand
Outstanding as of December 31, 2021	3,743,400	$ 25.55	8.06	$ 26,272				
Outstanding as of December 31, 2022					6,242,784	$ 17.12	7.74	$ 5,83
Granted	3,429,026	$ 9.95			2,285,596	$ 9.51		
Exercised	(44,850)	$ 11.04			(258,372)	$ 5.94		
Cancelled	(884,792)	$ 25.33			(969,055)	$ 18.10		
Outstanding as of December 31, 2022	6,242,784	$ 17.12	7.74	$ 5,835				
Options exercisable as of December 31, 2022	2,466,054	$ 20.23	5.87	$ 1,520				
Outstanding as of December 31, 2023					7,300,953	$ 15.00	7.90	$ 52,29
Options exercisable as of December 31, 2023					3,416,648	$ 18.07	6.91	$ 19,69

Using the Black-Scholes option pricing model, the weighted average fair value of options granted during the year ended December 31, 2022 December 31, 2023 was $7.36. $7.29.

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The following weighted average assumptions were used in determining the fair value of options granted in the years ended December 31, 2022 December 31, 2023 and 2021: 2022:

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Risk-free interest rate	3.07 %	0.86 %	3.87 %	3.07 %
Expected dividend yield	0.0 %	0.0 %	0.0 %	0.0 %
Expected term (years to liquidity)	5.99	6.22	6.06	5.99
Expected volatility	88.63 %	87.62 %	89.67 %	88.63 %

10. Income Taxes

The Company has not recorded a current or deferred tax provision for the years ended December 31, 2022 and 2021.

The effective income tax rate differed from the amount computed by applying the federal statutory rate to the Company's loss before income taxes as follows:

	For Year Ended December 31,	
	2022	2021
Tax effected at statutory rate	21.0 %	21.0 %
State taxes	6.8	6.8
Stock compensation	(2.0)	0.9
Non-deductible expenses	(0.6)	(1.6)
Federal research and development credits	7.5	6.5
Other	(0.7)	(1.5)
Change in valuation allowance	(32.0)	(32.1)
	— %	— %

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11. Income Taxes

The Company has not recorded a current tax provision for the years ended December 31, 2023 and 2022.

The effective income tax rate differed from the amount computed by applying the federal statutory rate to the Company's loss before income taxes as follows:

	For Year Ended December 31,	
	2023	2022
Tax effected at statutory rate	21.0 %	21.0 %
State taxes	6.3	6.8
Stock compensation	(2.3)	(2.6)
Non-deductible expenses	(0.3)	—
Federal research and development credits	4.9	7.5
Other	0.1	(0.7)
Change in valuation allowance	(29.7)	(32.0)
	— %	— %

Deferred tax assets (liabilities) consist of the following at December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	As of December 31,		As of December 31,	
	2022	2021	2023	2022
Deferred tax assets:				
Net operating loss carryforwards	$ 93,505	$ 82,403	$ 110,120	$ 93,505
Tax credits	36,785	25,800	45,621	36,785
Capitalized Research & Development	27,446	—	49,699	27,446
Stock based compensation	7,489	4,751	8,328	7,489
Operating lease liability	5,329	7,365	3,217	5,329
Reserve and accruals	2,579	2,844	3,294	2,579
Deferred revenue	—	9,035	—	—
Total gross deferred tax assets	173,133	132,198	220,279	173,133

Valuation allowance	(167,275)	(124,233)	(216,524)	(167,275)
Total deferred tax assets	5,858	7,965	3,755	5,858
Total deferred tax liabilities:				
Operating lease right-of-use asset	(5,029)	(6,925)	(3,113)	(5,029)
Fixed and intangible assets	(829)	(1,040)	(642)	(829)
Total deferred tax liabilities	(5,858)	(7,965)	(3,755)	(5,858)
Total net deferred tax assets	$ —	$ —	$ —	$ —

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Total Net Deferred Tax Assets

Deferred tax assets are reduced by a valuation allowance if, based on the weight of available positive and negative evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2022 December 31, 2023 and 2021. 2022. The valuation allowance for deferred tax assets increased by $43.0 $49.2 million and $42.3 million $43.0 million in 2022 2023 and 2021, 2022, respectively. This increase mainly relates to the establishment of a valuation allowance against the Company's net domestic deferred tax assets in connection with net operating losses generated in each year, capitalized research expenses and additional tax credit carryforwards generated. Starting with tax years beginning after December 31, 2021, entities are required to capitalize all research and experimentation "R&D" expenses as defined under Section 174 of the Internal Revenue Code and amortize them over five years for domestic expenses and over fifteen years for foreign expenses. During the year, the Company capitalized $101.2 million $81.0 million of R&D expenses, net of current and prior year amortization deductions. The corresponding deferred tax asset as of December 31, 2022 December 31, 2023 is $27.4 million $49.7 million. As of December 31, 2022 December 31, 2023, the Company had approximately $343.0 million $403.2 million and $339.8 million $402.8 million of Federal and State operating loss carryforwards respectively, which begin to expire in 2032, except for $292.5 million $352.7 million of the Company's federal net operating loss carryforwards that do not expire. These loss carryforwards may be available to reduce future taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. As of December 31, 2022 December 31, 2023, the Company also had federal and state credit carryovers of $32.6 million $40.8 million and $5.3 million $6.1 million, respectively, which begin to expire in 2034 and 2023, 2024, respectively. The amount of loss and credit carryforwards that may be utilized in any future period may be limited based upon changes in the ownership of the Company's ultimate parent. Additionally, the deductibility of federal net operating losses generated after December 31, 2017 is limited to 80% of the Company's taxable income in any future taxable year.

The Company follows the provisions of ASC 740-10, “Accounting for Uncertainty in Income Taxes,” which specifies how tax benefits for uncertain tax positions are to be recognized, measured, and recorded in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim period guidance, among other provisions. As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company has not recorded any amounts for uncertain tax positions. The Company’s policy is to recognize interest and penalties accrued on any uncertain tax positions as a component of income tax expense, if any, in its statements of income.

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The Company’s net operating loss and tax credit carryforwards 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 percent as defined under Section 382 and 383 of the U.S. Internal Revenue Code of 1986, respectively, as well as similar state provisions. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. The Company conducted a Section 382 study covering the period of November 26, 2013 through June 30, 2022 December 31, 2023. The study concluded that ownership changes occurred during that period which limit the amount of the Company’s net operating losses and tax credit carryforwards that can be utilized before expiring. The carryforwards disclosed represent the amount of attributes that can be utilized based on the results of the study.

All of the Company’s tax years will remain open for examination by the federal and state tax authorities to the extent that the Company's tax attributes are utilized in future years to offset income or income taxes.

11. 12. Commitments and Contingencies

Operating Leases

620 Memorial Facility Lease

In March 2015, the Company entered into a 5-year lease of office and laboratory space for its corporate headquarters (the “Lease”) at 620 Memorial Drive in Cambridge, Massachusetts. The Lease was amended in February 2018, to add an additional space (the “Expansion Space”) at the current location and to extend the Lease term (the “Amended Lease”). The Amended Lease expires expired in September 2023. Annual rent payments, including the Expansion Space, increase increased from $1.4 million to $1.7 million $1.7

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million over the term of the Amended Lease. Variable lease payments include included the Company's allocated share of costs incurred and expenditures made by the landlord in the operation and management of the building.

On October 5, 2020, the Company entered into a Sublease Agreement (the "Sublease") with Orna Therapeutics, Inc. (the "Subtenant") to sublease the space covered by the Amended Lease at 620 Memorial Drive, Cambridge, Massachusetts. The Sublease term commenced on February 1, 2021 and ends ended on August 31, 2023, unless terminated earlier.. The Sublease provides provided for initial annual base rent of approximately $1.9 million. The Subtenant is was obligated to pay for certain costs, taxes and operating expenses, subject to certain exclusions. The Sublease is was subordinate to that certain Indenture of Lease, dated March 5, 2015, by and between 620 Memorial Leasehold LLC and Scholar Rock, Inc., as amended.

301 Binney Facility Lease

In November 2019, the Company entered into a lease of office and laboratory space at 301 Binney Street in Cambridge, Massachusetts to be used as its new corporate headquarters. The expiration date of the lease is in August 2025 and the Company has the option to extend the term by two years. The base rent is $6.9 million per year, subject to an annual increase of 3.5%, and the Company was subject to a free-rent period through mid-August 2020. Variable lease payments include the Company's allocated share of costs incurred and expenditures made by the landlord in the operation and management of the building. The lease included incentives of $14.1 million in the form of an allowance for tenant improvements related to the design and build out of the space. In connection with the lease, the Company has secured a letter of credit for $2.3 million which renews automatically each year. The lease commencement date, for accounting purposes, was reached in September 2020.

Other information related to the Company's leases (excluding the Company's sublease income of $2.0 million and $2.7 million for the years ending December 31, 2023 and 2022, respectively) is as follows (in thousands, except lease term and discount rate):

	For Year Ended December 31, 2023
Lease Cost:	
Operating lease cost	$ 8,331
Variable lease cost	2,105
Total lease cost	$ 10,436

	For Year Ended December 31,

	2023
Other information:	
Operating cash flows used for operating leases	$ 9,057
Weighted average remaining lease term	1.6
Weighted average incremental borrowing rate	7.6 %

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Other information related to the Company's leases (excluding the Company's sublease income of $2.7 million and $2.3 million for the years ending December 31, 2022 and 2021, respectively) is as follows (in thousands, except lease term and discount rate):

	For Year Ended December 31, 2022
Lease Cost:	
Operating lease cost	$ 8,675
Variable lease cost	2,080
Total lease cost	$ 10,755

	For Year Ended December 31, 2022
Other information:	
Operating cash flows used for operating leases	$ 9,183
Weighted average remaining lease term	2.5
Weighted average incremental borrowing rate	7.5 %

The following is a maturity analysis of the annual undiscounted cash flows reconciled to the carrying value of the operating lease liabilities as of December 31, 2022 December 31, 2023 (in thousands):

Year Ending December 31,		
2023	9,057	
2024	8,051	8,051
2025	4,498	4,498

Total lease payments	21,606	12,549
Less imputed interest	(1,954)	(749)
Total operating lease liability	$ 19,652	$11,800
Short-term portion of operating lease liability	7,852	7,408
Long-term portion of operating lease liability	11,800	4,392

The Company recorded approximately $8.7 million $8.3 million and $8.6 million $8.7 million in rent expense (excluding sublease income) for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

Specifica Antibody Library

On December 20, 2019 (the "Effective Date"), the Company entered into a Library Development and Transfer Agreement with Specifica Inc. ("Specifica"), whereby Specifica is responsible for developing and delivering a customized antibody display library (the "Library") for the Company to use to identify antibodies for further research, development, and commercialization. As of December 31, 2022 the Company has paid $2.9 million of the total $3.7 million in fees expected to be paid through 2023 related to the Library. As the return right has lapsed, all $3.7 million in fees have been recognized as expense to date.

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of its business. The Company was not subject to any material legal proceedings during the years ended December 31, 2022 December 31, 2023 and 2021. 2022.

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12. 13. Debt

On October 16, 2020 (the "Closing Date") the Company entered into a Loan and Security Agreement with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") for $50.0 million (the "Loan and Security Agreement"). Tranche 1 of $25.0 million was funded on the Closing Date. The Company had an additional $25.0 million in loan proceeds available under Tranche 2 which was funded in December 2021, in conjunction with the Company entering into the First Amendment 1. to Loan and Security Agreement with Oxford and SVB. The Loan and Security Agreement was to mature on May 1, 2025 and required interest-only payments through November 2022, with principal payments to commence in December 2022. Pursuant to the Loan and Security Agreement, the Company was required to maintain cash in an SVB account equal to the lesser of 100% of the Company's consolidated cash or 105% of the dollar amount of the outstanding debt.

On November 10, 2022, the Company entered into the Second Amendment 2 to Loan and Security Agreement (the “Amendment 2”) to increase the Company’s borrowing capacity under the Loan and Security Agreement (the “Amendment”) to increase the total agreement to an amount up to $100.0 million, comprised of the original $50.0 million loan which remains outstanding and two additional $25.0 million tranches. The first $25.0 million tranche is available under Amendment 2, was available at the Company’s discretion through December 2023 upon achievement of certain development and business performance milestones. The Company did not exercise this tranche. The second $25.0 million tranche available under Amendment 2, may be available upon the Company’s request, at Oxford and SVB’s discretion. The Amendment 2 also extended the interest-only payment period for an additional 24 months through November 2024, with principal payments to commence in December 2024, or for an additional 36 months through November 2025 upon achievement of certain development and business performance milestones, with principal payments to commence in December 2025. The maturity of the loan was extended to November 2027.

Effective upon the Amendment 2, the interest rate on the unpaid principal is the greater of the Wall Street Journal prime rate plus 4.60% or 9.35% per annum. Prepayment is permitted and may include a pre-payment fee ranging from 0% - 3% (of the principal amount being prepaid), depending on when the prepayment is made. The Company is also required to make a final payment equal to 2% of the original principal amount.

In conjunction with the Amendment 2, the Company was required to pay $0.9 million for the accrued portion of the final payment on the previous outstanding balance balance.

Table of $0.9 million. Contents

On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“FDIC”) as receiver. Afterward, the FDIC transferred all deposits of the former Silicon Valley Bank to Silicon Valley Bridge Bank, N.A., as operated by the FDIC. On March 27, 2023, Silicon Valley Bridge Bank was closed by the Office of the Comptroller of the Currency, and the FDIC was appointed as receiver. First Citizens Bank then entered into an agreement with the FDIC to purchase out of FDIC receivership substantially all loans and certain other assets and assume all customer deposits and certain other liabilities of Silicon Valley Bridge Bank. On March 27, 2023, Silicon Valley Bridge Bank and its U.S. branches began operating as Silicon Valley Bank, a division of First Citizens Bank.

On April 18, 2023, the Company entered into Amendment 3 to the Loan and Security Agreement to amend certain provisions relating to the Company’s operating accounts.

The following table shows required payments (excluding interest), during the next five years on debt outstanding at December 31, 2022 December 31, 2023 (in thousands):

Year Ending December 31,	Total future payments	Total future payments
2023	$ —	
2024	1,389	$ 1,389
2025	16,667	16,667
2026	16,667	16,667
2027	16,277	16,277
Total payments	$ 51,000	$ 51,000

The Company incurred costs on behalf of the lender recorded as a debt discount of $0.4 million and incurred debt issuance costs of $0.1 million, both of which are recorded as a deduction from the carrying amount of the debt and are being amortized as interest expense over the term of the loan. The final payment fee will be treated as an additional debt discount and accreted to the debt balance over the term.

For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, the Company recorded total interest expense for the debt of $4.7 million $6.5 million and $2.1 million $4.7 million, respectively.

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13. 14. Agreements

Collaboration with Gilead

On December 19, 2018 (the “Effective Date”), the Company entered into a three-year Master Collaboration Agreement (the “Gilead Collaboration Agreement”) with Gilead to discover and develop specific inhibitors of TGFβ activation focused on the treatment of fibrotic diseases. Under the collaboration, Gilead had exclusive options to license worldwide rights to product candidates that emerge from three of the Company’s TGFβ programs (each a “Gilead Program”). Pursuant to the Gilead Collaboration Agreement, the Company was responsible for antibody discovery and preclinical research through product candidate nomination, after which, upon exercising the option for a Gilead Program, Gilead would be responsible for the program’s preclinical and clinical development and commercialization. Such option could have been exercised by Gilead at any time from the Effective Date through a date that is 90 days following the expiration of the Research Collaboration Term for a given Gilead Program (no later than March 19, 2022), or until termination of the Gilead Program, whichever is

earlier (the “Option Exercise Period”). On January 6, 2022, Gilead agreed to terminate its option exercise period for all programs.

Revenue associated with the research and development and license performance obligations relating to the Gilead Programs was recognized as revenue as the research and development services were provided using an input method, according to the costs that were incurred on each Gilead Program and the costs that were expected to be incurred to satisfy the performance obligation. The transfer of control occurred over time. In management’s judgment, this input method was the best measure of progress towards satisfying the performance obligation. The amounts allocated to the three material rights provided by the options (“Material Rights”) was to be deferred on the Company’s consolidated balance sheet until either exercise or termination of the respective options.

A $25.0 million preclinical milestone was achieved in December 2019 for the successful demonstration of efficacy in preclinical in vivo proof-of-concept studies. As a result, the associated $25.0 million was included in the consideration transferred and proportionally allocated to the performance obligations, as it was probable that a future material reversal would not occur.

The Company recognized the revenue related to the research and development services based on a cost input method over the research term for each respective Gilead Program, which spanned from January 2019 through December 2021. In January 2022, upon Gilead’s termination of its option exercise period for all programs, the Company recognized revenue of $33.2 million $33.2 million attributable to the Material

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Rights in the Company’s consolidated statements of operations and comprehensive loss, after which all revenue related to the Gilead Collaboration Agreement had been fully recognized.

14. 15. Net Loss per Share

The Company calculates basic net loss per share by dividing net loss by the weighted average number of common shares outstanding, excluding restricted common stock. The weighted average number of common shares used in the basic and diluted net loss per share calculation includes the pre-funded warrants issued in connection with the Company’s November 2020 and June 2022 follow-on offerings as the pre-funded warrants are exercisable at any time for nominal cash consideration. As of December 31, 2022 December 31, 2023, no 8,154,695 pre-funded warrants have been exercised and 27,689,692 19,534,997 pre-funded warrants are outstanding. The Company has generated a net loss in all periods presented, so the basic and diluted net loss per share are the same, as the inclusion of the potentially dilutive securities would be anti-dilutive.

Basic and diluted net loss per share is calculated as follows (in thousands, except share and per share data):

	Year Ended December 31, 2022	Year Ended December 31, 2021	Year Ended December 31, 2023	Year Ended December 31, 2022
Net loss	$ (134,502)	$ (131,799)	$ (165,789)	$ (134,502)
Weighted average common shares outstanding, basic and diluted	59,611,656	36,711,833	83,347,086	59,611,656
Net loss per share, basic and diluted	$ (2.26)	$ (3.59)	$ (1.99)	$ (2.26)

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The following table sets forth the outstanding common stock equivalents, presented based on amounts outstanding at each period end, that have been excluded from the calculation of diluted net loss per share for the periods indicated because their inclusion would have been anti-dilutive:

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Restricted stock units	1,667,522	314,901	2,089,552	1,667,522
Stock options	6,242,784	3,743,400	7,300,953	6,242,784
Warrants	10,459,181	—	9,988,156	10,459,181
	18,369,487	4,058,301	19,378,661	18,369,487

15. 16. Retirement Plan

The Company sponsors a 401(k) retirement plan, in which substantially all employees are eligible to participate upon employment. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. Effective, January 1, 2020, the Company adopted a policy to match 50% of the employee contributions to the 401(k) plan up to a maximum of 6% of the participating employee's eligible earnings, resulting in a maximum company match of 3% of the participating employee's eligible earnings subject to statutory limitations. The Company recognized $0.8 million $0.9 million and $0.7 million $0.8 million in

expense related to the match during the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

16. 17. Restructuring

On May 16, 2022, In May 2022, the Company announced a reduction in workforce in connection with the restructuring of its business to prioritize and focus on its clinical stage assets. The restructuring resulted in a reduction of the Company's workforce by 39 positions, or approximately 25%, and occurred during the second quarter of 2022. As a result, the Company recorded restructuring costs of $1.9 million related to severance benefits for the affected employees, including salary continuation, coverage of medical insurance premiums and outplacement services, of which $1.4 million was recorded to research and development expense and $0.5 million was recorded to general and administrative expenses in the second quarter of 2022. At December 31, 2022, all amounts have been paid. The Company also incurred $0.1 million of non-cash expense, during the second quarter of 2022, related to equity modifications associated with the extension of the post-termination option exercise period for the vested portion of the affected employees' outstanding stock options, as well as modifications of certain restricted stock units.

Exhibit 10.7 10.8

SECOND THIRD AMENDMENT
TO
SCHOLAR ROCK HOLDING CORPORATION
2022 INDUCEMENT EQUITY PLAN

A. The Scholar Rock Holding Corporation 2022 Inducement Equity Plan (the "Plan") is hereby amended by deleting the first sentence of Section 3(a) and substituting therefore the following:

> "The maximum number of shares of Stock reserved and available for issuance under the Plan shall be 3,000,000 4,000,000 shares, subject to adjustment as provided in Section 3(c)."

B. The effective date of this Second Third Amendment shall be February 3, 2023 January 25, 2024.

C. Except as amended herein, the Plan is confirmed in all other respects.

Approved by the Board of Directors on February 3, 2023 January 25, 2024.

Exhibit 10.26 10.32

SCHOLAR ROCK, INC.

SECONDAMENDMENTTOLOANANDSECURITYEMPLOYMENT AGREEMENT

THIS SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "**Amendment**") is entered into as of November 10, 2022, by and among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 to the Loan Agreement (as defined below) or otherwise a party thereto from time to time including Oxford in its capacity as a Lender and SILICON VALLEY BANK, a California corporation with an office located at 3003 Tasman Drive, Santa Clara, CA 95054 ("**Bank**" or "**SVB**") (each a "**Lender**" and collectively, the "**Lenders**"), and SCHOLAR ROCK HOLDING CORPORATION, a Delaware corporation ("**Parent**"), and SCHOLAR ROCK, INC., a Delaware corporation (together with Parent, individually and collectively, jointly and severally, "**Borrower**") with an office located at 301 Binney Street, 3rd Floor, Cambridge, MA 02142.

A. WHEREAS, Collateral Agent, Borrower and Lenders have entered into that certain Loan and SecurityAgreementdatedasofOctober16,2020,asamendedbythatcertainFirstAmendmenttoLoanandSecurity Agreement dated as of November 16, 2021 (as further amended, supplemented or otherwise modified from time to time,the"**LoanAgreement**")pursuanttowhichLendershaveprovidedtoBorrowercertainloansinaccordancewith the terms and conditions thereof;

B. WHEREAS, Borrower has requested that Collateral Agent and Lenders modify certain provisions of the Loan Agreement; and

C. WHEREAS, Borrower, the Lenders party to this Amendment (constituting the Required Lenders) and Collateral Agent desire to amend such provisions as provided herein and subject to the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, Lenders and Collateral Agent hereby agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Agreements with Respect to the Loan Agreement.

2.1 Loan Agreement; Partial Prepayment. Notwithstanding anything to the contrary contained in the Loan Agreement (including Section 2.2(d) thereof), each Lender and Borrower hereby agree that, in connection with the transactions contemplated by this Amendment, Borrower will be permitted to prepay the Credit Extensions owing only to SVB as of the Second Amendment Effective Date (such amount, the "**SVB Prepayment Amount**"), which prepayment will be less than all of the Term Loans outstanding prior to the Second Amendment Effective Date. Furthermore, each Lender and Borrower agree that in connection with such prepayment, Borrower will pay (a) all accrued and unpaid interest then owing on the SVB Prepayment Amount, and (b) SVB's Pro Rata Share of the Second Amendment Accrued Final Payment.

2.2 The agreements and consents set forth in this Section 2 are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right, remedy or obligation which Lender or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.

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3. Amendments to Loan Agreement.

3.1 Preamble. The preamble in the first paragraph of the first page of the Loan Agreement is amended and restated as follows:

"**THIS LOAN AND SECURITY AGREEMENT** (as the same may from time to time be amended, modified, supplemented or restated, this "**Agreement**") dated as of October 16, 2020 (the "**Effective Date**") among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender and SILICON VALLEY BANK, a California corporation with an office located at 3003 Tasman Drive, Santa Clara, CA 95054 ("**Bank**" or "**SVB**") (each a "**Lender**" and collectively, the "**Lenders**"), SCHOLAR ROCK HOLDING CORPORATION, a Delaware corporation ("**Parent**") and SCHOLAR ROCK, INC., a Delaware corporation (together with Parent, individually and collectively, jointly and severally, "**Borrower**"), with an office located at 301 Binney Street, 3rd Floor,

Cambridge, MA 02142, provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:"

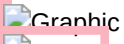
3.2 Section 2.2(a)(Term Loans – Availability). Clause (ii) of Section 2.2(a) of the Loan Agreement is amended and restated, and clauses (iii), (iv) and (v) are hereby added, as follows:

"(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Second Draw Period, to make term loans to Borrower (but in a single disbursement) in an aggregate amount up to Twenty-Five Million Dollars ($25,000,000.00) according to each Lender's Term B Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term B Loan**", and collectively as the "**Term B Loans**"). After repayment, no Term B Loan may be re-borrowed.

(iii) Subject to the terms and conditions of this Agreement, SVB will make a term loan to Borrower on or about the Second Amendment Effective Date in an aggregate amount of Twenty-Five Million Dollars ($25,000,000.00) according to SVB's Term C Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term C Loan**", and collectively as the "**Term C Loans**"). The proceeds of the Term C Loan will be used by Borrower (and are permitted pursuant to this Agreement) to prepay the aggregate principal amount of SVB's Credit Extensions of Term A Loan and Term B Loan outstanding as of the Second Amendment Effective Date (which prepayment shall refinance all Credit Extensions made by SVB pursuant to its Term A Loan Commitment and Term B Loan Commitment). Each Lender and Borrower hereby agree that no proceeds of the Term C Loan will be used to repay any amounts due and owing to Oxford under the Term A Loan and/or Term B Loan as of the Second Amendment Effective Date. After repayment, no Term C Loan may be re-borrowed.

(iv) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Term D Draw Period, to make term loans to Borrower (but in a single disbursement) in an aggregate amount up to Twenty-Five Million Dollars ($25,000,000.00) according to each Lender's Term D Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term D Loan**", and collectively as the "**Term D Loans**"). After repayment, no Term D Loan may be re-borrowed.

(v) Subject to the terms and conditions of this Agreement, the Lenders may, in their sole discretion and subject to Lenders receiving credit approval, agree to make term loans to Borrower (but in a single disbursement) prior to the Amortization Date in an aggregate amount equal to Twenty Five Million Dollars ($25,000,000.00) and, if made, according to a commitment schedule to be provided by the Lenders prior to the Funding Date of such term loans (such term loans are hereinafter referred to singly as a "**Term E Loan**", and collectively as the "**Term E Loans**"; each Term A Loan, Term B Loan, Term C Loan, Term D Loan or Term E Loan is hereinafter referred to singly as a "**Term Loan**" and the Term A Loans, the Term B Loans, Term C Loans, Term D Loans and the Term E Loans are hereinafter referred to collectively as the "**Term Loans**"). After repayment, no Term E Loan may be re-borrowed."




3.3 Section2.2(b)(Repayment). Section2.2(b)oftheLoanAgreementisamendedandrestatedas follows:

"Repayment. Borrower shall make monthly payments in arrears of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to (x) thirty-six (36) months if the Amortization Date is December 1, 2024 and (y) twenty-four (24) months if the Amortization Date is December 1, 2025. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d)."

3.4 Section2.2(e)(AcknowledgmentofTermALoanandTermBLoan). Section2.2(e)oftheLoan and Security Agreement is hereby added as follows:

"(e) AcknowledgmentofTermALoanandTermBLoan. Oxford agrees that, as of the Second Amendment Effective Date and pursuant to the transactions contemplated by the Second Amendment, the Credit Extensions it made to Borrower prior to the Second Amendment Effective Date, which constitute Oxford's Pro Rata Share of the principal amounts of the Term A Loan and Term B Loan, will each continue as the aggregate outstanding principal amount of the Term A Loan and Term B Loan, respectively, as shown on Schedule1.1 as amended by the Second Amendment. Borrower agrees and acknowledges that Oxford's Term A Loan Commitment and Term B Loan Commitment have been fully extended and Oxford has no obligation to make any further Credit Extensions of the Term A Loan or the Term B Loan. Furthermore, following any repayment (including the prepayments contemplated in the Second Amendment), no Term A Loan or Term B Loan may be reborrowed and, as of the Second Amendment Effective Date, any Term Loan Commitment of SVB associated with the Term A Loan and/or the Term B Loan will be terminated."

3.5 Section2.5(f)(SecondAmendmentAccruedFinalPayment). Section2.5(f)oftheLoan Agreement is hereby added as follows:

"(f) Second Amendment Accrued Final Payment. A fully earned, non-refundable Final Payment in the aggregate amount of Nine Hundred Twenty-Two Thousand Three Hundred Seventy-Nine and 30/100 Dollars ($922,379.30) in respect of the Term A Loans and Term B Loans (the "**SecondAmendmentAccruedFinal Payment**") to be shared between the Lenders in accordance with their

respective Pro Rata Shares (in effect immediately prior to the repayment of the Term A Loan and Term B Loan held by SVB with the proceeds of the Term C Loan) due and payable on the Second Amendment Effective Date. The Second Amendment Accrued Final Payment shall not reduce the Final Payment otherwise due pursuant to Section 2.5(b) hereof. From and after the Second Amendment Effective Date, the Final Payment in respect of the Term A Loan and Term B Loan held by Oxford shall accrue from the Second Amendment Effective Date."

3.6 Section5.9(UseofProceeds). Section5.9oftheLoanAgreementisamendedtoaddthefollowing sentence to the end of such section:

"Additionally, Borrower will be permitted to use the proceeds of the Credit Extensions of the Term C Loan to repay all outstanding Credit Extensions made by SVB of the Term A Loan and the Term B Loan as of the Second Amendment Effective Date as well as any accrued and unpaid interest thereon and any other fees associated therewith (including any Final Payment)."

3.7 Section 13 (Definitions). The following terms and such definitions in Section 13.1 of the Loan Agreement hereby are amended and restated in their entirety as follows:

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"**Amortization Date**" is December 1, 2024; provided, however, upon the occurrence of the Term D Milestone, then the Amortization Date with respect to all Term Loans shall automatically be extended to December 1, 2025.

"**Approved Fund**" is any (a) Person, investment company, fund, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business and that is administered or managed by (i) a Lender, (ii) an Affiliate of a Lender, or (iii) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender, or (b) any Person (other than a natural person) which temporarily warehouses loans, or provides financing or securitizations, in each case, for any Lender or any entity described in the preceding clause (a).

"**Basic Rate**" is the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the greater of (a) nine and thirty-five hundredths of one percent (9.35%), and (b) the sum of (i) the "prime rate" reported in The Wall Street Journal on the last Business Day of the month that immediately precedes the month in which the interest will accrue, and (ii) four and six tenths of one percent (4.60%). If The Wall Street Journal no longer reports the "prime rate" or if The Wall Street Journal ceases to exist, Collateral Agent may, in good faith, select a replacement publication and shall notify Borrower of such replacement publication. Notwithstanding the foregoing, the Basic Rate for the Term Loan for the period

from the Second Amendment Effective Date through and including November 30, 2022, shall be ten and eighty-five hundredths of one percent (10.85%).

"**Final Payment Percentage**" is two percent (2.00%).

"**MaturityDate**" is, for each Term Loan, November 1, 2027.

"**Obligations**" are all of Borrower's obligations to pay when due any debts, principal, interest, Lenders' Expenses, the Prepayment Fee (if any), the Second Amendment Accrued Final Payment, the Final Payment, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents, or otherwise, including, without limitation, all obligations relating to letters of credit (including reimbursement obligations for drawn and undrawn letters of credit), cash management services, and foreign exchange contracts, if any, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower's duties under the Loan Documents.

"**Prepayment Fee**" is, with respect to any funded Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

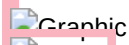
(i) foraprepaymentmadeonoraftertheSecondAmendmentEffectiveDatethrough and including the first anniversary of the Second Amendment Effective Date, three percent (3.00%) of the principal amount of such Term Loan prepaid;

(ii) for a prepayment made after the date which is after the first anniversary of the SecondAmendmentEffectiveDatethroughandincludingthesecondanniversaryoftheSecondAmendmentEffective Date, two percent (2.00%) of the principal amount of such Term Loan prepaid; and

(iii) foraprepaymentmadeafterthedatewhichisafterthesecondanniversaryofthe Second Amendment Effective Date, zero percent (0.00%) of the principal amount of such Term Loan prepaid.

"**TermLoan**" is defined in Section 2.2(a)(v) hereof.

3.8 Section13(Definitions). Thefollowingtermsandsuchdefinitionsareherebyaddedto Section 13.1 of the Loan Agreement as follows:

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"**Second Amendment**" means that certain Second Amendment to Loan and Security Agreement , dated as of the Second Amendment Effective Date, by and among Borrower, Parent,

Oxford as a lender and Collateral Agent and SVB as a lender.

"**SecondAmendmentAccruedFinalPayment**" is defined in Section 2.5(f) hereof.

"**Second Amendment Effective Date**" is November 10, 2022.

"**TermCLoan**" is defined in Section 2.2(a)(iii) hereof.

"**Term D Draw Period**" is the period commencing on the date of the occurrence of the Term D Milestone and ending on the earliest of (i) December 31, 2023, (ii) the date that is ninety (90) days after the achievement of the Term D Milestone and (iii) the occurrence of an Event of Default; provided, however, that the Term D Draw Period shall not commence if on the date of the occurrence of the Term D Milestone an Event of Default has occurred and is continuing.

"**TermDLoan**" is defined in Section 2.2(a)(iv) hereof.

"**Term D Milestone**" is Borrower's delivery to Collateral Agent and the Lenders of evidence, satisfactory to Collateral Agent and the Lenders in their sole but reasonable discretion, that Borrower has either (i) (A) dosed at least twenty (20) patients in any single cohort of Part B of the DRAGON Phase 1 clinical trial for SRK-181, (B) disclosed positive efficacy data for SRK-181 at a scientific conference or by other means prior to December 31, 2023 and (C) after first satisfying clauses (A) and (B) of this clause (i), Borrower has received unrestricted net cash proceeds of not less than One Hundred Million Dollars ($100,000,000.00) from the issuance and sale of its equity securities after the Second Amendment Effective Date but prior to December 31, 2023 in a single equity financing transaction; or (ii) (A) dosed at least twenty
(20) patients in any single cohort of Part B of the DRAGON Phase 1 clinical trial for SRK-181, (B) disclosed efficacy data for SRK-181 at a scientific conference or by other means prior to December 31, 2023 and (C) Borrower has entered into a new joint venture, collaboration or other strategic partnership transaction for SRK-181 after the Second Amendment Effective Date and Borrower has received unrestricted net cash proceeds of not less than One Hundred Million Dollars ($100,000,000.00) from the issuance and sale of its equity securities and/or an upfront payment concurrently with the closing of such transaction from the counterparty to such transaction or any of its Affiliates.

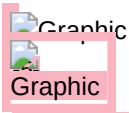
"**TermELoan**" is defined in Section 2.2(a)(v) hereof.

3.9 Schedule1.1(LendersandCommitments). Schedule1.1oftheLoanAgreementisamendedand restated with Schedule 1.1 attached to this Amendment.

4. LimitationofAmendment.

4.1 The amendment set forth above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right, remedy or obligation which Lenders or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.

4.2 ThisAmendment shall be construed in connection with andas part of the Loan Documents and all terms,conditions,representations,warranties,covenantsandagreementssetforthintheLoan Documentsarehereby ratified and confirmed and shall remain in full force and effect.



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5. Representations and Warranties. To induce Collateral Agent and Lendersto enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

5.1 ImmediatelyaftergivingeffecttothisAmendment(a)therepresentationsandwarrantiescontained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date) and (b) no Event of Default has occurred and is continuing;

5.2 Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

5.3 TheorganizationaldocumentsofBorrowerdeliveredtoCollateralAgentontheEffectiveDate,and updated pursuant to subsequent deliveries by or on behalf of the Borrower to the Collateral Agent, remain true, accurate and complete andhave not been amended, supplemented orrestated and are and continue to be in full force and effect;

5.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of itsobligationsundertheLoanAgreement,asamendedbythisAmendment,donotcontravene(i)anymateriallawor regulation binding on or affecting Borrower, (ii) any material contractual restriction with a Person binding on Borrower,(iii)anymaterialorder,judgmentordecreeofanycourtorothergovernmentalorpublicbodyorauthority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;

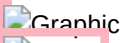
5.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made;

5.6 This Amendment has been duly executed and delivered by Borrower and is the binding obligation ofBorrower,enforceableagainstBorrowerinaccordancewithitsterms,exceptassuchenforceabilitymaybelimited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws relating to or affecting creditors' rights and general equitable principles.

6. ReleasebyBorrower.

6.1 FOR GOOD AND VALUABLE CONSIDERATION, Borrower hereby forever relieves,releases, anddischargesCollateralAgentandeachLenderandtheirrespectivepresentorformeremployees,officers,directors, agents, representatives, attorneys, and eachof them,from any and allclaims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description orcharacterwhatsoever,whetherknownorunknown,suspectedorunsuspected,absoluteorcontingent,arisingoutof orinanymannerwhatsoeverconnectedwithorrelatedtofacts,circumstances,issues,controversiesorclaimsexisting or arising from the beginning of time through and including the date of execution of this Amendment solely to the extentsuchclaimsariseoutoforareinanymannerwhatsoeverconnectedwithorrelatedtotheLoanDocuments,the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination,negotiation,administration,servicingand/orenforcementofanyoftheforegoing(collectively"**Released Claims**").

6.2 Byenteringintothisrelease,Borrowerrecognizesthatnofactsorrepresentationsareeverabsolutely certain and itmay hereafter discover factsin addition to or differentfrom those which itpresently knowsorbelieves to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected in relation to the Released Claims; accordingly,ifBorrowershouldsubsequentlydiscoverthatanyfactthatitrelieduponinenteringintothisreleasewas untrue,orthatanyunderstandingof the facts was incorrect,Borrower shallnotbe entitledto set aside this releaseby reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever.Borrower



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acknowledges that it is not relying upon and has not relied upon any representation or statement made by Bank with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

6.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaimagainstanyaction,suit,orotherproceedingthatmaybeinstituted,prosecutedorattemptedinbreachof thisrelease.BorroweracknowledgesthatthereleasecontainedhereinconstitutesamaterialinducementtoCollateral AgentandtheLenderstoenterintothisAmendment,andthatCollateralAgentandtheLenderswouldnothavedone so but for Collateral Agent's and the Lenders' expectation that such release is valid and enforceable in all events.

7. Loan Document. Borrower, Lenders and Collateral Agent agree that this Amendment shall be a Loan Document. Except as expressly set forth herein, the Loan Agreement and the other Loan Documents shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.

8. Effectiveness. This Amendment shall be deemed effective upon the due execution of this Amendment by the parties hereto. Borrower hereby agrees that the following documents shall be delivered to Collateral Agent prior to or contemporaneously with delivery of this Amendment, each in form and substance satisfactory to Collateral Agent:

(a) this Amendment duly executed by each party hereto;

(b) a duly executed original Secured Promissory Note in favor of SVB according to its Term C Loan Commitment Percentage;

(c) the Operating Documents and good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency) of Borrower's and such Subsidiaries' jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the date hereof;

(d) updated Perfection Certificates for Borrower and each of its Subsidiaries duly executed by such Person;

(e) an officer's certificate for Borrower and each Subsidiary that is a party to the Loan Documents, in a form reasonably acceptable to Collateral Agent, duly executed by such Person;

(f) receipt of a duly executed Disbursement Letter and Loan Payment/Advance Request Form;

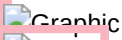
(g) all accrued and unpaid interest payable to SVB in connection with the repayment of SVB's Credit Extensions of the Term A Loan and Term B Loan set forth in this Amendment, as of the Second Amendment Effective Date, in an amount equal to $67,812.50, plus per diem in the amount of $7,534.72 accruing after the Second Amendment Effective Date;

(h) all accrued and unpaid interest payable to Oxford in connection with its Term A Loan and Term B Loan, as of the Second Amendment Effective Date, in an amount equal to $67,812.50, plus per diem in the amount of $7,534.72 accruing after the Second Amendment Effective Date;

(i) a duly executed legal opinion of counsel to Borrower dated as of the date hereof and in form and substance reasonably acceptable to Collateral Agent and based upon the agreed form of the legal opinion dated October 16, 2020 delivered to Collateral Agent in connection with the Loan Agreement; and

(j) the Second Amendment Accrued Final Payment.

9. **Counterparts.**This Amendment may be executed in any number of counterparts, each of which shall be deemedanoriginal,andallofwhich,takentogether,shallconstituteoneandthesameinstrument.Deliveryby



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electronic transmission (e.g. ".pdf") of an executed counterpart of this Amendment shall be effective as a manually executed counterpart signature thereof.

10. **GoverningLaw.**ThisAmendmentandtherightsandobligationsofthepartiesheretoshallbegovernedby and construed in accordance with the laws of the State of New York.

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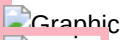

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IN WITNESS WHEREOF, the parties hereto have caused this Second Amendment to Loan and Security Agreement to be executedasof the date first set forth above.

BORROWER:

SCHOLARROCKHOLDINGCORPORATION

By: /s/ Junlin Ho

Name: Junlin Ho
Title: Secretary

SCHOLARROCK,INC.

By: /s/ Junlin Ho

Name: Junlin Ho
Title: General Counsel and Secretary

COLLATERALAGENTAND LENDER:

OXFORDFINANCE LLC

By: /s/ Colette H. Featherly

Name: Colette H. Featherly

Title: Senior Vice President

COLLATERALAGENTANDLENDER:

LENDER:

SILICONVALLEYBANK

By: /s/ John Sansone

Name: John Sansone

Title: Vice President

(Signature Page to Second Amendment to Loan and Security Agreement)

SCHEDULE1.1

LendersandCommitments

Term A Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$12,500,000.00	100.00%
SILICON VALLEY BANK**	$0.00	0.00%
TOTAL	**$12,500,000.00**	**100.00%**

Term B Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$12,500,000.00	100.00%
SILICON VALLEY BANK**	$0.00	0.00%
TOTAL	**$12,500,000.00**	**100.00%**

Term C Loans

Lender	Term Loan Commitment	Commitment Percentage
SILICON VALLEY BANK**	$25,000,000.00	100.00%
TOTAL	**$25,000,000.00**	**100.00%**

Term D Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$12,500,000.00	50.00%
SILICON VALLEY BANK	$12,500,000.00	50.00%
TOTAL	**$25,000,000.00**	**100.00%**

Aggregate (all Term Loans)

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$37,500,000.00	50.00%
SILICON VALLEY BANK	$37,500,000.00	50.00%
TOTAL	**$75,000,000.00**	**100.00%**

****** On the Second Amendment Effective Date, the proceeds of the Term C Loan were used to prepay in full the Term A Loan in the principal amount of $12,500,000 held by SVB and the Term B Loan in the principal amount of
$12,500,000 held by SVB.

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Exhibit 10.31

SCHOLARROCK,INC.

AMENDED AND RESTATED EMPLOYMENTAGREEMENT

This Amended and Restated Employment Agreement ("Agreement") is made between Scholar Rock, Inc., a Delaware corporation (the "Company"), and Junlin Ho Tracey Sacco (the "Employee") and is effective as commencing on the Employee's first day of March 1, 2023 employment at the Company (the "Effective Date"). Except with respect to the Restrictive Covenant Agreement and the Equity Documents (each as defined below), this Agreement supersedes in all respects all prior agreements between the Employee and the Company regarding the subject matter herein, including without limitation (i) the Employment Agreement between the Employee and the Company dated May 23, 2018 (the "Prior Agreement") and (ii) any other offer letter, employment agreement or severance agreement.

WHEREAS, the Company desires to continue to employ the Employee and the Employee desires to continue which is expected to be employed by the Company on the

new terms and conditions contained herein.

NOW, THEREFORE,in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

1. Employment.

(a) Term. The term of this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions hereof (the "Term"). The Employee's employment with the Company will continue to be "at will," meaning that the Employee's employment may be terminated by the Company or the Employee at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Employee shall serve as the General Counsel & Corporate Secretary Chief Commercial Officer (the "CCO") of the Company, and shall have such duties and authorities as may from time to time be prescribed by the Chief Executive Officer of the Company (the "CEO"). The Employee shall devote her the Employee's full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Employee may serve on other boards of directors, in each instance with the prior written approval of the CEO, or engage in religious, charitable or other community activities as long as such services and activities do not materially interfere with the Employee's performance of her the Employee's duties to the Company as provided in this Agreement.

2. CompensationandRelatedMatters.

(c) Work Location. During the Term, the Employee's primary work location will be the Company's offices in Massachusetts; provided that the Employee may work from the Employee's home office in accordance with the Company's policies and procedures relating to remote work, as may be in effect from time to time.

2. Compensation and Related Matters.

(a) BaseSalary. During the Term, the Employee's annual base salary shall be $431,000. $415,000. The Employee's base salary shall be reviewed annually by the Compensation Committee of the Board of Directors of Scholar Rock Holding Corporation (such Board of Directors, the "Board" and such Compensation Committee, the "Compensation Committee") or the CEO. Company. The base salary in effect at any given

time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices.

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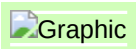
(b) IncentiveCompensation. During the Term, the Employee shall be eligible to receive cash incentive compensation as determined bythe Board or the Compensation Committee from time to time. The Employee's target annual incentive compensation shall be forty percent (40%) 40% of her the Employee's Base Salary (the Salary. The target annual incentive compensation in effect at any given time is referred to herein as the "Target Annual Incentive Compensation"). ; provided that any incentive compensation for the calendar year in which the Employee's employment commences will be prorated based on the Effective Date. Except as otherwise provided herein, to



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earn incentive compensation, the Employee must be employed by the Company on the day such incentive compensation is paid. The incentive compensation, if any, will be paid out no later than March 15th of the year following the applicable bonus year.

(c) Signing Bonus. The Employee shall receive a signing bonus of $25,000 (the "Signing Bonus"), less applicable payroll taxes, on the first regularly scheduled payroll date following the Effective Date, provided that if the Employee leaves the employment of the Company for any reason (excluding any termination of employment on account of Employee's death or disability, Employee's resignation for Good Reason, or by the Company without Cause) within 12 months of the date on which the Signing Bonus is paid to the Employee, the Employee will repay the Company the gross amount of the Signing Bonus within 10 days following the Date of Termination (as such terms with initial capitalization are defined below).

(d) Expenses. The Employee shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by her the Employee during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company.

(d) (e) Other Benefits. During the Term, the Employee shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e)(f) Vacations. During the Term, the Employee shall be entitled to paid vacation in accordance with the Company's policies and procedures. procedures as may be amended from time to time. The Employee shall also be entitled to all paid holidays given by the Company in accordance with the policies and procedures then in effect and established by the Company.

(f)(g) Equity.. The equity awards held by On or after the Effective Date, in connection with the commencement of the Employee's employment and as an inducement grant consistent with the requirements of NASDAQ Stock Market Rule 5635(c), subject to the approval of the Board or the Compensation Committee and the Employee's employment with the Company on the date of grant, the Employee shall continue be granted a stock option to purchase 225,000 shares of SR Holding Corporation's ("SR Holding's") common stock (the "Stock Option Award") at an exercise price per share equal to the closing price of SR Holding's common stock on the Nasdaq Global Market on the date of grant (or if no closing market price is reported for such date, the closing market price on the immediately preceding date for which a closing market price is reported). The Stock Option Award will vest with respect to 25% of the shares of SR Holding's common stock underlying the Stock Option Award on the first anniversary of the Effective Date (the "Vesting Commencement Date"), and the remaining 75% of the shares of SR Holding's common stock underlying the Stock Option Award shall vest in 12 equal quarterly installments following the Vesting Commencement Date, subject to the Employee's continued Service Relationship (as defined in SR Holding's 2022 Inducement Equity Plan (as amended and/or restated from time to time, the "Plan")) with SR Holding through each applicable vesting date. The Stock Option Award will be governed by the subject to all terms and conditions of and other provisions set forth in the applicable equity incentive plan(s) of Scholar Rock Holding Corporation ("SR Holding") Plan and a Stock Option Award Agreement (such agreement, with the applicable award agreement(s) (collectively, Plan, the "Equity Documents"). The Employee may also be eligible to receive future equity awards, in the sole discretion of the Board or the Compensation Committee.

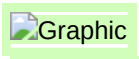
3. Termination. During the Term, the Employee's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death.The

(a) Death. The Employee's employment hereunder shall terminate upon the Employee's employmenthereundershallterminateuponher death.

(b) TerminationbyCompanyforCause.TheCompanymayterminatethe

(b) Termination by Company for Cause. The Company may terminate the Employee's employment hereunder for Cause. For purposes of this Agreement, "Cause" "Cause" shall mean: (i) conduct by the Employee constituting a material act of misconduct in connection with the performance of her the Employee's



duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by the Employee of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud, or any conduct by the Employee that would reasonably be expected to result in material injury or reputational harm to the Company or any of its subsidiaries or affiliates if she the Employee were retained in her the Employee's position; (iii) continued non-performance by the Employee of her the Employee's duties hereunder (other than by reason of the Employee's physical or mental illness, incapacity or disability) which has continued for more than 30 days following written notice of such non- performance non-performance from the CEO; Company; (iv) a material breach by the Employee of any of the provisions contained in Section 7 Continuing Obligations (as defined below) which has not been cured (or is incapable of this Agreement; or otherwise cannot be cured) within 30 days after the Company gives the Employee written notice regarding such breach; (v) a material violation by the Employee of the Company's written employment policies; policies which has not been cured (or which is incapable of or otherwise cannot be cured) within 30 days after the Company gives the Employee written notice regarding such violation; or (vi) failure to cooperate with a bona fide internal investigation or an

investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

(c) Termination Without Cause. The Company may terminate the Employee's employment hereunder at any time without Cause. Any termination by the Company of the Employee's employment under this Agreement which does not constitute a termination for Cause under Section 3(b) and does not result from the death of the Employee under Section 3(a) shall be deemed a termination without Cause.

(d) Termination by the Employee. The Employee may terminate her the Employee's employment hereunder at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" "Good Reason" shall mean that the Employee has complied with the "Good Good Reason Process" Process (hereinafter defined) following the occurrence of any of the following events: events without the Employee's consent: (i) a material diminution in the Employee's responsibilities, authority or duties; (ii) a material diminution in the Employee's Base Salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (iii) a material change of more than 30 miles in the geographic location at which the Employee provides is required to provide services to the Company, except for

required travel for the Company's business; or Company; (iv) the material breach by the Company of this Agreement Agreement; or (v) any directive to the Employee by the Company. "Good Company to engage in a willful violation of law. "Good Reason Process" Process" shall mean that (i) the Employee reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Employee notifies the Company in writing of the first occurrence of the Good Reason condition within 60 days of the first occurrence of such condition; (iii) the Employee cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period" "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Employee terminates her the Employee's employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(e) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Employee's employment by the Company or any such termination by the Employee shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice "Notice of Termination" Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(f) Date of Termination. "Date For purposes of Termination" this Agreement, "Date of Termination" shall mean: (i) if the Employee's employment is terminated by her the Employee's death, the date of her the Employee's death; (ii) if the Employee's employment is terminated by the Company for Cause under Section 3(c) 3(b), the date on which a Notice of Termination is given; (iii) if the Employee's employment is terminated by the Company without

Cause under Section 3(c), the date on which a Notice of Termination is given or the date otherwise specified by the Company in the Notice of Termination; (iv) if the Employee's employment is terminated by the Employee under Section 3(d) without other than for Good Reason, 30 14 days after the date on which a Notice of Termination is given, and (iv) (v) if the Employee's employment is terminated by the Employee under Section 3(d) with for Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Employee gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

4. Compensation Upon Termination.

4. CompensationUpon Termination.

(a) TerminationGenerally. If the Employee's employment with the Company is terminated for any reason, the Company shall pay or provide to the Employee (or to her the Employee's authorized representative or estate) (i) any Base Salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement) and unused vacation that accrued through the Date of Termination on or before the time required by law but in no event more than 30 days after the Employee's Date of Termination; and (ii) any vested benefits the Employee may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans and (iii) in the case of any termination of employment on account of Employee's death or disability, any accrued but unpaid Incentive Compensation for the prior fiscal year (collectively, the "Accrued Benefit").

(b) Termination by the Company Without without Cause or by the Employee withfor Good Reason. During the Term, if the Employee's employment is terminated by the Company without Cause as provided in Section 3(c), or the Employee terminates herthe Employee's employment for Good Reason as provided in Section 3(d), then the Company shall pay the Employee herthe Employee's Accrued Benefit. In addition, subject to the Employee signing a separation agreement in a form and manner satisfactory to the Company, containing, among other provisions, a general release of claims in favor of the Company and related persons and entities confidentiality, return (with customary exclusions for: (i) severance rights under this Agreement, (ii) any rights to indemnification, (iii) rights to Accrued Benefits, (iv) rights to vested equity, and (v) any claims that cannot be released as a matter of property law), a reaffirmation of all of the Employee's Continuing Obligations (as defined below), and, non-disparagement, in the Company's sole discretion, a form one-year post employment noncompetition agreement, and manner

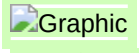
satisfactory to shall provide that if Employee breaches any of the Company Continuing Obligations, all payments of the Severance Amount shall immediately cease (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

, which shall include a 7 business day revocation period:

(i) the Company shall pay the Employee an amount equal to 9 months of the Employee's Base Salary (the "Severance Amount");provided in the event the Employee is entitled to any payments pursuant to the Restrictive Covenant Agreement, the Severance Amount received in any calendar year will be reduced by the amount the Employee is paid in the same such calendar year pursuant to the Restrictive Covenant Agreement (the "Restrictive Covenant Agreement Setoff"). Notwithstanding the foregoing, if the Employee breaches any of the provisions contained in Section 7 of this Agreement, Continuing Obligations, all payments of the Severance Amount shall immediately cease;

(ii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall, pay to for the Employee a monthly cash payment for period of 9 months following the Date of Termination or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to is shorter, pay the cost of the monthly employer contribution (either by direct payment to the group

health plan provider or the COBRA provider or by reimbursing the Employee for such cost) that the Company would have made to provide health insurance to the



Employee if the Employee had remained employed by the Company; provided, however, if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Employee for the time period specified above. Such payments shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates; and

(iii) the amounts payable under Section 4(b)(i) and (ii), to the extent taxable, shall be paid out in substantially equal installments in accordance with the Company's payroll practice over 9 months 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, the Severance Amount 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 day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

5. Compensation Upon Termination after a Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Employee and the Company regarding the Employee's rights and obligations upon the occurrence of a Change in Control (as defined below) of the Company. These provisions are intended to assure and

encourage in advance the Employee's continued attention and dedication to her the Employee's assigned duties and her the Employee's objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay the Severance Amount and other benefits upon a termination of employment, if such termination of employment occurs within 18 months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning 18 months after the occurrence of a Change in Control.

(a) ChangeinControl. During the Term, if within 18 months after a Change in Control, the Employee's employment is terminated by the Company without Cause as provided in Section 3(c) or the Employee terminates her the Employee's employment for Good Reason as provided in Section 3(d), then, subject to the signing of the Separation Agreement and Release by the Employee and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

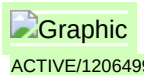
, which shall include a 7 business day revocation period:

(i) the Company shall pay the Employee a lump sum in cash in an amount equal to 1 times the sum of (A) the Employee's current Base Salary (or the Employee's Base Salary in effect immediately prior to the Change in Control or the Employee's Base Salary in effect immediately before Good Reason existed under Section 3(d)(ii), if higher) higher than the Employee's then-current Base Salary) plus (B) the Employee's Average Annual Incentive Compensation (For (collectively, the "Change in Control Payment"); provided that the Change in Control Payment shall be reduced by the amount of the Restrictive Covenant Agreement Setoff, if applicable. For purposes of this Agreement, "Average "Annual Incentive Compensation" Compensation" shall mean the Target Annual Incentive Compensation the Employee would have been entitled to receive in the fiscal year of

termination the Date of Termination (or the Employee's Target Annual Incentive Compensation in the fiscal year immediately prior to the Change in Control, if higher). In For the avoidance of doubt, in no event shall "Average "Annual Incentive Compensation" include any sign-on bonus, retention bonus or any other special bonus.); bonus;

(ii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, the Equity

Documents, all time-based stock options and other time- based time-based stock-based awards held by the Employee that are subject solely to time-based vesting (the "Time-Based Equity Awards") shall immediately accelerate and become fully



vested and exercisable or nonforfeitable as of the later of (i) the Date of Termination; Termination and (ii) the effective date of the Separation Agreement and Release (the "Accelerated Vesting Date")**;** and

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall, pay to for the Employee a monthly cash payment for period of 12 months following the Date of Termination or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to is shorter, pay the cost of the monthly employer contribution (either by direct payment to the group health plan provider or the COBRA provider or by reimbursing the Employee for such cost) that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; provided, however, if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Employee for the time period specified above. Such payments shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates; and

(iv) The amounts payable under Section 5(a)(i) and (iii), to the extent taxable, shall be paid or commence to 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 payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) AdditionalLimitation.

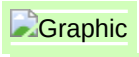
(b) Additional Limitation.

(i) Anything in this Agreement 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 the Employee, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and

the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 $1.00 less than the amount at which the Employee becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Employee receiving a higher After Tax Amount (as defined below) than the Employee would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity- based equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A- 24(b) &A-24(b) or (c).

(ii) For purposes of this Section 5(b), the "After "After Tax Amount" Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Employee as a result of the Employee's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Employee shall be deemed to pay federal income taxes at the highest

marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.



(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Employee within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Employee. Any determination by the Accounting Firm shall be binding upon the Company and the Employee.

(c) Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

"Changein Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than SR Holding,

any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of SR Holding or any of its subsidiaries),

together with all “affiliates” and “associates” (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the “beneficial owner” (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of SR Holding representing 50 percent 50% or more of the combined voting power of SR Holding’s then outstanding securities having the right to vote in an election of the Board (“VotingSecurities”) (in such case other than as a result of an acquisition of securities directly from SR Holding); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

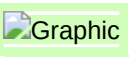
(iii) the consummation of (A) any consolidation or merger of SR Holding where the stockholders of SR Holding, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent 50% of the voting shares of SR Holding issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of SR Holding and its affiliates on a consolidated basis.

Notwithstanding the foregoing, a “Change Change in Control” Control shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by SR Holding which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent 50% or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from SR Holding) and immediately thereafter beneficially owns 50 percent 50% or more of the combined voting power of all of the then outstanding Voting Securities, then a “Change Change in Control” Control shall be deemed to have occurred for purposes of the foregoing clause (i).

6. Section 409A.

6. Section409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Employee's separation from service within the meaning of Section 409A of the Code, the Company determines that the Employee is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Employee becomes entitled to under this Agreement on account of the Employee's separation from service



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the Employee's separation from service would be considered deferred compensation otherwise subject to the 20 percent 20% additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six 6 months and one 1 day after the Employee's separation from service, or (B) the Employee's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Employee during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of

in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Employee's termination of employment, then such payments or benefits shall be payable only upon the Employee's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section

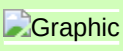
1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Employee or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Confidential Information, Noncompetition and Cooperation Continuing Obligations.

(a) Restrictive Covenant Agreement. As a material condition of this Agreement, the Employee will execute the Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement (the "Restrictive Covenant Agreement"), attached hereto as Exhibit A, prior to the Effective Date. The terms Employee acknowledges and agrees that the Employee received the Restrictive Covenant Agreement with this Agreement and at least 10 business days before the commencement of the Employee's employment. For purposes of this Agreement, the obligations in this Section 7 and those that arise in the Restrictive Covenant Agreement and any other written agreement related to confidentiality, assignment of inventions, or other restrictive covenants signed by Employee Non- with the Company after the date of the Restrictive Covenant Agreement shall collectively be referred to as the "Continuing Obligations".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Competition, Non-Solicitation, Confidentiality (b)Third-Party Agreements and Assignment Rights. The Employee hereby confirms that the Employee is not bound by the terms of any agreement with any previous employer or other party which restricts in any way the Employee's use or disclosure of information, other than confidentiality restrictions (if any), or the Employee's engagement in any business. The Employee represents to the Company that the Employee's execution of this

Agreement, between the Employee's employment with the Company and the performance of the Employee's proposed duties for the Company will not violate any obligations the Employee attached hereto as Exhibit A (the "Restrictive Covenant Agreement") continue may have to be any such previous employer or other party. In the Employee's work for the Company, the Employee will not disclose or make use of any information in full force violation of any agreements with or rights of any such previous employer or other party, and effect. the Employee will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(b) (c) Litigation and Regulatory Cooperation. During and after the Employee's employment, the Employee shall cooperate fully with any reasonable request of the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Employee was employed by the Company. The Employee's full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Employee's employment, the Employee also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Employee was employed by the Company. The Company shall reimburse the Employee for any reasonable out-of-pocket expenses incurred in connection with the Employee's performance of obligations pursuant to this Section 7(b) 7(c).

(c) (d) Relief. The Employee agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Employee of the promises set forth in this Section 7, Continuing Obligations, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, subject to Section 8 of this Agreement, the Employee agrees that if the Employee breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company. In addition, in the event the Employee breaches, this Section 7 or proposes to breach, any portion of the Continuing Obligations during a period when she the Employee is receiving severance payments pursuant to Section 4 or Section 5 hereof, the Company shall have the right to suspend or terminate such severance payments. Such suspension or termination shall not limit the Company's other options with respect to relief for such breach and shall not relieve the Employee of her the Employee's duties under this Agreement.

(d) (e) ProtectedDisclosuresandOtherProtectedAction. Nothing contained in this Agreement limits the Employee's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company.

8. ArbitrationofDisputes. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of the Employee's employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination or retaliation, whether based on race, religion, national origin, sex, gender, age, disability, sexual orientation, or otherwise) any other protected class under applicable law, including without limitation Massachusetts General Laws Chapter 151B) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of the American Arbitration Association ("AAA") in Boston, Massachusetts in accordance with the Employment Dispute Resolution Rules of the AAA, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. In the event that any person or entity other than the Employee or the Company may be a party with regard to any such

controversy or claim, such controversy or

claim shall be submitted to arbitration subject to such other person or entity's agreement.

Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 8 shall be specifically enforceable. Notwithstanding the foregoing, this Section 8 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 8.

9. ConsenttoJurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 8 of this Agreement, the parties hereby consent to the jurisdiction of the Superior Court of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts. Accordingly, with respect to any such court action, the Employee (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by

statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Integration. This Agreement, together with the Restrictive Covenant Agreement Continuing Obligations, and the Equity Documents, constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including, without limitation, the Prior Agreement.

matter.

11. Withholding. All payments made by the Company to the Employee under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

12. Successor to the Employee. This Agreement shall inure to the benefit of and be enforceable by the Employee's personal representatives, executors, administrators, heirs, distributees, devisees and legatees. In the event of the Employee's death after her the Employee's termination of employment but prior to the completion by the Company of all payments due to her the Employee under this Agreement, the Company shall continue such payments to the Employee's beneficiary designated in writing to the Company prior to her the Employee's death (or to her the Employee's estate, if the Employee fails to make such designation).

13. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

14. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Employee's employment to the extent necessary to effectuate the terms contained herein.

15. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Employee at the last address the Employee has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

17. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Employee and by a duly authorized representative of the Company.

18. GoverningLaw. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts without giving effect to the conflict of laws principles thereof.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

20. SuccessortoCompany. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

21. GenderNeutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK. SIGNATURE PAGES FOLLOW.]

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

SCHOLAR ROCK, INC.

By:/s/ Caryn Parlavecchio
Its:Chief Human Resources Officer

EMPLOYEE

/s/ Tracey Sacco
Tracey Sacco

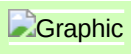

Exhibit A

SCHOLAR ROCK, INC.

Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement

In consideration and as a condition of my employment by or other service relationship with Scholar Rock, Inc. (including its subsidiaries and other affiliates and its and their successors and assigns, the "Company"), I agree to the terms and conditions of this Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement (the "Agreement"). For purposes of this Agreement, references to the employment relationship shall mean any employment, co-employment,

independent contractor or other service relationship, whether directly or through a third party, that I may have with the Company.

1. **Proprietary Information.** I agree that all information, whether or not in writing, concerning the Company's business, technology, business relationships or financial affairs which the Company has not released to the general public (collectively, "Proprietary Information") is and will be the exclusive property of the Company. By way of illustration, Proprietary Information may include information or material which has not been made generally available to the public, such as: (a) *corporate information*, including plans, strategies, methods, policies, resolutions, negotiations or litigation; (b) *marketing information*, including strategies, methods, customer identities or other information about customers, prospect identities or other information about prospects, or market analyses or projections; (c) *financial information*, including cost and performance data, debt arrangements, equity structure, investors and holdings, purchasing and sales data and price lists; and (d) *operational and technological information*, including plans, specifications, manuals, forms, templates, pre-clinical and clinical testing data and strategies, software, designs, methods, procedures, formulas, discoveries, inventions, improvements, concepts and ideas; and (e) *personnel information*, including personnel lists, reporting or organizational structure, resumes, personnel data, compensation structure, performance evaluations and termination arrangements or documents. Proprietary Information also includes information received in confidence by the Company from its customers or suppliers or other third parties.

2. **Recognition of Company's** such agreements in the event I have acces 

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to such proprietary information.

4. **Commitment to Company; Avoidance of Conflict of Interest.** While an employee of theCompany, I will devote my full-time efforts to the Company's business and I will not engage in any other business activity that conflicts with my duties to the Company. I will advise the president of the Company or his or her nominee at such time as any activity of either the Company or another business presents me with a conflict of interest or the appearance of a conflict of interest as an employee of the Company. I will take whatever action is requested of me by the Company to resolve any conflict or appearance of conflict which it finds to exist.

5. **Developments.** I will make full and prompt disclosure to the Company of all inventions, discoveries, designs, developments, methods, modifications, improvements, processes, algorithms, databases, computer programs, formulae, techniques, trade secrets, graphics or images, and audio or visual works and other works of authorship (collectively "Developments"), whether or not patentable or copyrightable, that are created, made, conceived or reduced to practice by me (alone or jointly with others) or under my direction during the period of my employment. I acknowledge that all work performed by me for the Company is on a "work for hire" basis, and I hereby do assign and transfer and, to the extent any such assignment cannot be made at present, will assign and transfer, to theCompany and its successors and assigns all my right, title and interest in all Developments that (a) relate to

Rights. I will not, at any time, without the Company's prior written permission, either during or after my employment, disclose any Proprietary Information to anyone outside of the Company, or use or permit to be used any Proprietary Information for any purpose other than the performance of my duties as an employee of the Company, provided, however, that this sentence shall not prohibit disclosure required by law or to any of my attorneys on a confidential basis. I will cooperate with the Company and use my best efforts to prevent the unauthorized disclosure of all Proprietary Information. I will deliver to the Company all copies of Proprietary Information in my possession or control upon the earlier of a request by the Company or termination of my employment.

3. **Rights of Others.** I understand that theCompany is now and may hereafter be subject to non-disclosure or confidentiality agreements with third parties which require the Company to protect or refrain from unauthorized use of proprietary information. I agree to be bound by the terms of

interest in all Developments that (a) relate to the business of the Company or any of the products or services being researched, developed, manufactured or sold by the Company or which may be used with such products or services; or (b) result from tasks assigned to me by the Company; or (c) result from the use of premises, resources, proprietary information or know-how, or personal property (whether tangible or intangible) owned, leased or contracted for by the Company ("Company-Related Developments"), and all related patents, patent applications, trademarks and trademark applications, copyrights and copyright applications, and other intellectual property rights in all countries and territories worldwide and under any international conventions ("Intellectual Property Rights").

To preclude any possible uncertainty, I have set forth on Exhibit A attached hereto a complete list of Developments that I have, alone or jointly with others, conceived, developed or reduced to practice prior to the commencement of my employment with the Company that I consider to be my property or the property of third parties and that I wish to have excluded from the scope

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of this Agreement ("Prior Inventions"). If disclosure of any such Prior Invention would cause me to violate any prior confidentiality agreement, I understand that I am not to list such Prior Inventions in Exhibit A but am only to disclose a cursory name for each such invention, a listing of the party(ies) to whom it belongs and the fact that full disclosure as to such inventions has not been made for that reason. I have also listed on Exhibit A all patents and patent applications in which I am named as an inventor, other than those which have been assigned to the Company ("Other Patent Rights"), if

all files, letters, notes, memoranda, reports, records, data, sketches, drawings, notebooks, layouts, charts, quotations and proposals, specification sheets, or other written, photographic or other tangible material containing Proprietary Information, and other materials of any nature pertaining to the Proprietary Information of the Company and to my work, and will not take or keep in my possession any of the foregoing or any copies.

7. **Enforcement of Intellectual Property Rights.** I will cooperate fully with the Company

assigned to the Company ("Other Patent Rights"). If no such disclosure is attached, I represent that there are no Prior Inventions or Other Patent Rights. If, in the course of my employment with the Company, I incorporate a Prior Invention into a Company product, process or machine or other work done for the Company, I hereby grant to the Company a nonexclusive, royalty-free, paid-up, irrevocable, worldwide license (with the full right to sublicense) to make, have made, modify, use, sell, offer for sale and import such Prior Invention. Notwithstanding the foregoing, I will not incorporate, or permit to be incorporated, Prior Inventions in any Company-Related Development without the Company's prior written consent.

This Agreement does not obligate me to assign to the Company any Development which, in the sole judgment of the Company, reasonably exercised, is developed entirely on my own time and does not relate to the business efforts or research and development efforts in which, during the period of my employment, the Company actually is engaged or reasonably would be engaged, and does not result from the use of premises, resources, proprietary information, know-how or equipment owned or leased by the Company. However, I will also promptly disclose to the Company any such Developments for the purpose of determining whether they qualify for such exclusion. I understand that to the extent this Agreement is required to be construed in accordance with the laws of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this Section 5 will be interpreted not to apply to any invention which a court rules and/or the Company agrees falls within such classes. I also hereby waive all claims to any moral rights or other special rights which I may have or accrue in any Company-Related Developments.

6. **Documents and Other Materials.** I will keep and maintain adequate and current records of all Proprietary Information and Company-Related Developments developed by me during my

Rights. I will cooperate fully with the Company, both during and after my employment with the Company, with respect to the procurement, maintenance and enforcement of Intellectual Property Rights in Company-Related Developments. I will sign, both during and after the term of this Agreement, all papers, including without limitation copyright applications, patent applications, declarations, oaths, assignments of priority rights, and powers of attorney, which the Company may deem necessary or desirable in order to protect its rights and interests in any Company-Related Development. If the Company is unable, after reasonable effort, to secure my signature on any such papers, I hereby grant a power of attorney by designating and appointing each officer of the Company as my agent and attorney-in-fact to execute any such papers on my behalf, and to take any and all actions as the Company may deem necessary or desirable in order to protect its rights and interests in any Company-Related Development.

8. **Restrictive Covenants.**

A. Non-Competition Restrictive Covenants

In order to protect the Company's Proprietary Information and good will, during my employment and for a period of one (1) year following the termination of my employment for any reason, unless the Company terminates my employment without Cause (as defined below) or lays me off, or such shorter period as the Company designates in writing to me in connection with the ending of my employment relationship (the "Restricted Period"), I will not directly or indirectly, anywhere in the United States, whether as owner, partner, shareholder, director, manager, consultant, agent, employee, co-venturer, or otherwise, engage in, participate in, or perform: (a) any job, position, function, role, or activity that (i) is the same as or similar to that which I performed for the Company during any part of the two-year period immediately preceding the end of my employment with the Company and (ii) involves products, services, or a line of business (in each

employment, which records will be available to and remain the sole property of the Company at all times.

All files, letters, notes, memoranda, reports, records, data, sketches, drawings, notebooks, layouts, charts, quotations and proposals, specification sheets, or other written, photographic or other tangible material containing Proprietary Information, whether created by me or others, which come into my custody or possession, are the exclusive property of the Company to be used by me only in the performance of my duties for the Company. Any property situated on the Company's premises and owned by the Company, including without limitation computers, disks and other storage media, filing cabinets or other work areas, is subject to inspection by the Company at any time with or without notice. In the event of the termination of my employment for any reason, I will deliver to the Company

products, services, or a line of business (in each case, including but not limited to the research, development, manufacture, or commercialization of any products, services, or line of business) that is competitive with or that substitutes for or that eliminates the need for, any products, services, or a line of business (in each case, including but not limited to the research, development, manufacture, or commercialization of any products, services, or a line of business) of the Company at any time during the two-year period immediately preceding the end of my employment with the Company; or (b) any other job, position, function, role, or activity that would likely or inevitably, even if unintentionally, require or result in the use or disclosure of the Company's Proprietary Information or the use of the Company's customer goodwill, provided that this shall not prohibit any possible investment in publicly traded stock of a company representing less than one percent of the

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stock of such company. Furthermore, I acknowledge and agree that the Company shall have the option of enforcing the aforementioned non-competition restriction, up to and including the full duration of the Restricted Period. In the event the Company elects to enforce the post-employment portion of the non-competition restriction, the Company will cause to be paid to me fifty percent (50%) of my highest annualized base salary paid by the Company within the two (2) years preceding the termination of my employment, for as long as the Company elects to enforce said post-employment non-competition restriction, subject further to limitations on payments owed to an employee who has breached a fiduciary duty owed to the Company or who has unlawfully taken Company property to the extent permitted by applicable law. I acknowledge and agree that any

10. **Prior Agreements.** I hereby represent that, except as I have fully disclosed previously in writing to the Company, I am not bound by the terms of any agreement with any previous employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of my employment with the Company or to refrain from competing, directly or indirectly, with the business of such previous employer or any other party. I further represent that my performance of all the terms of this Agreement as an employee of the Company does not and will not breach any agreement to keep in confidence proprietary information, knowledge or data acquired by me in confidence or in trust prior to my employment with the Company. I will not disclose to the Company or induce the Company to use any confidential or

applicable law. I acknowledge and agree that any payments I receive pursuant to this Section 8(a) shall reduce (and shall not be in addition to) any severance or separation pay that I am otherwise entitled to receive from the Company pursuant to an agreement, plan or otherwise. For purposes of this Agreement, and notwithstanding anything to the contrary in any other agreement between the Company and me, "Cause" shall mean a reasonable and good faith basis for the Company to be dissatisfied with my job performance, my conduct or my behavior.

B. Non-Solicitation Restrictive Covenants

In order to protect the Company's Proprietary Information and good will, during the Restricted Period, I will not, directly or indirectly, in any manner, other than for the benefit of the Company, (a) call upon, solicit, divert, take away, accept or conduct any business from or with any of the customers or prospective customers of the Company or any of its suppliers, in each case in competition with the Company, and/or (b) solicit, entice, attempt to persuade any other employee or consultant of the Company to leave the Company for any reason or otherwise participate in or facilitate the hire, directly or through another entity, of any person who is employed or engaged by the Company or who was employed or engaged by the Company within six months of any attempt to hire such person.

I acknowledge that the covenants in this Section 8 are necessary because the Company's legitimate business interests cannot be adequately protected solely by the other covenants in this Agreement. I further acknowledge and agree that if I violate any of the provisions of this Section 8, the running of the Restricted Period will be extended by the time during which I engage in such violation(s).

9. **Government Contracts.** I acknowledge that the Company may have from time to time agreements with other persons or with the United States Government or its agencies which impose obligations or restrictions on the Company regarding induce the Company to use any confidential or proprietary information, know-how or material belonging to any previous employer or others.

11. **Remedies Upon Breach.** I understand that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and I consider them to be reasonable for such purpose. Any breach of this Agreement is likely to cause the Company substantial and irrevocable damage and therefore, in the event of such breach, theCompany, in addition to such other remedies which may be available, will be entitled to specific performance and other injunctive relief, without the posting of a bond. If I violate this Agreement, in addition to all other remedies available to the Company at law, in equity, and under contract, I agree that I am obligated to pay all the Company's costs of enforcement of this Agreement, including attorneys' fees and expenses.

12. **Publications and Public Statements.** I will obtain the Company's written approval before publishing or submitting for publication any material that relates to and/or incorporates any Proprietary Information.

13. **No Employment Obligation.** I understand that this Agreement does not create an obligation on theCompany or any other person to continue my employment. I acknowledge that, unless otherwise agreed in a formal written employment agreement signed on behalf of the Company by an authorized officer, my employment with the Company is at will and therefore may be terminated by the Company or me at any time and for any reason, with or without cause.

14. **Survival and Assignment by the Company.** I understand that my obligations under this Agreement will continue in accordance with its express terms regardless of any changes in my title, position, duties, salary, compensation or benefits or other terms and conditions of employment. I further

inventions made during the course of work under such agreements or regarding the confidential nature of such work. I agree to comply with any such obligations or restrictions upon the direction of the Company. In addition to the rights assigned under Section 5, I also assign to the Company (or any of its nominees) all rights which I have or acquired in any Developments, full title to which is required to be in the United States under any contract between the Company and the United States or any of its agencies.

other terms and conditions of employment. Further, I understand that my obligations under this Agreement will continue following the termination of my employment regardless of the manner of such termination and will be binding upon my heirs, executors and administrators. The Company will have the right to assign this Agreement to its affiliates, successors and assigns. I expressly consent to be bound by the provisions of this Agreement for the benefit of the Company or any parent, subsidiary or affiliate to whose employ I may be transferred without the necessity that this Agreement be resigned at the time of such transfer.

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15. **Exit Interview.** If and when I depart from the Company, I may be required to attend an exit interview. For twelve (12) months following termination of my employment, I will notify the Company of any change in my address and of each subsequent employment or business activity, including the name and address of my employer or other post-Company employment plans and the nature of my activities. If I am named an inventor in one or more patent applications that resulted during my employment with the Company, I agree to use commercially reasonable efforts to keep the Company apprised of my contact information for an additional twenty-four (24) months.

16. **Disclosure to Future Employers.** During the Restricted Period, I will provide a copy of this Agreement to any prospective employer, partner or co-venturer prior to entering into an employment, partnership or other business relationship with such person or entity.

17. **Waiver**. The Company and I acknowledge and agree that the Company may unilaterally waive my post-employment non-competition obligations

19. **Interpretation.** This Agreement will be deemed to be made and entered into in the Commonwealth of Massachusetts, and will in all respects be interpreted, enforced and governed under the laws of the Commonwealth of Massachusetts. I hereby agree to consent to personal jurisdiction of the state and federal courts situated within Suffolk County, Massachusetts for purposes of enforcing this Agreement, and waive any objection that I might have to personal jurisdiction or venue in those courts.

20. **Independence of Obligations**. My obligations under this Agreement are independent of any obligation, contractual or otherwise, the Company has to me. The Company's breach of any such obligation shall not be a defense against the enforcement of this Agreement or otherwise limit my obligations under this Agreement.

21. **Protected Disclosures; Defend Trade Secrets Act of 2016**. I understand that nothing contained in this Agreement limits my ability to communicate with any federal, state or local governmental agency or commission, including to

under Section 8(a), and in the event of such a waiver, the Company is not required to provide me with the post-employment compensation described therein. The Company's election not to provide me with the post-employment compensation described in Section 8(a) shall be deemed a waiver of my post-employment non-competition obligations under Section 8(a). Otherwise, no waiver of any of my obligations under this Agreement shall be effective unless made in writing by the Company. The failure of the Company to require my performance of any term or obligation of this Agreement, or the waiver of any breach of this Agreement, shall not prevent the Company's subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

18. **Severability.** In case any provisions (or portions thereof) contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect the other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein. If, moreover, any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it shall be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it shall then appear.

provide documents or other information, without notice to the Company. I also understand that nothing in this Agreement limits my ability to share compensation information concerning myself or others, except that this does not permit me to disclose compensation information concerning others that I obtain because my job responsibilities require or allow access to such information. I understand that pursuant to the federal Defend Trade Secrets Act of 2016, I shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

22. **Other Agreements; Amendment**. This Agreement supplements and does not supersede any other confidentiality, assignment of inventions or restrictive covenant agreement between the Company and me. In the event of any conflict between this Agreement and my employment agreement with the Company dated or on about the date hereof, my employment agreement shall control. Otherwise, to the extent that this Agreement addresses other subject matters, this Agreement supersedes any other agreements between the Company and me with respect to such subject matters. This Agreement may be amended only in a written agreement executed by a duly authorized officer of the Company and me.

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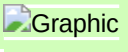

WHEREOF,thepartieshaveexecutedthisAgreement effectiveonthe date and year first above written.

SCHOLAR ROCK, INC. **I UNDERSTAND THAT THIS AGREEMENT AFFECTS IMPORTANT RIGHTS. BY SIGNING BELOW, I CERTIFY THAT I HAVE READ IT CAREFULLY AND AM SATISFIED THAT I UNDERSTAND IT COMPLETELY. I ACKNOWLEDGE I HAVE BEEN NOTIFIED BY THE COMPANY OF THE RIGHT TO CONSULT WITH COUNSEL OF MY OWN CHOOSING PRIOR TO SIGNING THIS AGREEMENT, AND THATI WAS PROVIDED WITH THIS AGREEMENTBY THE EARLIER OF A FORMAL OFFER OF EMPLOYMENT OR TEN (10) BUSINESS DAYS BEFORE THE COMMENCEMENT OF MY EMPLOYMENT.**

I ACKNOWLEDGE AND AGREE THAT THE TERMS OF THIS AGREEMENT WILL APPLY TO MY ENTIRE SERVICE RELATIONSHIP WITH THE COMPANY, INCLUDING WITHOUT LIMITATION ANY PERIOD OF SERVICE PRIOR TO THE DATE OF MY SIGNATURE BELOW.

IN WITNESS WHEREOF,the undersigned has executed this Agreement as a sealed instrument and it shall become effective upon the later of (i) the full execution by both parties; or (ii) ten (10) business days after the Company provided me with notice of this Agreement.

EMPLOYEE

Signed: /s/ Tracey Sacco

Type or print name: Tracey Sacco

/s/ JAY BACKSTROM

By: Jay T. Backstrom Date:
Its: President and CEO1/13/2023

EMPLOYEESCHOLAR ROCK, INC.

/s/ Junlin Ho/s/ Caryn Parlavecchio
Authorized Signatory

Date: 1/13/2023

Graphic

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EXHIBIT A

Junlin

To: **Scholar Rock, Inc.**

From: Tracey Sacco

Date: 1/13/2023

SUBJECT: **Prior Inventions**

The following is a complete list of all inventions or improvements relevant to the subject matter of my employment by the Company that have been made or conceived or first reduced to practice by me alone or jointly with others prior to my engagement by the Company:

XHo No inventions or improvements

See below:

Additional sheets attached

The following is a list of all patents and patent applications in which I have been named as an inventor:

XNone

See below:

6

[SignaturePageto Amended and Restated Employment Agreement]ACTIVE/120649963.3

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Exhibit 21.1

SUBSIDIARIES OF SCHOLAR ROCK

HOLDING CORPORATION

Subsidiary	**Jurisdiction**
Scholar Rock, Inc.	Delaware
Scholar Rock Securities Corporation	Massachusetts

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 Nos. 333-254057, 333-249715, 333-231920 and 333-268329) of Scholar Rock Holding Corporation,

(2) Registration Statement (Form S-8 Nos. 333-263349, 333-238082 and 333-256065) pertaining to the 2018 Stock Option and Incentive Plan and 2018 Employee Stock Purchase Plan, of Scholar Rock Holding Corporation,

(3) Registration Statement (Form S-8 No. 333-225192) pertaining to the 2017 Stock Option and Incentive Plan, 2018 Stock Option and Incentive Plan, and 2018 Employee Stock Purchase Plan, of Scholar Rock Holding Corporation, and

(4) Registration Statement (Form S-8 Nos. 333-266658 and 333-268327) pertaining to the 2022 Inducement Equity Plan, of Scholar Rock Holding Corporation, and

(5) Registration Statement (Form S-8 No. 333-270318) pertaining to the 2018 Stock Option and Incentive Plan, 2018 Employee Stock Purchase Plan, and 2022 Inducement Equity Plan, of Scholar Rock Holding Corporation

of our report dated March 7, 2023 March 19, 2024, with respect to the consolidated financial statements of Scholar Rock Holding Corporation, included in this Annual Report (Form 10-K) of Scholar Rock Holding

Corporation for the year ended December 31, 2022December 31, 2023.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 7, 2023 19, 2024

Exhibit 31.1

Certifications

I, Jay T. Backstrom, certify that:

1. I have reviewed this Annual Report on Form 10-K of Scholar Rock Holding Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances

under which such statements were made, not misleading with respect to the period covered by this report;

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-

15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its

consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable

assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our

conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the

registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or

persons performing the equivalent functions):

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

b) Any fraud, whether or not material, that

involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2023 March 19, 2024

/s/ Jay T. Backstrom

Jay T. Backstrom
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certifications

I, Edward H. Myles, certify that:

1. I have reviewed this Annual Report on Form 10-K

of Scholar Rock Holding Corporation;

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

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

the registrant as of, and for, the periods presented in this report;

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

   a) Designed such disclosure controls and procedures, or caused such disclosure controls

and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over

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

principles;

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

d) Disclosed in this report any

change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially

affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the

registrant's ability to record, process, summarize and report financial information; and

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

Date: March 7, 2023 March 19, 2024

/s/ Edward H. Myles

Edward H. Myles

Chief Operating Officer & Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Scholar Rock Holding Corporation (the "Company") for the year ended December 31, 2022 December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies,

pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to his or her knowledge, that:

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

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

This certification is being provided pursuant to 18 U.S.C. 1350 and is not to be deemed a part of the Report, nor is it to be deemed to be “filed” for any purpose whatsoever.

Date: March 7, 2023March 19, 2024	/s/ Jay T. Backstrom Jay T. Backstrom President and Chief Executive Officer
Date: March 7, 2023March 19, 2024	/s/ Edward H. Myles Edward H. Myles Chief Operating Officer & Chief Financial Officer

EXHIBIT 97

SCHOLAR ROCK HOLDING CORPORATION COMPENSATION RECOVERY POLICY
Adopted as of November 28, 2023

Scholar Rock Holding Corporation, a

Delaware corporation (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below.

1. Overview

The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market.

2. Compensation Recovery Requirement

In the event the Company is required to prepare

a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less

than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. “Applicable Rules” means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. “Board” means the Board of Directors of the Company.

d. “Committee” means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. “Covered Person” means any Executive Officer. A person’s status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such

Erroneously Awarded Compensation regardless of the person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered Person with respect to Erroneously Awarded Compensation received before the person began service

as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person

[*Signature Page to Scholar Rock Holding Corporation Board Consent*]

served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means December 1, 2023.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery

Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based

on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based

Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive-Based Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual

payment, grant or vesting occurs.

h. “Exchange” means the Nasdaq Stock Market LLC.

i. “Executive Officer” means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation and received Incentive-Based Compensation after beginning service

in any such role (regardless of whether such Incentive-Based Compensation was received during or after such person's service in such role): the president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice president 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 similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions

for the Company.

j. “Financial Reporting Measures” mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. “Financial

Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required 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.

l. “Incentive-Based Compensation” means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure.

m. “Restatement Date” means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the

Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this

Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled

to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

6. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other set-off;

e. cancelling or offsetting against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such

person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

7. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining

whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

8. Policy Administration

This Policy shall be administered by the Committee; provided, however, that the Board shall have exclusive authority to authorize the Company to prepare a Financial Restatement. In doing so, the Board may rely on a

recommendation of the Audit Committee of the Board. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any

provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

9. Compensation Recovery Repayments not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.

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