

Annual Report





To Our Shareholders:

2024 was a transformational year for Scholar Rock. With the success of SAPHIRE, our pivotal Phase 3 trial evaluating the safety and efficacy of apitegromab in spinal muscular atrophy (SMA), we are on our way to fulfilling our mission to deliver life changing therapies and create new possibilities for people living with serious diseases starting with those living with SMA. We entered 2025 on the threshold of commercialization of apitegromab for SMA, which if approved, will mark our transition into a fully-integrated commercial-stage biotechnology company. Our achievements in the past year have set the foundation for continued success, giving our team tremendous momentum to potentially launch our first product and expand our pipeline of clinical programs, and brought us closer to making a meaningful difference in the lives of people with serious disease.

SMA is a progressive neuromuscular disorder. Despite the innovation and improvements achieved with the current standard of care treatments, all of which address the SMN protein deficiency, muscle weakness remains a core unmet need. Those living with SMA need and want more: more gain in motor function, more muscle strength.

We designed and conducted SAPHIRE to see if we could help address the unmet need and create new treatment possibilities for those living with SMA. We were thrilled to report that SAPHIRE achieved its primary endpoint of statistically significant and clinically meaningful improvement in motor function using a gold standard, SMA-

specific scale (Hammersmith Functional Motor Scale Expanded), demonstrating its potential to transform the lives of people with SMA who are receiving SMN-targeted therapies. Apitegromab is now the first and only anti-myostatin therapeutic candidate to demonstrate a statistically significant functional improvement in a pivotal Phase 3 study. These positive results from SAPHIRE bring us closer to offering a much-needed treatment option and the first muscle-targeted therapy for SMA.

To support the potential commercialization of apitegromab, we completed an upsized public offering. We also prepared and submitted the biologics license application (BLA) in the United States and the marketing authorization application (MAA) in Europe allowing us to be on track for a U.S. commercial launch upon approval in 2025, with European launch anticipated in 2026. In preparation, we are engaging with the SMA community, leading the first ever muscle focused disease education in SMA, building a top-tier commercial and medical affairs organization, and establishing the infrastructure needed to deliver apitegromab to SMA patients if it is approved. SMA has benefited from three SMN-targeted therapies and the global market has grown to \$4.5 billion annually. Our team is making excellent progress, and we are well positioned for a successful commercial launch. We believe we have the right medicine and the right market and we are executing the right plan.

Building on the success of SAPHIRE, we plan to initiate the Phase 2 OPAL clinical trial in the third quarter of 2025 to evaluate apitegromab in SMA patients under two years of age who have been or are continuing to be treated with any currently approved SMN therapy. This trial will expand our efforts to provide treatment options for SMA as early as possible for people with SMA. As part of our efforts to serve a growing number of patients living with devastating neuromuscular diseases, we are also exploring development of apitegromab in neuromuscular conditions where progressive muscle weakness is present, such as Duchenne muscular dystrophy (DMD), Becker muscular dystrophy, facioscapulohumeral muscular dystrophy (FSHD), and amyotrophic lateral sclerosis (ALS).

Last year, we also entered the next frontier of our highly selective anti-myostatin approach by leveraging our platform to expand into cardiometabolic disorders including obesity. We were excited to initiate the Phase 2 EMBRAZE trial exploring the combination of apitegromab and GLP-1 receptor agonists for people living with obesity. Enrollment for EMBRAZE was completed in September, and we expect to report topline data from the trial in the second quarter of 2025. These outcomes will inform and guide our clinical development plans for SRK-439, our highly selective anti-myostatin program designed for obesity and cardiometabolic disease, for which we presented preclinical data at multiple medical conferences. We plan to submit an Investigational New Drug (IND) Application for SRK-439 in the third quarter of 2025. We look forward to demonstrating the potential of our industry-leading approach to selective myostatin inhibition to address the ongoing challenges that patients encounter with muscle loss and weakness when being treated with GLP-1 receptor agonist therapies for obesity.

As Scholar Rock evolves into a fully integrated biotechnology company and we prepare for our first anticipated drug approval, I would like to express my gratitude to our shareholders for their support and trust in our vision, and to recognize our employees for their exceptional dedication to our mission of creating possibilities for patients. I would also like to sincerely thank the many patients, families, and investigators who participated, or are participating, in our clinical programs.

With the potential for our first FDA-approved medicine on the horizon, and as we continue to advance and expand our promising clinical programs, Scholar Rock is well-positioned to accelerate breakthroughs and deliver potentially life-changing therapies for patients.

Sincerely,

Jay T. Backstrom, M.D., MPH
President & Chief Executive Officer

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, 2024

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
(State or Other Jurisdiction of
Incorporation or Organization)

82-3750435
(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, 2024, 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 \$394.7 million based on the closing price of the registrant's common stock on June 30, 2024. 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 February 24, 2025, there were 94,676,763 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 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, 2024, 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 (the “Exchange Act”). 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 2 EMBRAZE clinical trial) and SRK-181, including the progress, completion, timing of results, and actual results of our clinical trials;
- 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, and any related restrictions, limitations or warnings in the label of any approval for apitegromab;
- our success in identifying and executing a development program for our preclinical product candidates, including SRK-439, SRK-373, SRK-256 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;
- the fact that topline or interim data from our clinical studies may not be predictive of the final or more detailed results of such study or the results of other ongoing or future studies;
- the potential benefit of orphan drug exclusivity, Orphan Drug Designation, Fast Track Designation and Rare Pediatric Disease Designation for apitegromab, SRK-181 and any other of our product candidates that may receive one or more of these designations;
- 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, SRK-439, SRK-373, SRK-256 or any of our 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;
- our ability, 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 and when it is approved or receives pricing or reimbursement approval;
- the rate and degree of market acceptance of our product candidates, if approved;

- our ability to establish or maintain collaborations or strategic relationships;
- our expectations relating to the potential of our proprietary platform technology;
- 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;
- 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 a “smaller reporting company” as defined by Rule 12b-2 of the Exchange Act; 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 United States Securities and Exchange Commission (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.

PART I

Item 1. Business

I. Overview

We are a late-stage biopharmaceutical company focused on the discovery, development and 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 investigational, fully human monoclonal antibody that inhibits myostatin activation by selectively binding the pro- and latent forms of 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 in vitro affinity for pro- and latent myostatin and maintains myostatin specificity and is being developed for the treatment of cardiometabolic disorders.
- SRK-181, an investigational 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.
- SRK-373, a novel, preclinical, investigational TGFβ inhibitor that selectively inhibits the activation of latent TGFβ1 isoform in the context of fibrotic extracellular matrix and that avoids perturbing TGFβ1 presented by cells of the immune system and is being developed for the treatment of fibrotic diseases.
- SRK-256, a novel, preclinical, investigational inhibitor that selectively inhibits RGMc or hemojuvelin, the co-receptor of bone morphogenic protein 6 (“BMP6”) and hence inhibits BMP6 signaling. BMP6 signaling is critical for iron homeostasis and SRK-256 has wide potential applicability in states of iron-restricted anemias.
- Additional discovery and early preclinical programs related to the selective modulation of growth factor signaling.

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 completed 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) and announced positive top-line results in October 2024. The study achieved its primary endpoint (see “Phase 3 SAPPHIRE Pivotal Trial” below). We submitted a U.S. Biologics License Application (“BLA”) to the FDA in January 2025 and are planning to submit a European Union marketing authorization application to the European Medicines Agency (“EMA”) in the first quarter of 2025. If apitegromab is approved, we

expect to initiate a commercial product launch in the fourth quarter of 2025 in the United States, with a commercial launch of apitegromab in Europe to follow.

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. We have subsequently presented data from the TOPAZ trial over 24-months (2022), 36-months (2023) and 48-months (2024). At 48-months over 90% of TOPAZ patients with nonambulatory Type 2 and 3 SMA receiving a survival motor neuron (“SMN”) therapy remained on apitegromab treatment and showed sustained clinical benefit, a continued favorable safety profile with no new safety findings (see “Phase 2 TOPAZ Proof-of-Concept Trial” below). Additionally, we are conducting a long-term extension study, ONYX, for patients from both the TOPAZ and SAPPHIRE studies, who were receiving apitegromab in 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 EMA granted Priority Medicines (“PRIME”) designation in March 2021 and the EC granted 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 are developing SRK-439 towards a potential investigational new drug application (“IND”) submission in the third quarter of 2025. In 2024, we presented preclinical data at scientific conferences which support the potential of SRK-439 to increase lean mass and contribute to a favorable body composition in conjunction with a GLP-1 receptor agonist (“GLP-1 RA”) treatment. To inform the development of SRK-439, in May 2024 we initiated the Phase 2 EMBRAZE proof-of-concept trial, designed to assess the safety and efficacy of apitegromab to preserve muscle mass in individuals living with obesity and on background therapy of a GLP-1 RA. In September 2024, we announced that we completed enrollment in the Phase 2 EMRAZE proof-of-concept trial. Top-line results from this trial are expected in the second quarter of 2025.

We believe that apitegromab has the potential to be the first muscle-targeted therapy that 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 with SMA under 2 years of age) and indications for other neuromuscular disorders beyond SMA.

Our second product candidate, SRK-181, a highly selective inhibitor of the activation of latent TGFβ1, 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 antibody therapies). SRK-181 is being 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 antibody therapies. We completed enrollment of the DRAGON trial in December 2023 and continue to treat patients who remain on study. 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”). Safety, efficacy and biomarker data were presented in June 2024 at the American Society of Clinical Oncology (“ASCO”) annual meeting and in November 2024 at the Society for Immunotherapy of Cancer (“SITC”) 39th Annual Meeting. The data showed encouraging responses in heavily pretreated and anti-PD-(L)1 resistant patients across multiple tumor types. 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. We anticipate that emerging data from the DRAGON trial will be presented at medical meetings in 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, monoclonal antibody discovery 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.

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

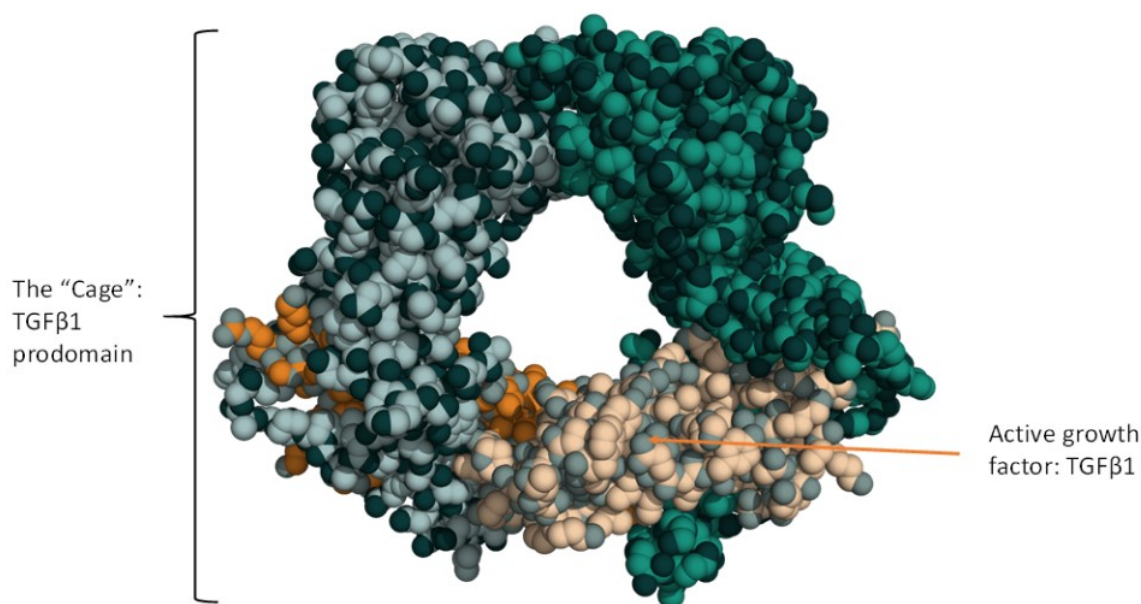
Our innovative approach is rooted in our novel understanding of the molecular mechanisms of growth factor activation and signaling and is designed to discover and develop monoclonal antibody product candidates that can inhibit the activation of a growth factor with an unprecedented degree of selectivity. Our proprietary platform is designed to generate highly selective antibodies 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 TGF β 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 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 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, TGF β 1 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 TGF β superfamily by solving a high-resolution x-ray crystal structure of this latent form of TGF β 1 (as illustrated in the graphic below).



Structural representation of the latent form of TGF β 1 wherein the prodomain wraps around the active growth factor

This research explained at a molecular level why the secreted form of TGF β 1 is inactive. The prodomain, though physically separated from the mature growth factor domain, forms a “cage” around the active form of TGF β 1, blocking 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 TGF β 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 effects. For example, two members of the TGF β 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 TGF β are pan inhibitors, meaning that they do not distinguish among the three isoforms of TGF β , namely, TGF β 1, TGF β 2 and TGF β 3. 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 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, monoclonal antibody discovery capabilities, and assay development to test the characteristics of our monoclonal antibodies. In addition to this know-how, our proprietary platform is covered by 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
- 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 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.; and Novartis 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:

- ***Continue advancing apitegromab 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 recently completed SAPPHERE, 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 SMN therapy (e.g., therapies that upregulate the expression of SMN, such as SMN splicing modulators). In October 2024, the Company announced positive top-line results that showed the study achieved its primary endpoint. See "Phase 3 SAPPHERE Pivotal Trial" below.
- ***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 multiple muscle disorders in which muscle atrophy is a key feature of disease pathogenesis. 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 completed enrollment of the Phase 1 DRAGON 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 in December 2023 and continue to treat patients who remain on study. 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.
- ***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 TGF β portfolio have the potential to address other disorders associated with increased TGF β signaling, including tissue and organ fibrosis. To advance the discovery and development of selected inhibitors originating from our TGF β 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 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 TGF β 1 function in connective tissue while having no impact on the activation or signaling of TGF β 1 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 BMP6 (a TGF β 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 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; 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:

Scientific Platform Yielding Growing Pipeline Across High Value Therapeutic Areas

TARGET	CANDIDATE	DISCOVERY/ PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	COMMERCIAL
Latent Myostatin	SPINAL MUSCULAR ATROPHY Apitegromab					BLA/MAA submission in Q1 2025 ¹
	CARDIOMETABOLIC DISORDERS Apitegromab in Obesity*			EMBRAZE		
	SRK-439 (novel anti-myostatin antibody)					
Latent TGFβ-1	IMMUNO-ONCOLOGY SRK-181: Selective context-independent, anti-latent TGFβ-1)					
	FIBROSIS SRK-373: Selective context-dependent (LTBP1 & LTBP3) anti-latent TGFβ-1					
RGMc	ANEMIA SRK-256: Selective anti-RGMc					
Undisclosed	NEUROMUSCULAR DISORDERS					

*Utilized data from previously completed Ph 1 study in healthy volunteers and initiate a Ph 2 POC trial in 2024. 1 Anticipated milestones.
LTBP1=Latent transforming growth factor beta binding protein 1; LTBP3=Latent transforming growth factor beta binding protein 3; POC=Proof of concept; RGMc=Repulsive guidance molecule C; TGFβ-1=Transforming growth factor beta-1.

VI. Our Product Candidates

a. Latent Myostatin

Utilizing our proprietary platform, we targeted the precursor form of myostatin and generated two novel antibodies, each with a design tailored for specific patient populations: apitegromab for SMA and SRK-439 for obesity. Both antibodies are novel, highly selective inhibitors of the activation of myostatin from its inactive precursor in 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.

SRK-439 has also shown robust preclinical efficacy, as detailed in “Cardiometabolic Disorders – SRK-439 (inhibitor of latent myostatin)” section below. We believe that these results, from two diet-induced obesity (“DIO”) mice models provide the scientific rationale and support the hypothesis that inhibition of myostatin in combination with GLP-1 RA-driven weight loss may lead to retention of lean muscle.

i. Role of Myostatin

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 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. Animals lacking functional myostatin genes, or its receptor, have larger muscles and increased strength compared to normal 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 TGF β 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 TGF β 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.

iii. Spinal Muscular Atrophy: Apitegromab (inhibitor of latent myostatin activation)

We believe that the therapeutic potential for apitegromab in improving motor function is more optimal when a given disease bears certain features, including neuromuscular disorders with muscle atrophy as a key component of disease pathogenesis, presence of intact or partially intact muscle innervations, absence of significant muscle structural abnormalities, and where validated clinical outcome measures are available to assess muscle function in a clinical trial. SMA is a genetic disorder with onset commonly in childhood and where 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 muscle atrophy that in turn leads to many of the motor function impairments. Validated outcome measures, such as the Hammersmith Functional Motor Scale Expanded (“HFMSE”), are available for SMA clinical trials that are relevant to muscle function. These endpoints therefore measure an outcome that may be more likely to be directly affected by apitegromab.

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 TGF β 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. We have subsequently presented data from the TOPAZ trial over 24-months (2022), 36-months (2023) and 48-months (2024). See “Phase 2 TOPAZ Proof-of-Concept Trial” below. In October 2024, we announced positive top-line results from 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 reported that the study achieved its primary endpoint. See “Phase 3 SAPPHIRE Pivotal Trial” below. We submitted a BLA to the FDA in January 2025 and requested priority review, and we plan to submit a marketing authorization application to the EMA in the first quarter of 2025. Assuming marketing approval is obtained, we plan to commercially launch apitegromab in the U.S. in the fourth quarter of 2025 with a commercial launch of apitegromab in Europe to follow.

We believe that apitegromab has the potential to be the first muscle-targeted therapy that 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 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 completed SAPHIRE, 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. In October 2024, the Company announced positive top-line results that showed the study achieved its primary endpoint.

Beyond Type 2 and Type 3 SMA, we believe that apitegromab has the potential for therapeutic benefit 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.

5. Phase 3 SAPHIRE Pivotal Trial

On October 7, 2024, we announced positive top-line data from our Phase 3 SAPHIRE clinical trial evaluating the efficacy and safety of apitegromab, an investigational muscle-targeted therapy, in patients with SMA.

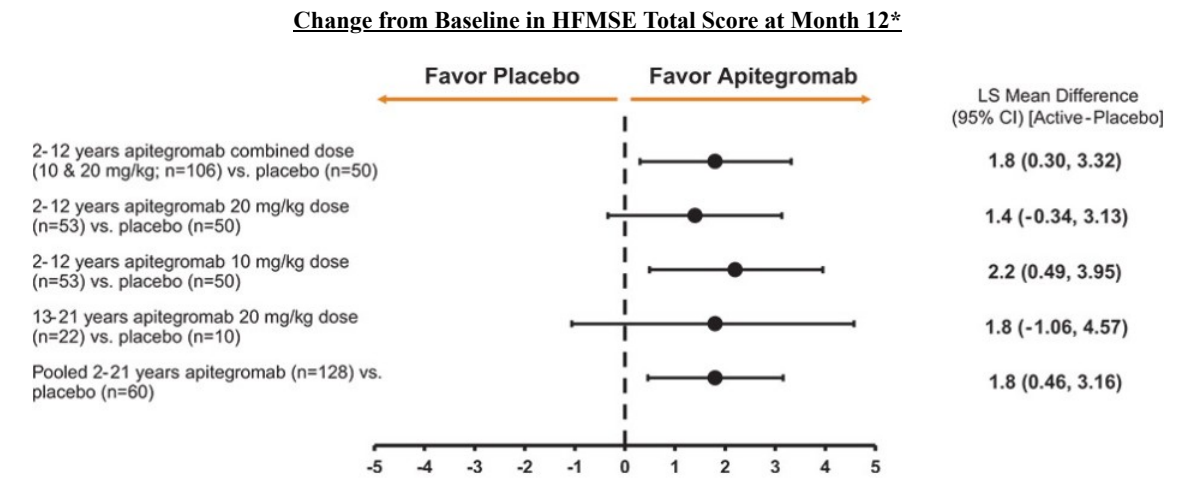
SAPHIRE was a randomized, double-blind, placebo-controlled, Phase 3 clinical trial that evaluated the safety and efficacy of apitegromab in nonambulatory patients with Types 2 and 3 SMA who are receiving current standard of care therapies (either nusinersen or risdiplam). SAPHIRE enrolled 156 patients ages 2–12 years old in the main efficacy population. These patients were randomized 1:1:1 to receive either apitegromab 10 mg/kg, apitegromab 20 mg/kg, or placebo by intravenous infusion every 4 weeks. An exploratory population that enrolled 32 patients ages 13–21 years old was also evaluated. These patients were randomized 2:1 to receive either apitegromab 20 mg/kg or placebo.

The study achieved its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement for apitegromab compared to placebo in motor function as measured by the HFMSE in SMA patients on chronic dosing of standard of care therapies (either nusinersen or risdiplam). Based upon the similar pharmacological profiles of the 20 mg/kg and 10 mg/kg doses of apitegromab, the statistical analysis plan was prespecified to analyze both the combined dose (10 mg/kg and 20 mg/kg) and the 20 mg/kg dose, each compared to placebo, as the primary analysis. Statistical significance was achieved per the prespecified statistical analysis plan (Hochberg multiplicity adjustment) for the primary analysis where the p-value needs to be ≤ 0.025 if only one prespecified analysis crosses the statistical significance boundary of ≤ 0.05 .

- In the main efficacy population (ages 2–12), the mean difference in change from baseline in HFMSE was 1.8 points ($p = 0.0192$) for all patients receiving apitegromab 10 mg/kg and 20 mg/kg ($n=106$) compared to placebo ($n=50$). Patients receiving 20 mg/kg of apitegromab ($n=53$) showed a 1.4 point mean difference compared to placebo ($p=0.1149$).
- The prespecified analysis of the 10 mg/kg dose showed that patients receiving 10 mg/kg of apitegromab ($n=53$) showed an improvement of 2.2 points (nominal $p=0.0121$) compared to placebo.
- Based upon PK/PD data from the SAPHIRE trial, similar levels of target engagement were observed for the 10 mg/kg and 20 mg/kg dose groups.

Motor function outcomes were meaningful and consistent across the main efficacy population and in the ages 13–21 exploratory population, and favored apitegromab ($n=22$) compared to placebo ($n=10$).

The table below summarizes the changes from baseline in HFMSE total score at month 12 across the various dose and age groups studied in SAPPHIRE.

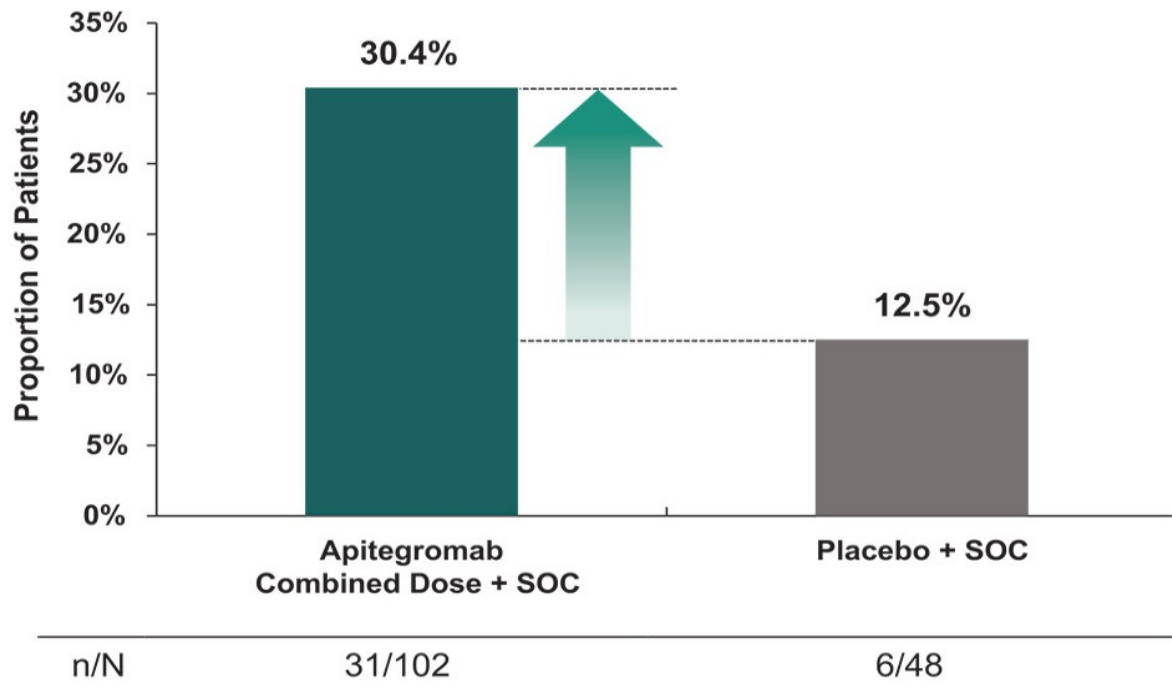


Abbreviations: CI, Confidence Interval; LS, Least Squares.

*n values at 12-month endpoint

30.4% of patients receiving apitegromab in the main efficacy population (ages 2-12) had ≥ 3 point improvement in HFMSE at Month 12 versus 12.5% of patients on placebo, as shown below.

Proportion of Patients With ≥ 3 Point Improvement at Month 12 in HFMSE

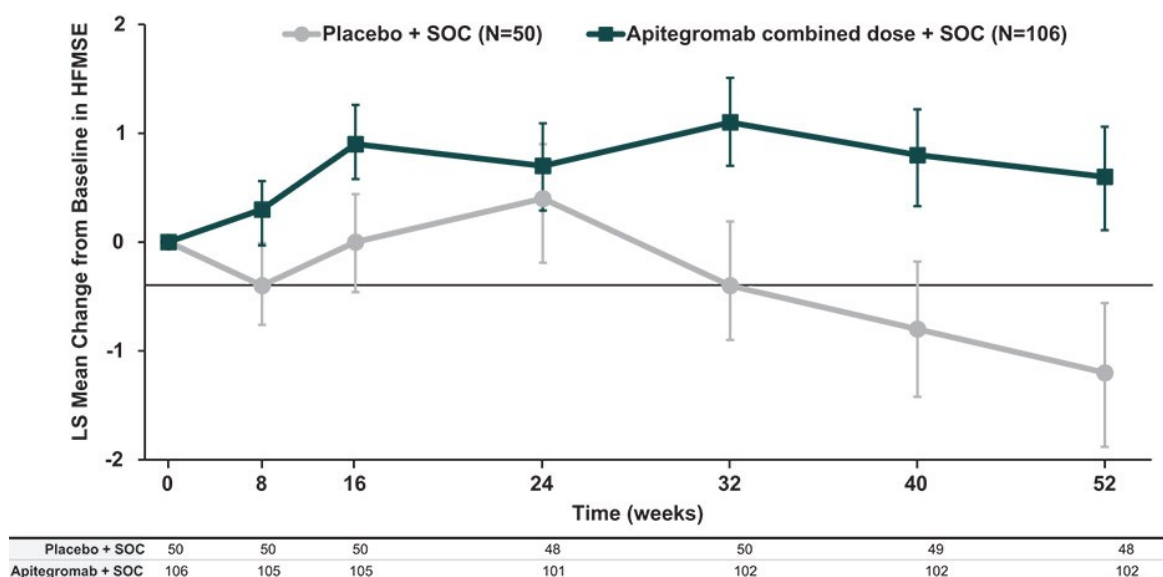


Proportion of patients achieving ≥ 3 Point Improvement in HFMSE was higher for apitegromab vs. placebo in combined dose (odds ratio 3.0, $p=0.0256$)

Abbreviation: SOC = standard of care.

Patients receiving apitegromab in the main efficacy population (ages 2–12) demonstrated early motor function improvement compared to placebo from the first measured time point at 8 weeks, and clinical benefit expanded at 52 weeks as measured by HFMSE, as shown below.

HFMSE Improvement vs. Placebo in SAPPHERE



Abbreviations: CI=Confidence Interval; HFMSE=Hammersmith Functional Motor Scale Expanded; LS=Least Squares; SOC=standard of care.

Treatment with apitegromab was well-tolerated across all age groups. There were no clinically relevant differences in the adverse event profile by dose, 10 mg/kg versus 20 mg/kg. No new safety findings were observed in the SAPPHERE clinical trial; the profile was consistent with that observed in the Phase 2 TOPAZ clinical trial, including an extension study which had over four years of treatment as of the cut-off date. Serious adverse events (“SAEs”) were consistent with the underlying disease and the current standard of care received by patients; no SAEs were assessed as related to apitegromab. There were no study drug discontinuations due to adverse events. The most common adverse events were pyrexia, nasopharyngitis and cough, observed in 29.2%, 24.5% and 24.5% of patients in the main efficacy population (10 mg/kg and 20 mg/kg combined), respectively. The table below summarizes the adverse events observed in the trial.

Summary of Adverse Events in SAPPHIRE

Summary of Adverse Events	Main Efficacy Population				Exploratory Subpopulation	
	Placebo + SOC (N = 50) n (%)	10 mg/kg + SOC (N = 53) n (%)	20 mg/kg + SOC (N = 53) n (%)	SRK-015 + SOC (N = 106) n (%)	Placebo + SOC (N = 10) n (%)	20 mg/kg + SOC (N = 22) n (%)
AE	43 (86.0)	51 (96.2)	46 (86.8)	97 (91.5)	9 (90.0)	19 (86.4)
SAE	5 (10.0)	9 (17.0)	12 (22.6)	21 (19.8)	1 (10.0)	0
AE Grade ≥ 3	5 (10.0)	9 (17.0)	11 (20.8)	20 (18.9)	1 (10.0)	1 (4.5)
AE Leading to treatment discontinuation	0	0	0	0	0	0
AE Leading to study withdrawal	0	0	0	0	0	0
AE with highest incidence						
Pyrexia	16 (32.0)	18 (34.0)	13 (24.5)	31 (29.2)	1 (10.0)	2 (9.1)
Nasopharyngitis	10 (20.0)	15 (28.3)	11 (20.8)	26 (24.5)	4 (40.0)	6 (27.3)
Cough	11 (22.0)	15 (28.3)	11 (20.8)	26 (24.5)	1 (10.0)	4 (18.2)
SAE with highest incidence						
Pneumonia	0	3 (5.7)	4 (7.5)	7 (6.6)	0	0
Dehydration	0	2 (3.8)	1 (1.9)	3 (2.8)	0	0

We are also continuing our long-term extension study, ONYX, for patients from both the TOPAZ and SAPPHIRE studies, who are receiving apitegromab in conjunction with current standard of care. Following trial completion, 98% of SAPPHIRE patients (185/188) enrolled in the ONYX open-label expansion study.

6. Phase 2 TOPAZ Proof-of-Concept Trial

We completed enrollment in our Phase 2 TOPAZ proof-of-concept trial of apitegromab in SMA in January 2020. TOPAZ was a Phase 2 active treatment study evaluating the safety, efficacy, PK, and PD of apitegromab 2 and 20 mg/kg in 58 patients ages 2 to 21 years old with Type 2 and Type 3 SMA (nonambulatory and ambulatory). One patient discontinued from the 12-month treatment period for reasons that were determined to be unrelated to apitegromab treatment. All remaining patients completed the 12-month treatment period and opted into the extension period.

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. The primary efficacy objectives evaluated in the TOPAZ trial, HFMSE and Revised Hammersmith Scale (“RHS”), are clinically meaningful outcome measures validated for SMA. The HFMSE is a validated measure for the assessment of gross motor function in SMA, while the RHS is a revised version and used for ambulatory patients in TOPAZ.

Results of the primary analysis showed that improvement in motor function, as measured by RHS or HFMSE, was observed at Month 12 in the majority of patients, regardless of age, SMA type, or time of SMN therapy initiation (Crawford Neurology 2024). Ambulatory patients ages 5 to 21 years old showed stabilization in RHS scores over the 12 months of treatment, while nonambulatory patients showed overall improvement. Substantial improvement in motor function, a mean improvement of 6.2 points for HFMSE total score at Month 12, was observed in Cohort 3, with dose response between those randomized to 20 mg/kg and 2 mg/kg (7.1 points and 5.3 points, respectively).

Treatment with apitegromab was well tolerated. Incidence and severity of adverse events were consistent with the underlying patient population and SMN therapy. The most frequently reported treatment-emergent adverse events included headache (24%), pyrexia (22%), upper respiratory tract infection (22%), cough (22%), and nasopharyngitis (21%). Five patients experienced a serious treatment-emergent adverse event, all assessed by the respective trial investigator as unrelated to apitegromab.

In August 2024, the Company reported that long-term apitegromab data continued to show sustained motor function benefit over 48 months (Crawford WMS 2024). Over 90 percent of nonambulatory patients remained on treatment in the extension study over 48 months. Treatment-emergent adverse events (“TEAEs”) were consistent with previous reports at 12 months, with no new findings.

7. Phase 1 Healthy Volunteer Clinical Trial Results

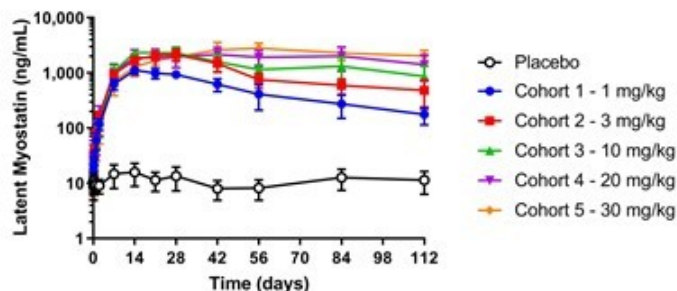
The randomized, double-blind, placebo-controlled, first-in-human, Phase 1 clinical trial was designed to evaluate the safety and tolerability, immunogenicity, PK, and PD of IV administered apitegromab in adult healthy volunteers. A total of 66 subjects were enrolled, including 40 subjects in the single 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 or hypersensitivity reactions. Immunogenicity was assessed by anti-drug antibody testing, and all subjects tested negative.

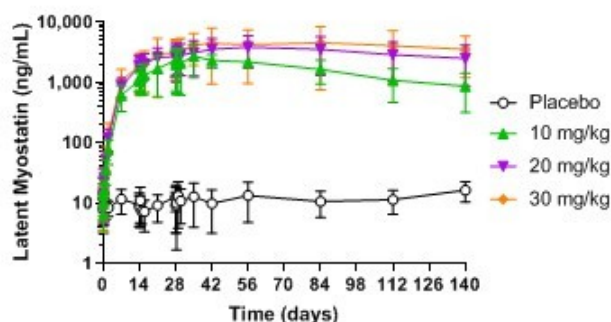
Pharmacokinetics and pharmacodynamics results. Apitegromab displayed a PK profile generally consistent with that commonly observed with monoclonal antibodies. Drug exposure was dose proportional, and the serum half-life was approximately 23 to 33 days across the apitegromab dose groups. The findings 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.

Single-Ascending Dose



Multiple-Ascending Dose



Apitegromab engages latent myostatin in Phase 1 clinical trial subjects

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

We see potential for apitegromab broadly across SMA (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 where muscle atrophy is a key component of disease pathogenesis. 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.

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 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 comorbidities associated with obesity primarily cardiometabolic including cardiovascular disease and type 2 diabetes.

The GLP-1 RAs, 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 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.

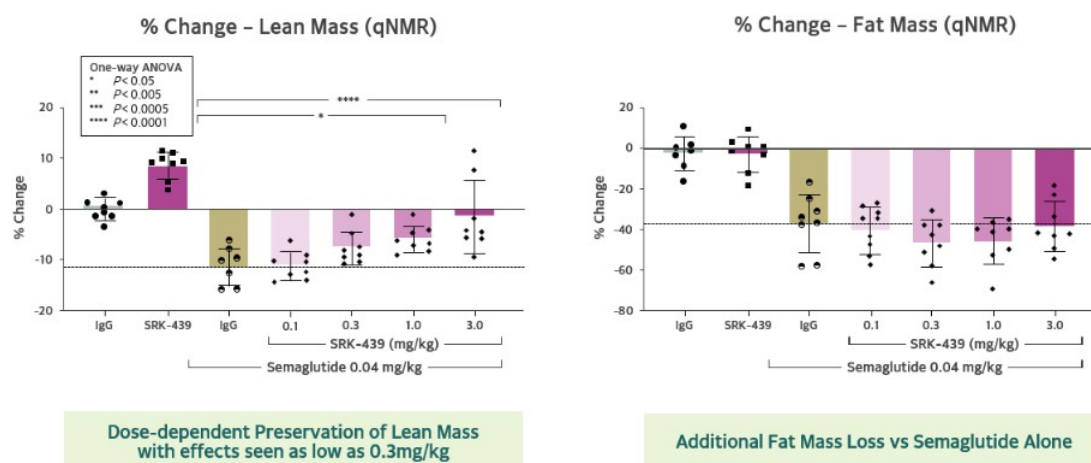
3. SRK-439: A Novel Anti-myostatin Antibody for the Treatment of Obesity

In addition to our work to advance apitegromab in SMA, we have leveraged our expertise in anti-myostatin and its effect on 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 developability profile, including suitability for subcutaneous dosing and a low dosing volume. We believe the selectivity of 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 lead to retention of lean muscle.

We are advancing this preclinical program and plan to submit an IND in the third quarter of 2025.



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. To inform the development of SRK-439, in May 2024 we initiated the Phase 2 EMBRAZE proof-of-concept trial, designed to assess the safety and efficacy of apitegromab to preserve muscle mass in individuals living with obesity and on background therapy of a GLP-1 RA. In September 2024, we announced that we completed enrollment and top-line results from this trial are expected in the second quarter of 2025.

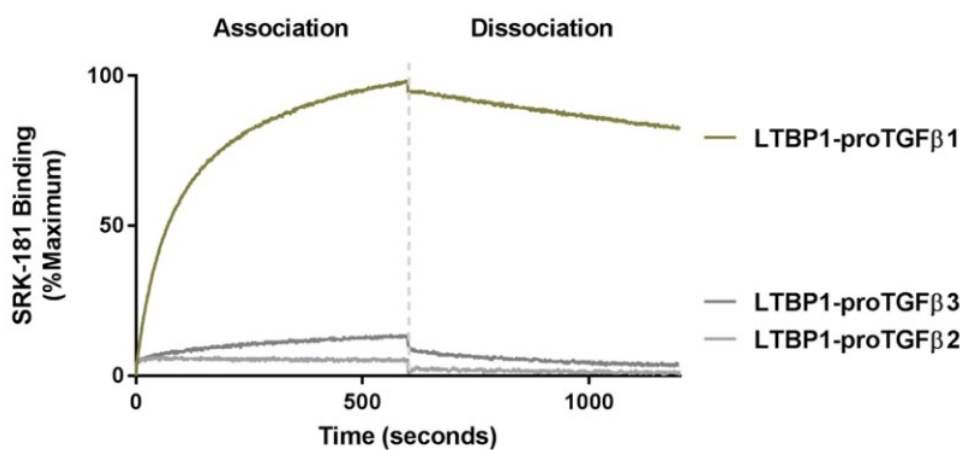
b. Inhibiting TGF β – SRK-181 (context-independent latent TGF β 1 inhibitor) and LTBP (matrix-selective latent TGF β 1 inhibitor).

We have been a pioneer in developing a differentiated approach to harnessing the therapeutic potential of the TGF β 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 TGF β , including for oncology and fibrosis.

The TGF β superfamily plays a central role in a wide range of cellular processes including growth and differentiation, immune regulation and fibrosis. TGF β 1 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 (“LAP”) — 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. TGF β 1 is produced by a variety of cell types, including fibroblasts, which deposit latent TGF β 1 in connective tissue, as well as regulatory T cells, cancer cells and macrophages, which display latent TGF β 1 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 TGF β 1, our founder, Dr. Springer elucidated a new understanding of the mechanism that underlies the activation of latent precursor forms of members of the TGF β superfamily of protein growth factors. This research explained at a molecular level why the secreted form of TGF β 1 is inactive. The prodomain, though physically separated from the mature growth factor domain, forms a “cage” around the active form of TGF β 1, blocking the ability of the growth factor to signal through its receptor. Integrin proteins are able to unlock the “cage” by binding to the prodomain of the latent

TGF β 1 complex and applying force to pull the complex open, allowing the mature growth factor to be released and signal in its microenvironment. While mature TGF β 1 shares a high degree of structural similarity with its closely related family members, TGF β 2 and TGF β 3, 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 TGF β 1. By specifically targeting the TGF β 1 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 TGF β 1 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 TGF β 1 with high affinity and high selectivity, which is evidenced by minimal or no binding to latent TGF β 2 or latent TGF β 3 isoforms. Integrins, such as α V β 6 and α V β 8, can trigger the activation of TGF β 1 and TGF β 3. In addition, biochemical evidence suggests that certain proteases (e.g., Plasmin and Kallikreins) may also induce TGF β 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 TGF β 1.



SRK-181 selectively binds to proTGF β 1 complexes with minimal or no binding to proTGF β 2 or proTGF β 3 complexes.

i. TGF β 1 in Cancer Therapy

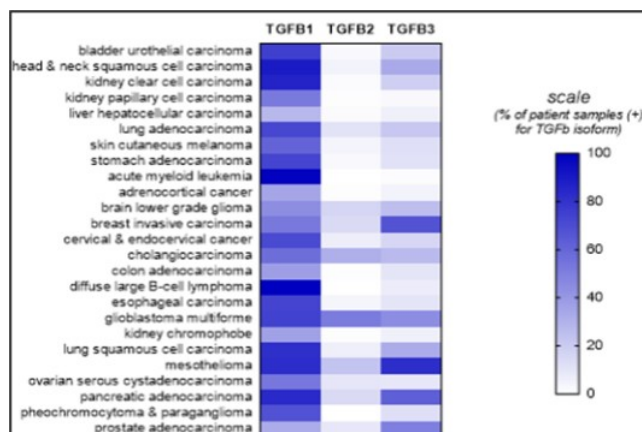
We believe that specific inhibition of TGF β 1 may have a significant impact on the treatment of patients in certain oncology settings.

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 (e.g., acquired resistance). In many human cancers, TGF β 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 melanoma tumors identified multiple TGF β -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 TGF β pathway as a major determinant of primary resistance to atezolizumab.

Our analysis of publicly available human tumor data has identified TGF β 1 as the predominant TGF β isoform expressed in many human solid tumors.



National Cancer Institute - Cancer Genome Atlas Program RNAseq analysis of >10,000 samples spanning 33 tumor types show high expression of the TGF β 1 isoform in many tumor types

ii. SRK-181 in Cancer Immunotherapy - Inhibitor of Latent TGF β 1 Activation

Our second product candidate, SRK-181, a highly selective inhibitor of the activation of latent TGF β 1, 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 TGF β 1 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 TGF β 1 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, TGF β 2 and TGF β 3. Treatment of animals with these non-selective TGF β inhibitors has been associated with a range of toxicities, most notably cardiac toxicity. Furthermore, since each of these growth factors signals through the same TGF β receptor, ALK5, inhibitors of the TGF β receptor kinase suffer from similar dose-limiting toxicities. In preclinical studies of our antibodies, we have observed selective inhibition of TGF β 1 activation in vitro and immunomodulatory and antifibrotic activity in multiple disease models in 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 TGF β 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, TGF β 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 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.

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 and completed enrollment in December 2023. We continue to treat patients who remain on study. Safety, efficacy and biomarker data were presented in June 2024 at the ASCO annual meeting and in November 2024 at the SITC 39th Annual Meeting. The data showed encouraging responses in heavily pretreated and anti-PD-(L)1 resistant patients across multiple tumor types. Data presented continues to support proof-of-concept for SRK-181 in 30 heavily pretreated patients with ccRCC resistant to anti-PD-1. SRK-181 was generally well tolerated and showed promising anti-tumor activity in this patient population. Of 30 patients in the ccRCC cohort, seven patients treated with SRK-181 in combination with pembrolizumab had documented response, achieving a best tumor reduction of 40% to 100%, with an objective response rate of 23.3%. In the biomarker analysis, SRK-181 combined with pembrolizumab established proof of mechanism in patients by creating a proinflammatory tumor microenvironment across multiple tumor types. Safety data from ccRCC cohort continue to show SRK-181 is generally well tolerated. In ccRCC patients, responders had higher basal levels of activated CD8+ T cells, higher T-regs, as well as higher TGFβ1 expression. The data cutoff for all analyses was September 9, 2024.

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 beyond what is expected from continuing PD-1 alone. We anticipate that emerging data from the DRAGON trial will be presented at medical meetings in the future.

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

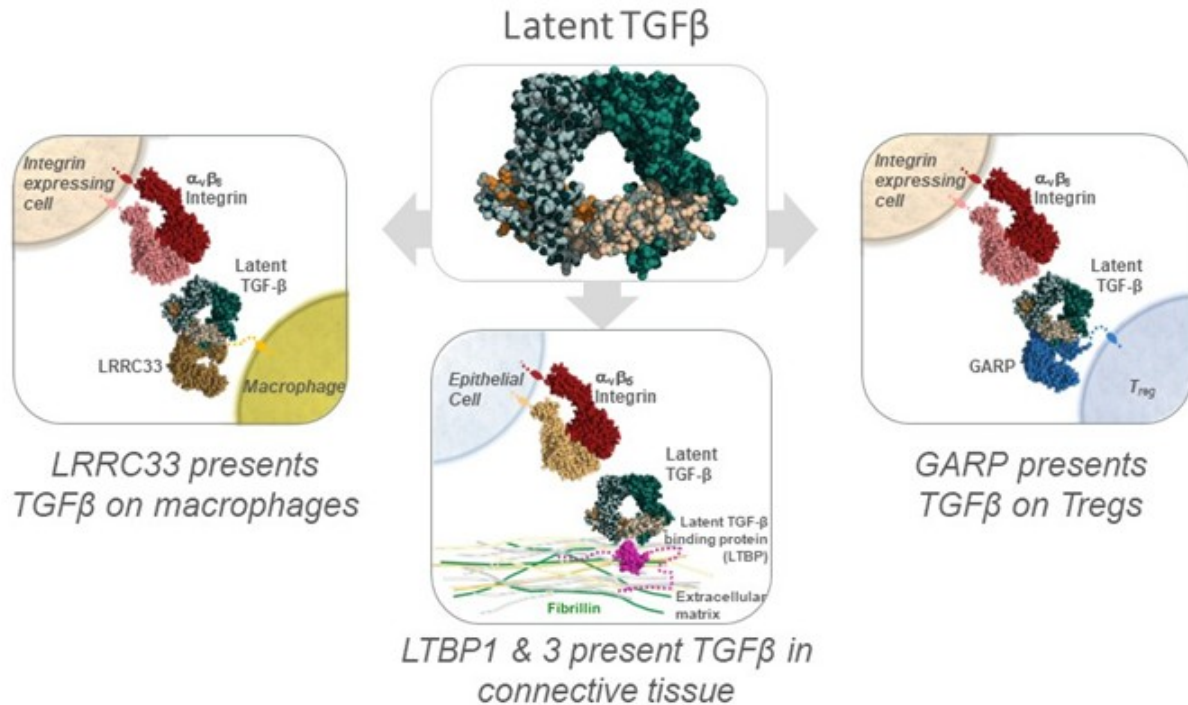
In addition to cancer immunotherapy, we believe SRK-181 has the potential for use in other oncology settings, such as in immunotherapy-naïve patients, in combination with other therapies beyond checkpoint inhibitors and in myelofibrosis.

iii. Fibrosis: 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. 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 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 SRK-373, a highly potent, anti-latent TGFβ1 antibody that selectively inhibits

TGF β 1 activation within the extracellular matrix by targeting latent TGF β 1 associated with latent TGF β -binding proteins (LTBPs), thus enabling specific inhibition of TGF β 1 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.



When latent TGF β 1 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 TGF β 1 complex in a particular microenvironment. Unlike TGF β 1, 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.

c. SRK-256: 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 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.

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 SRK-256, 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. SRK-256 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 acquisition and development of our own proprietary 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.

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.

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 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- 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.

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 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, 2024, we have 30 pending patent families across multiple programs. Among the pending families, 24 have been nationalized, from which 24 applications have matured into U.S. issued patents with additional issued patents in multiple jurisdictions globally. Collectively, there are 337 national or direct utility applications pending or issued. In addition, there are four patent family filings which are in the priority year. We continue to review and harvest new inventions for new patent filings.

As of December 31, 2024, three granted patents, EP2981822, EP2981822 and EP3368069, are the subject of ongoing opposition proceedings before the European Patent Office (“EPO”). We have no other contested proceedings relating to any patents 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.”

a. Platform

Our novel approach to generating selective modulators of supracellular activation of growth factors is broadly embodied in our earliest “platform” patent family, PCT/US2014/036933 (published as WO 2014/182676). This patent family is directed to methods for modulating the activation of the TGFβ superfamily of growth factors and methods for screening for a monoclonal antibody that 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 family 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 11,827,698 (issued 11/28/2023). There is also a granted European (“EP”) platform patent: EP2981822 (granted on 09/02/2020). These U.S. and EP patents are projected to expire in 2034.

Specifically, EP2981822 originally granted with 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 the subject of ongoing opposition proceedings before the EPO. It was revoked by the opposition division in November 2024, but the revocation decision is subject to appeal.

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.

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.

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

Thirteen 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.

Three 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, 11,135,291, and 11,925,683 issued in June 2019, October 2021, and March 2024, respectively, with 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 host cells and methods of making antibodies with pH sensitive binding to pro/latent myostatin.

A 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 and full chain sequences of apitegromab, and pharmaceutical compositions of the antibodies.

A third family, PCT/US2023/085574 (published as WO2024138076), was filed with claims directed to specific amino acid sequences of additional antibodies in our proprietary myostatin inhibitor portfolio. If granted, this family is projected to expire in December 2043.

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. This family is projected to expire in September 2036. The first U.S. application issued in May 2019 as U.S. Patent 10,287,345 with claims 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. A third U.S. application issued as U.S. Patent 12,006,359 in June 2024. The issued claims are directed to a method of improving body composition by administering an antibody comprising heavy and light chain sequences of our proprietary activation inhibitors (such as apitegromab) or variants thereof.

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, as well as in other countries. Specifically, the U.S. application granted in March of 2021 as U.S. Patent 10,946,036. The granted claims are directed to add-on or combination therapy for treating spinal muscular atrophy with a myostatin inhibitor and a 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. 7344337). Likewise, the European counterpart granted as EP 3368069B1 and has been validated in 37 states. The originally 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. It was revoked by the opposition division in April 2024, but the revocation decision is being appealed.

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 are also two PCT applications related to the phase 2 and phase 3 clinical trials of apitegromab in SMA. PCT/US2021/056517 (published as WO2022/093724) is directed to inventions deriving from the phase 2 clinical trial of apitegromab. This PCT was nationalized broadly. 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 deriving from the phase 2 and phase 3 clinical trials of apitegromab. If granted, patents from this family would expire in 2043. Both of these families are in early stages of prosecution.

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.

Finally, five 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, 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 U.S. 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. EP3365368 is the subject of ongoing opposition proceedings before the EPO. Additional patents in this family have been granted in other jurisdictions. 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, and patents have issued in April 2024 in Columbia, June 2024 in the Gulf Cooperation Council, and August of 2024 in Japan). Patents of this family are projected to expire in 2039. Separately, 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. Two U.S. patents issued in September of 2021 as U.S. 11,130,803 and in October of 2024 as U.S. 12,122,823, with claims which cover the SRK-181 clinical candidate and pharmaceutical compositions thereof; and a European patent issued in November of 2021 as EP3677278; and the corresponding Hong Kong patent issued in June of 2022, 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). If granted, patents deriving from these PCT applications would expire in 2042. Another PCT application, PCT/US2024/018970 (published as WO 2024/187051) discloses methods of treating certain cancers and identification of patient populations using biomarkers. If granted, patents derived from this PCT is expected to expire in 2044. One additional patent family to our TGFβ1 inhibitor program is currently in the priority year. Antibodies claimed in these patent families protect our SRK-181 clinical candidate.

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 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; PCT/US2022/73740 (published as WO 2023/288277), which is expected to expire in 2042. Three U.S. patents (U.S. Pat. Nos. 11,214,614, 11,365,245 and 12,173,059) and one Colombian patent 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 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 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 Japanese patent (JP Patent No. 7128801) issued in August 2022 with claims directed to antibodies and antigen-binding fragments which specifically bind human pro-TGFβ1-GARP complex, a process for their production and related compositions. Additional patents have also been granted in other jurisdictions including in Australia (AU 2017294772).

d. RGMc-Selective Inhibitors

PCT/US2019/057687 (published as WO2020/086736) is directed to RGMc-selective inhibitors and is projected to expire in 2039. A Japanese patent application was allowed in December 2024 and will grant in early 2025. The Japanese patent will have claims which cover a pharmaceutical composition comprising the SRK-256 clinical candidate and the use thereof for treating anemia, including anemia of chronic disease and anemia in subjects diagnosed with cancer, such as myelofibrosis. Also, a Chinese patent application was allowed in December 2024, with similar claims. Applications are pending in other jurisdictions, including U.S. and EP.

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, three granted patents, EP2981822, EP3365368 and EP3368069, are the subject of ongoing opposition proceedings before the EPO, as of December 31, 2024. While there are 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.

Additionally, the Unitary Patent/Unified Patent Court system in Europe became fully operational in June 2023. As such, European patents which are subject to the jurisdiction of the Unified Patent Court (“UPC”) face limited precedent for the court, increasing the uncertainty of any litigation.

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 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 internal antibody display and discovery 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 human use 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. 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.

Many of the companies against which we may compete have significantly greater financial resources and expertise than we do in research and development, manufacturing, and commercialization of approved products. These competitors compete with us in recruiting and retaining qualified scientific and management personnel and may compete with us in establishing clinical trial sites and patient recruitment for clinical trials.

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 targeted treatments and no approved muscle-targeted treatments for SMA to date. The SMA drug development pipeline reflects a focus on addressing the significant remaining unmet needs of individuals living with SMA as well as the life cycle management of the existing approved SMN targeted treatments. To address the remaining unmet needs to further improve and sustain muscle function by contributing to the impact on the overall disease progression in SMA, we are pioneering a novel approach by developing the first muscle-targeted treatment in SMA.

We are developing apitegromab, an investigational fully human monoclonal antibody designed to inhibit myostatin activation by selectively binding the pro- and latent forms of myostatin in the 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 molecules or other treatments for SMA, including Roche, Biogen, and NMD 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 treatments for SMA.

In addition, Novartis, Roche and Biogen are in late-stage development of alternate formulations or dosing regimen of their respective approved SMN treatments, including an additional formulation of Novartis' onasemnogene abeparvovec, an oral tablet for Roche's risdiplam, as well as a high dose formulation of Biogen's antisense oligonucleotide (ASO), nusinersen. Apitegromab is being developed with the intention to be used in individuals living with SMA who are currently on an approved SMN targeted treatment.

b. Competition for SRK-181

Our competitors for SRK-181 may include other companies developing inhibitors of the TGFβ signaling pathway, such as antifibrotic therapies and cancer immunotherapies to be used in combination with CPI therapy.

For the latter, many companies, including AbbVie Inc, Roche, Bicara Therapeutics, Novartis, Bristol Myers Squibb (acquired Forbuis) and Merck KGaA, Merck (acquired Tilos Therapeutics) 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.

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 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 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 IND application, which must become effective before human clinical trials may begin;
- 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 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.

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 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 data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and 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 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 patients to evaluate 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.
- 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.

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 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 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 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 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 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.

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 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.

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. Under current statutory provisions, FDA may award a priority review voucher for an approved rare pediatric disease product application only if the sponsor has received rare pediatric disease designation for the drug by December 20, 2024, and after September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. Congress may vote to reauthorize this program, but its future remains uncertain.

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 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 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, 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 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 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 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 these laws.
- 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 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.
- The federal government and many state governments require pharmaceutical companies to submit periodic reports on product pricing.
- 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.
- 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 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. In addition, the California Privacy Rights Act, or CPRA, amendment to the CCPA was passed in November 2020, and as of January 1, 2023 has imposed additional obligations on companies covered by the legislation. The CPRA significantly modified the CCPA, including by expanding consumers' rights with respect to 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 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 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 included provisions that address pharmaceutical pricing. Among other things, for example, the FDA:

- subjected biological products to potential competition by lower cost biosimilars;
- increased 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;
- established annual fees and taxes on manufacturers of certain branded prescription drugs;
- expanded 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;
- created a new Medicare Part D coverage gap discount program (later replaced under the Inflation Reduction Act of 2022 (the "IRA"));
- expanded eligibility criteria for Medicaid programs and for entities eligible for discounts under the PHS Act's 340B Drug Pricing Program; and
- created a new requirement to annually report the identity and quantity of drug samples that manufacturers and authorized distributors of record provide to physicians.

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:

- As a result of the Budget Control Act of 2011 and subsequent legislation, there is an aggregate reduction to Medicare payments to providers of, on average, 2% per fiscal year that went into effect on April 1, 2013 and will remain in effect through 2031. As a result of the Statutory Pay-As-You-Go Act of 2010 and subsequent legislation, Medicare payments to providers may be further reduced by 4% starting in 2025, absent further legislation.
- The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously 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.
- 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.
- The IRA includes several 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 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 Trump administration may reverse or otherwise change these measures, both the Trump administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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.

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.

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.

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.

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.

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

Depending upon the timing, duration and specifics of FDA approval of 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. The first biological product determined to be interchangeable with a reference product for any condition of use is also eligible for a period of exclusivity during which time the FDA may not determine that another product is interchangeable with the same reference product for any condition of use. The FDA may approve multiple “first” interchangeable products so long as they are all approved on the same first day of marketing.

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 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 that fairly responds to 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.

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 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 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 provide that, by January 31, 2025, all ongoing clinical trials must have transitioned to the 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 a product-specific waiver or 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. The incentive in the case of orphan medicinal products is that 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 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 EU 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 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 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 of the European Economic Area (“EEA”) (Iceland, Liechtenstein and Norway). 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 EU Member State through the mutual recognition procedure. If the product has not received a national MA in any EU Member State at the time of application, it can be approved simultaneously in various EU Member States through the

decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the EU 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 involved (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.

iv. European Union Data and Market Exclusivity

In the EU, innovative 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 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, 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 so as not to justify maintenance of market exclusivity. Orphan designation must be requested before submitting an application for an MA. We will be required to apply for the maintenance of the orphan designation granted to apitegomab 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 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 for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval, and in April 2024, the European Parliament proposed amendments to the legislative proposals. 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 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 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 to 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 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.

c. Regulation in the United Kingdom

The UK formally left the EU on January 31, 2020. 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 provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, the UK has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended). The regulatory regime in the UK therefore currently aligns in many respects with EU medicines regulations, however it is possible that these regimes will diverge in the future now that the UK’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 UK 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”. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, and the medicines aspects of the Windsor Framework have applied since January 1, 2025. This new framework fundamentally changes the previous system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA is now responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA no longer has any role in approving medicinal products destined for Northern Ireland under the EU centralized procedure. A single UK-wide MA will be granted by the MHRA for all novel 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. In addition, the new arrangements require all medicines placed on the UK market to be labelled “UK only”, indicating they are not for sale in the EU.

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). However, on December 12, 2024, the UK government introduced a legislative proposal—the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024—that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK and

increase the transparency of clinical trials conducted in the UK. This includes a notification scheme to enable lower-risk clinical trials to be automatically approved by the MHRA, where the risk is similar to that of standard medical care (although such trials would still require ethics committee approval). Such Regulations are expected to come into force in early 2026.

ii. Orphan Designation

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

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.

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.

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.

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. 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 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 approval, less favorable coverage policies and reimbursement rates may be implemented in the future, which could affect physician usage and patient 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 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 prescription drug 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. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, not necessarily all the drugs in each category or 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 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. 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.

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. We believe that passion for science is what guides us to excellence. Our commitment to changing the lives of people with serious disease is what motivates us to show up each and every day. Our people are our most important asset who help us achieve extraordinary results and create new possibilities for patients. They embody our values and bring them to life in everything we do. We are inspired and guided by these values of focusing on the patient, cultivating curiosity, collaborating with purpose, upholding high standards and accelerating breakthroughs in making a difference in the lives of patients, families and communities.

a. Employees

As of February 21, 2025, we had 196 full-time employees, of which 128 employees are engaged in research and development activities and 68 are engaged in general and administrative activities. All of our employees are based in the U.S. and a majority are based in Massachusetts. During 2024, 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 and starting to build our commercial function, with hires in various areas of clinical development, operations and commercial leadership. We anticipate continuing to add depth and new capabilities in key areas of our business in 2025, as well as hiring to support our infrastructure and overall anticipated growth. 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

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 mentorship guidelines, professional coaching, management and leadership training, online learning subscriptions and access to industry events and conferences. 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 earnings for both short-term and long-term performance. We provide employee salaries that are competitive within our industry based on position, skill level, experience and knowledge. Additionally, we offer both new hire equity and annual equity grants to 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.

In addition to ensuring our compensation programs are equitable, we also strive to provide employees with valuable recognition for their contributions to our success. We have a multi-tier reward & recognition program that aligns with our company values at all levels. Our rewards & recognition program begins with peer-to-peer recognition via an internal community board, followed by quarterly awards for outstanding achievements, and ends with an annual award for each one of our values.

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 people managers so that we can 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.

e. Health & Safety

Ensuring the safety and wellbeing of our employees and communities is of the utmost importance to us, particularly 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. We continue to offer access to COVID tests and masks at no cost to our employees and visitors.

The need to provide the flexibility to 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 (“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 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 will continue to infuse DE&I within the business including: identifying barriers that impact recruitment, development, and retention of underrepresented employees, identifying educational content, communicating the value and impact of 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.

XV. Facilities

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

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 this location. The expiration date was originally in August 2025 and included an option to extend the term by two years. In May 2024, we entered into the First Amendment to the Lease to extend the term for approximately two years, commencing on August 19, 2025 with an option to extend the term by five years.

We believe that our facility at 301 Binney Street is 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.

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, 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 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

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- 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 fail to receive or be delayed in receiving regulatory approval of apitegromab, SRK-181, SRK-439 and future product candidates.
 - We have never commercialized a product and are in the process of building and scaling our business for potential commercialization of apitegromab in the United States and Europe, 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.
 - Changes or disruptions at the FDA and other government agencies caused by funding cuts, government shutdowns, personnel reductions, substantial changes in leadership and policy, or other changes or disruptions to these agencies’ operations could prevent these agencies from performing functions on which the operation of our business relies, including the timely review and potential approval of our BLA application, and any such disruptions and changes could negatively impact our business.
 - 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.
 - 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.
 - 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 future product candidates, and our business could be materially harmed.

- 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 Our Business and 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.
- Our reliance on third parties, such as manufacturers, may subject us to risks relating to manufacturing scale-up and may 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 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 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 operation results and 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.
- 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 infringement may prevent or delay our product discovery, development, and commercialization efforts.

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.

Risks Related to Our Common Stock

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

Risks Related to Product Development, Regulatory Approval and Commercialization

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 fail to receive or be delayed in receiving regulatory approval of 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. Prior to filing the Biologics License Application (“BLA”) to the U.S. FDA for apitegromab as a treatment for patients with SMA in January 2025, we have not 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 or our analysis or interpretation of data from preclinical studies or clinical trials, the results of our clinical trials may not meet the level of statistical significance or amount of data required for approval, regulatory authorities may not agree with the statistical methods we used to evaluate our clinical data, or we may be unable to demonstrate that our product candidates’ clinical and other benefits outweigh their safety risks. A BLA must also include significant information regarding the 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 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.

We have never commercialized a product and are in the process of building and scaling our business for potential commercialization of apitegromab in the United States and Europe, 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 compliance, medical affairs and commercial organizations for the marketing, sales and distribution of apitegromab in the United States as well as Europe, if approved in each jurisdiction, 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, sell, and/or distribute apitegromab if 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.

Furthermore, we intend to commercialize apitegromab globally, if approved. In order to 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.

Changes or disruptions at the FDA and other government agencies caused by funding cuts, government shutdowns, personnel reductions, substantial changes in leadership and policy, or other changes or disruptions to these agencies' operations could prevent these agencies from performing functions on which the operation of our business relies, including the timely review and potential approval of our BLA application, and any such disruptions and changes could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, staffing levels, and statutory, regulatory, and policy changes, the FDA's and foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. Disruptions at the FDA and other agencies, including substantial leadership, personnel, and policy changes, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last few months, the U.S. government has issued executive orders that could adversely impact FDA staffing and resources. Such changes could significantly impact the ability of the FDA to timely review and take action on our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns or substantial leadership, personnel, and policy changes could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

In addition, changes in the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our products, including pricing and reimbursement framework under federal healthcare programs could affect the commercial viability of our products, create revenue uncertainty, and impact our ability to achieve profitability. Additionally, regulatory changes may introduce new challenges in obtaining FDA approval or navigating commercialization, and any delay in securing applicable regulatory approvals would adversely affect our business and prospects. These uncertainties could also present new challenges and/or opportunities as we navigate the submission of our BLA to the FDA and make other preparations for potential commercialization. Any delay in obtaining, or our inability to obtain, applicable regulatory approvals would delay or prevent commercialization of apitegromab and could materially adversely impact our business and prospects.

We are seeking priority review for apitegromab for the treatment of SMA, which we requested at the time of submission of our marketing application to the FDA, and may seek accelerated assessments for apitegromab at the time of submitting a marketing application to the EMA. Even if received, priority review designation may not result in a shorter timeline to approval, and such designation may be rescinded if a product no longer meets the qualifying criteria. An application for accelerated assessment may not be accepted by the EMA and, even if it is, there is no guarantee that a product will be granted a marketing authorization.

As appropriate, we may seek priority review at the time of submitting a marketing application for certain of our product candidates. For apitegromab for the treatment SMA, we have requested Priority Review which, if granted, would shorten the FDA's review time to six months from the date of filing acceptance. The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's Prescription Drug

User Fee Act (“PDUFA”) goal date for taking action on a marketing application from ten months to six months from FDA’s acceptance of the application for review. However, priority review does not guarantee a faster review or approval process or assure ultimate approval by the FDA. In addition, priority review designation may be rescinded if the FDA determines that a product no longer meets the qualifying criteria.

In addition, as appropriate, we may seek accelerated assessment of a marketing authorization application by the EMA for certain of our product candidates. The EMA may accept an application for accelerated assessment if the applicant can show that its product is of major interest for public health, particularly from the perspective of therapeutic innovation. Accelerated assessment reduces the timeframe for the EMA to review a marketing authorization application under the centralized procedure from 210 days (excluding “clock stops”, when applicants are required to provide additional information in response to questions from the EMA) to 150 days (excluding clock stops). There is no single definition of what constitutes major public health interest and the EMA may not accept an application for accelerated assessment. Even if an application for accelerated assessment is accepted, the evaluation of the marketing authorization application is subject to the same evidence requirements as evaluation under a standard timetable and there is no guarantee that a product will be granted a marketing authorization.

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.

Before obtaining regulatory approvals 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 development is expensive and can take many years to complete, and its outcome is inherently 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. Clinical trials may fail 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 may not be sufficient to apply for and obtain regulatory approval on the timelines we expect or at all. Other decisions or actions of regulatory agencies may affect our plans, progress or results.

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;
- 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;
- 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;
- 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.

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. 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 study for apitegromab in patients from both the TOPAZ and 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 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. 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, 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 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.

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 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 ONYX, our long-term extension study for patients from both the TOPAZ 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 ONYX long-term extension trials, or the medical condition of patients may be affected which could negatively affect the efficacy and safety results for apitegromab in the trials or reduce the amount of data or confound the data from this trial. In May 2024, we initiated the Phase 2 EMBRAZE proof-of-concept trial of apitegromab in combination with approved GLP-1 RAs in obesity. This study relies 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 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 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 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 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 delay our clinical development programs and harm our business, 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 or replicated in 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 future results 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 our Phase 2 TOPAZ clinical trial for the treatment of patients with Type 2 and Type 3 SMA. In 2024, we announced data from the Phase 2 TOPAZ trial extension period which showed patient outcomes at 48 months of treatment with apitegromab. These data show that continued treatment with apitegromab over the extended period was associated with sustained clinical benefit, a continued favorable safety profile with no new safety findings, and a retention rate of over 90% in patients with nonambulatory Types 2 and 3 SMA receiving SMN therapy. In January 2022, we initiated our Phase 3 SAPPHERE clinical trial of apitegromab for the treatment of patients with Type 2 and Type 3 SMA and in October 2024, we announced positive top-line data from our Phase 3 SAPPHERE clinical trial evaluating the efficacy and safety of apitegromab. We also announced in October 2023 our plans to expand into cardiometabolic disorders based on preclinical data with SRK-439, and we initiated the Phase 2 EMBRAZE proof-of-concept trial of apitegromab in combination with a GLP-1 RA in obesity in May 2024 with top-line results expected in the second quarter of 2025. We cannot assure you that any future clinical trials of apitegromab, such as our Phase 2 clinical trial in obesity, or 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 have initiated 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.

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, clinical data from our Phase 1 DRAGON trial in cancer immunotherapy, including preliminary safety, efficacy and biomarker data were presented in June 2024 at the ASCO 2024 annual meeting and in November 2024 at the SITC 39th Annual Meeting, and we will continue to present data from our Phase 1 DRAGON trial while the trial is ongoing. Tumor response data 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.

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 are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval. If we fail to produce positive results in our ongoing and planned preclinical studies and clinical trials in apitegromab, SRK-181, SRK-439 or if a regulatory authority interprets and analyzes the results as not positive, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, may be materially adversely affected.

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. 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;
- 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;
- 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 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 certain 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 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 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 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 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.

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 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.

We have received Orphan Drug designation from the FDA for apitegromab for the treatment of SMA, and following the EMA’s Committee for Orphan Medicinal Products’ 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
- the holder of the marketing authorization for the orphan medicinal product consents to a second 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 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.”

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

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, 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;
- 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 FDA's authority to grant rare pediatric disease designations expired on December 20, 2024. Under the amended statutory sunset provisions, the FDA may award a priority review voucher for an approved rare pediatric disease product application only if the sponsor has rare pediatric disease designation for the drug and if that designation was granted by December 20, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. 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 Fast Track designation or Breakthrough Therapy designation from the FDA 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 PRIME designation for certain of our product candidates.

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 eligible for this designation, we cannot assure that the FDA would decide to grant it. Although the FDA has granted Fast Track designation for apitegromab in SMA, 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.

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. See the sections of this Annual Report entitled, "Business — Government Regulation — US Biological Product Development — Expedited Development and Review Programs."

In March 2021, the EMA granted PRIME designation to apitegromab for the treatment of SMA. PRIME is a scheme provided by the EMA to enhance support for the development of medicines that target an unmet medical need. 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 entitled, "Business – Government Regulation – European Union Drug Development—European Union Expedited Review and Development."

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.

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. The safety and efficacy profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities. 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:

- 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. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. 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.

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. There may be delays in getting our product candidates, if approved, on hospital or insurance formularies or limitations on coverage that may be available in the early stages of commercialization for newly approved drugs. If any of our product candidates are approved but fail to achieve market acceptance among hospitals, physicians, patients or health care payors, we will not be able to generate significant revenues, which would have a material adverse effect on our business, prospects, financial condition and results of operations. 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:

- the efficacy and safety of such product candidate as demonstrated in clinical trials;
- the indications for which the product candidate is approved;
- efficacy and potential advantages compared to alternative treatments;
- the ability to obtain sufficient third-party coverage and adequate reimbursement;
- 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;
- the timing of market introduction of our products as well as competitive products;
- 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; and
- the prevalence and severity of any side effects.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market apitegromab, we may not be successful in commercializing apitegromab if and when it is approved.

We have recently begun to build our sales or marketing infrastructure and have limited experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must continue to develop a sales and marketing organization and/or outsource certain functions to third parties.

There are risks involved both with establishing our own sales and marketing capabilities and with entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing, third-party logistics providers, specialty distributors, specialty pharmacies, patient service providers and distribution services, our product revenue or the profitability of these product revenue to us may be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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.

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

Risks Related to Our Business and 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.

We have no experience manufacturing our product candidates on a commercial scale. 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 changing rates of inflation and interest rates. 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 affect the regulatory clearance of our 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 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, 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 and commercialize 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 contract manufacturers to manufacture sufficient quantities of apitegromab to produce validation batches. We do not have long-term supply agreements in place with many of our contract manufacturers, and each batch of our drug product for our product candidates is individually contracted through a purchase order governed by master service and quality agreements. If our existing drug product 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 would need to scale up the manufacturing process before we would be able to use the product candidate supplies they manufacture, which could result in delays to our clinical trials or future commercialization plans, if we are successful and gain approval.

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 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 or commercial supply. 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 commercial launches, which could negatively affect our business.

Our reliance on third parties, such as manufacturers, third-party logistics providers, specialty distributors, specialty pharmacies, and patient service providers, may subject us to risks relating to manufacturing scale-up and may cause us to undertake substantial obligations, including financial obligations.

In order to conduct later-stage clinical trials, or, 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 increase the manufacturing capacity for apitegromab in a timely or cost-effective manner to meet our supply requirements. If we successfully commercialize any of our product candidates, we may be required to establish large-scale commercial manufacturing capabilities. As our drug development pipeline increases and matures, we will have a greater need for clinical study and commercial manufacturing capacity. 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 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.

Our reliance on third-party logistics providers, specialty distributors, specialty pharmacies, and patient services providers may subject us to risks that could impact the commercialization and patient access to apitegromab. If apitegromab is approved, we expect to use limited distribution agreements, which could concentrate supply with a small number of specialty pharmacies, increasing the risk of distribution disruptions, capacity constraints, and gaps in patient access if these partners fail to perform. Additionally, third parties manage high-touch patient support, reimbursement processing, and copay assistance, and any failures in these areas could lead to delays in initiation of treatment, coverage denials, and financial barriers for patients. Additionally, challenges such as disruptions in logistics, quality-control issues, non-compliance with regulatory requirements, or delays in onboarding key distribution partners may arise. If we or our third-party distribution service providers fail to scale and manage commercial distribution operations efficiently, the launch, commercialization, or continued supply of apitegromab may be delayed or compromised, which could significantly harm our business, reputation, and financial results.

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 and potentially commercialize 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 personnel. Our ability to compete in the highly competitive biotechnology industry depends upon our ability to attract and retain highly qualified specialized personnel. As apitegromab 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 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 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 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 and potentially commercialize 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. 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, incidents or compromises.

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-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, incidents or compromises. 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, including regulatory fines, that may result from an interruption or breach of our systems.

Our employees, independent contractors, consultants, commercial partners, vendors and distributors 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 or EMA approval or approval from other foreign regulatory bodies of apitegromab, SRK-181, SRK-439 or any future product candidates and begin commercializing those products in the U.S. or in such other jurisdictions, 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 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 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 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, 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 entitled “Business – Government Regulation – Other Healthcare Laws.”

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 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 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 the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009. 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 and Phase 3 SAPPHIRE clinical trial of apitegromab in the European Economic Area ("EEA"), and are currently conducting 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 General Data Protection Regulation (the "EU GDPR") imposes a broad range of strict requirements on companies subject to the EU GDPR, including requirements relating to having legal bases and conditions for processing personal information relating to personal data and transferring such personal data 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 for high risk processing, and record-keeping. The EU GDPR imposes penalties in the event of 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.

The EU GDPR ceased to apply in the UK after the UK's exit from the EU on January 31, 2020, but the UK incorporated the EU GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law ("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. Although the UK is regarded as a third country under the EU's GDPR, 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. Likewise, personal data transfers from the UK to the EEA remain free flowing. The UK Government introduced a Data Protection and Digital Information Bill which failed in the UK legislative process. A new Data (Use and Access) Bill ("UK Bill") has been introduced into parliament. 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, or EC. Further, 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. The EC has issued 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 UK is not subject to the EC's 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 EC adopted its adequacy decision for the EU-U.S. Data Privacy Framework (“Framework”). On the basis of the new adequacy decision, personal data can flow safely from the EU to U.S. companies participating in the Framework, without having to put in place additional data protection safeguards. There has been an extension to the Framework to cover UK transfers to the United States. The long-term validity of the Framework remains uncertain as the Framework could be challenged like its predecessor frameworks. This complexity and the additional contractual burden increases our overall risk exposure. There may be further divergence in the future, including with regard to administrative burdens.

The EU GDPR and 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, in the United States, 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’s California Consumer Privacy Act (“CCPA”), creates 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 currently written, the CCPA, as amended by the California Privacy Rights Act, 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 entitled “Business – Government Regulation – European General Data Protection Regulation and “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 present 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, legal liability, and regulatory investigations and fines.

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, for example where third-party

data sources are used to train artificial intelligence models, or the output of artificial intelligence systems reproduce or incorporate third party intellectual property rights, in each case without the right to do so.

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, entered into force on August 1, 2024 and most provisions of which will become effective on August 2, 2026. This legislation imposes tiered obligations on providers and deployers of artificial intelligence systems which are put onto the EU market, or where the output is intended for use in the EU market, depending on the risk classification of the AI system, and encourages providers and deployers of artificial intelligence systems to account for EU fundamental rights 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, and if the AI systems are considered high risk, we would be required to implement substantive risk and quality management systems and post-market monitoring systems and adhere to specific and burdensome and costly ethical, accountability, and administrative requirements. Other jurisdictions, including the United States and UK, are also taking steps to regulate AI systems. 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, safe and ethical 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. A risk of our proprietary intellectual property rights being compromised through the use of artificial intelligence could arise through third party vendors using our data to train their models and/or to generate output for other users of their systems. There is also a risk (as with any hosted service) of security incidents occurring that could lead to unauthorized access to our data. In the event that personal data (including special category data relating to patients) were to be compromised, we may also face action from regulators and affected data subjects, and damage to our reputation.

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 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 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;

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- 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 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 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, including policy, leadership and personnel changes, 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.

A prolonged government shutdown or other disruption including significant leadership and personnel changes, 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.

Global events, including global health concerns 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 rates of inflation and interest, could adversely impact our business. For example, we are conducting ONYX, our long-term extension clinical trial of apitegromab in the EU could adversely affect the conduct of our clinical 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 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 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.

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 from payor to payor, state-to-state (for example, state Medicaid coverage and reimbursement for products may be subject to varying degrees of coverage restrictions or delays) or 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 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 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 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 only recently have 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;
 - 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;
 - 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;
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- 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.

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 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 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 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, 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 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 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 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 to any potential impact on patent protection and/or enforcement in the region, including, for example, payments to the Russian Patent Office and other 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:

- it is possible that our pending patent applications will not result in issued patents;
- we or our licensors, as the case may be, might not have been the first to 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;
- 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;
- 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;
- 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 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;
- 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 patents covering our proprietary technologies and our product candidates are expected to expire beginning in 2034, 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 pending patent applications covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2034 through 2046, 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 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 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 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 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, or interpretation thereof, could change in unpredictable ways that would weaken our ability to obtain new patents, to maintain, 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 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.

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 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 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.

Additionally, the Unitary Patent/Unified Patent Court system in Europe became fully operational in June 2023.

- The 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.

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 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, EP2981822 and EP3365368 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 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 have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unified Patent Court ("UPC"). As the UPC is a new court system, there is little precedent for the court, increasing the uncertainty of any litigation. 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 countries. Patents that remain under the jurisdiction of the UPC 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.

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 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.

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 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 not profitable and have incurred losses in each period since our inception. For the fiscal year ended December 31, 2024 and 2023, we reported a net loss of \$246.3 million and \$165.8 million, respectively. We have incurred losses since our inception, and as of December 31, 2024, we had an accumulated deficit of \$922.7 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, SRK-181, SRK-439, and any future product candidates and prepare for the commercialization of apitegromab, if approved.

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, 2024, we had approximately \$437.3 million in cash, cash equivalents and marketable securities. Based on our current operating plan, we believe that our existing cash, cash equivalents, marketable securities and cash available to us as of December 31, 2024, will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2026. 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, 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.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

As of December 31, 2024, we had net operating loss carryforwards for federal and state income tax purposes of \$512.6 million and \$498.8 million, respectively, which begin to expire in 2032, except for our post 2017 federal net operating loss carryforwards of \$462.1 million, and \$0.2 million of state net operating losses which do not expire. As of December 31, 2024, we also had available tax credit carryforwards for federal and state income tax purposes of \$54.9 million and \$7.7 million, respectively, which begin to expire in 2034 and 2025, respectively. Additionally, for taxable years beginning after December 31, 2017 the deductibility of the indefinite lived federal and state 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 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, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the 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.

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, 2024, the fair value of our cash, cash equivalents and investments in our marketable debt securities portfolio was approximately \$437.3 million and consisted primarily of investments in money market funds and U.S. treasury obligations and government agency 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, 2024, we had \$20,000 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.

The terms of our loan and security agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On February 10, 2025, we entered into an Amended and Restated Loan and Security Agreement (the “Amended and Restated Loan and Security Agreement”) with Oxford Finance LLC (“Oxford”). The Amended and Restated Loan and Security Agreement amends and restates in its entirety that certain Loan and Security Agreement dated as of October 16, 2020, as amended.

The Amended and Restated Loan and Security Agreement provides us with up to \$200.0 million of borrowing capacity. Our overall leverage and certain obligations and affirmative and negative covenants contained in the related documentation could adversely affect our financial health and business and future operations by limiting our ability to, among other things, satisfy our obligations under the Amended and Restated Loan and Security Agreement, refinance our debt on terms acceptable to us or at all, plan for and adjust to changing business, industry and market conditions, use our available cash flow to fund future acquisitions and make dividend payments, and obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity.

If we default under the Amended and Restated Loan and Security Agreement, Oxford may accelerate all of our repayment obligations and exercise all of their rights and remedies under the Amended and Restated Loan and Security Agreement and applicable law, potentially requiring us to renegotiate our agreement on terms less favorable to us. Further, if we are liquidated, the lenders’ right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Oxford could declare a default upon the occurrence of customary events of default, including events that they interpret as a material adverse change as delineated in the Amended and Restated Loan and Security Agreement, payment defaults or breaches of certain affirmative or negative covenants, thereby requiring us to repay the loan immediately. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. Additionally, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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 cash dividends is currently restricted by the terms of our debt facility with Oxford, 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, 2024, our executive officers, directors and their affiliates beneficially hold, in the aggregate, approximately 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 are 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, including reduced disclosure obligations regarding executive compensation.

While we are no longer an “emerging growth company”, we are 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, including reduced disclosure obligations regarding executive compensation if we are eligible to do so. 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 recent fiscal year and 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. We will remain a smaller reporting company until our public float exceeds \$250 million or our annual revenues exceed \$100 million with a public float greater than \$700 million as of the prior June 30 in any given year.

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 compliance costs and we anticipate that these activities will become more time-consuming and costly over time now that we no longer qualify as an emerging growth company.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we will be required to furnish a report by our management on our internal control over financial reporting. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting 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 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 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 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.

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.

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 amended and restated 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.

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 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 amended and restated certificate of incorporation or our bylaws, any action to interpret, apply, enforce, or determine the validity of our amended and restated 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 have had such provisions challenged in legal proceedings by stockholders. While the Delaware Supreme Court ruled in March 2020 in *Salzburg et al. v. Sciabacucchi* 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.

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, 2024, approximately 8,678,664 shares of our common stock were reserved for issuance upon exercise of outstanding common stock purchase warrants. As of December 31, 2024, we also have 17,362,147 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. Additionally, 11,956,594 shares of our common stock were reserved for issuance upon exercise of outstanding stock options and vested restricted stock units. The exercise 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.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

The sales of a substantial number of the shares and/or the exercise and sale of a substantial number of the pre-funded warrants and common stock purchase 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.

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 January 1, 2024 through December 31, 2024, we did not sell any shares of common stock through the 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, 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. 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 (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 20 years at biotechnology companies including publicly-traded organizations.

Item 2. Properties

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

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. The expiration date was originally in August 2025 and included an option to extend the term by two years. In May 2024, we entered into the First Amendment to the Lease to extend the term for approximately two years, commencing on August 19, 2025 with an option to extend the term by five years.

We believe that our existing facility is 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.

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 February 24, 2025, there were approximately four 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. 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 under this item is incorporated herein by reference to Item 12 of Part III of this Annual 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, 2024.

Unregistered Sales of Securities

Not applicable.

Issuer Purchases of Equity Securities

None.

Item 6. Reserved

Not applicable.

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 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 investigational, fully human monoclonal antibody that inhibits myostatin activation by selectively binding the pro- and latent forms of 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 in vitro affinity for pro- and latent myostatin and maintains myostatin specificity and is being developed for the treatment of cardiometabolic disorders.
- SRK-181, an investigational 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.
- SRK-373, a novel, preclinical, investigational TGFβ inhibitor that selectively inhibits the activation of latent TGFβ1 isoform in the context of fibrotic extracellular matrix and that avoids perturbing TGFβ1 presented by cells of the immune system and is being developed for the treatment of fibrotic diseases.

- SRK-256, a novel, preclinical, investigational inhibitor that selectively inhibits RGMc or hemojuvelin, the co-receptor of bone morphogenic protein 6 (“BMP6”) and hence inhibits BMP6 signaling. BMP6 signaling is critical for iron homeostasis and SRK-256 has wide potential applicability in states of iron-restricted anemias.
- Additional discovery and early preclinical programs related to the selective modulation of growth factor signaling.

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 completed 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) and announced positive top-line results in October 2024. The study achieved its primary endpoint. We submitted a U.S. Biologics License Application to the FDA in January 2025 and are planning to submit a European Union marketing authorization application to the European Medicines Agency (“EMA”) in the first quarter of 2025. If apitegromab is approved, we expect to initiate a commercial product launch in the fourth quarter of 2025 in the United States, with a commercial launch of apitegromab in Europe to follow.

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. We have subsequently presented data from the TOPAZ trial over 24-months (2022), 36-months (2023) and 48-months (2024). At 48-months over 90% of TOPAZ patients with nonambulatory Type 2 and 3 SMA receiving a survival motor neuron (“SMN”) therapy remained on apitegromab treatment and showed sustained clinical benefit, a continued favorable safety profile with no new safety findings. Additionally, we are conducting a long-term extension study, ONYX, for patients from both the TOPAZ and SAPPHIRE studies, who were receiving apitegromab in 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 EMA granted Priority Medicines (“PRIME”) designation in March 2021 and the EC granted 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 are developing SRK-439 towards a potential IND submission in the third quarter of 2025. In 2024, we presented preclinical data at scientific conferences which support the potential of SRK-439 to increase lean mass and contribute to a favorable body composition in conjunction with a GLP-1 receptor agonist (“GLP-1 RA”) treatment. To inform the development of SRK-439, in May 2024 we initiated the Phase 2 EMBRAZE proof-of-concept trial, designed to assess the safety and efficacy of apitegromab to preserve muscle mass in individuals living with obesity and on background therapy of a GLP-1 RA. In September 2024, we announced that we completed enrollment in the Phase 2 EMBRAZE proof-of-concept trial. Top-line results from this trial are expected in the second quarter of 2025.

We believe that apitegromab has the potential to be the first muscle-targeted therapy that is aimed at improving motor function in patients with SMA who are receiving an SMN therapy. We also 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 with SMA under 2 years of age) and indications for other neuromuscular disorders beyond SMA.

Our second product candidate, SRK-181, a highly selective inhibitor of the activation of latent TGF β , 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 (referred to together as anti-PD-(L)1 antibody therapies). SRK-181 is being 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 antibody therapies. We completed enrollment of the DRAGON trial in December 2023 and continue to treat patients who remain on study. 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, ccRCC, and HNSCC. Safety, efficacy and biomarker data were presented in June 2024 at the ASCO annual meeting and in November 2024 at the SITC 39th Annual Meeting. The data showed encouraging responses in heavily pretreated and anti-PD-(L)1 resistant patients across multiple tumor types. 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. We anticipate that emerging data from the DRAGON trial will be presented at medical meetings in the future.

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, including neuromuscular disorders, cardiometabolic disorders, cancer, fibrosis, and iron-restricted anemia. Our proprietary platform is designed to generate highly selective antibodies 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 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.

We have incurred significant operating losses since inception. Our net losses were \$246.3 million for the year ended December 31, 2024. As of December 31, 2024, we had an accumulated deficit of \$922.7 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future in performing our ongoing activities, as we:

- develop our commercialization capabilities to support product sales, marketing and distribution activities;
- continue development activities for apitegromab, including the completion of our Phase 3 SAPPHIRE pivotal clinical trial in SMA, the conduct of ONYX, our long-term extension study 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 clinical trial;
- continue research and development activities for our cardiometabolic program, including our Phase 2 EMBRAZE proof-of-concept trial with apitegromab and advancing SRK-439 towards a potential IND submission in the third quarter of 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.

To date, we have not generated any revenue from product 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.

Financial Operations Overview

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 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 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, SRK-373, SRK-256 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, SRK-373, SRK-256 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, SRK-373, SRK-256 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, human resources and commercial 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, professional fees and corporate expenses. We expect general and administrative expense to increase as we continue to invest in building the infrastructure to support the commercialization of apitegromab.

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.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 except percentages):

and 2023 (in thousands,

	Year Ended December 31,		Change	
	2024	2023	\$	%
Operating expenses:				
Research and development	\$ 184,550	\$ 121,900	\$ 62,650	51.4 %
General and administrative	67,504	49,395	18,109	36.7 %
Total operating expenses	252,054	171,295	80,759	47.1 %
Loss from operations	(252,054)	(171,295)	(80,759)	47.1 %
Other income (expense), net	5,760	5,506	254	4.6 %
Net loss	<u>\$ (246,294)</u>	<u>\$ (165,789)</u>	<u>\$ (80,505)</u>	48.6 %

Operating Expenses

Research and Development

Research and development expense was \$184.6 million for the year ended December 31, 2024 compared to \$121.9 million for the year ended December 31, 2023, an increase of \$62.7 million, or 51.4%. The following table summarizes our research and development expense for the years ended December 31, 2024 and 2023 (in thousands, except percentages):

	Year Ended December 31,		Change	
	2024	2023	\$	%
External costs by program:				
Apitegromab	\$ 78,290	\$ 40,701	\$ 37,589	92.4 %
SRK-181	9,957	14,200	(4,243)	(29.9)%
SRK-439	11,638	631	11,007	1,744.4 %
Other early programs and unallocated costs	3,047	5,187	(2,140)	(41.3)%
Total external costs	102,932	60,719	42,213	69.5 %
Internal costs:				
Employee compensation and benefits	64,354	44,594	19,760	44.3 %
Facility and other	17,264	16,587	677	4.1 %
Total internal costs	81,618	61,181	20,437	33.4 %
Total research and development expense	<u>\$ 184,550</u>	<u>\$ 121,900</u>	<u>\$ 62,650</u>	51.4 %

The increase in research and development expense was primarily attributable to the following:

- An increase in our external research and development costs of \$42.2 million, which primarily consisted of:
 - \$37.6 million increase in costs associated with apitegromab primarily due to clinical trial costs, particularly the conduct of ONYX, our long-term extension study for patients from both the TOPAZ and SAPPHIRE studies and our Phase 2 EMBRAZE proof-of-concept study (including purchases of

- GLP-1 RA drug), as well as an increase in drug supply manufacturing, including to support lifecycle management initiatives;
 - \$4.2 million decrease in costs associated with SRK-181 mostly due to purchases of pembrolizumab in 2023 which were used in the Phase 1 DRAGON clinical trial;
 - \$11.0 million increase in preclinical costs and manufacturing development for SRK-439; and
 - \$2.1 million decrease in costs in other early development candidates and unallocated costs;
- \$20.4 million increase in internal research and development costs, which was primarily driven by an increase in employee related costs, including salaries, benefits and non-cash equity-based compensation expense related to increased headcount, as well as an increase in temporary support expense.

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 development activities for apitegromab in SMA, including the completion of our Phase 3 SAPPHIRE pivotal clinical trial in SMA, the conduct of ONYX, our long-term extension study for patients from both the TOPAZ and SAPPHIRE studies and the associated drug supply, as well as costs associated with supporting our cardiometabolic program, including our Phase 2 EMBRAZE proof-of-concept trial of apitegromab and our preclinical program, SRK-439. Additionally, we will continue to invest in our pipeline. We expect costs of our SRK-181 program to decrease, as we completed enrollment of the Phase 1 DRAGON clinical trial in December 2023.

General and Administrative

General and administrative expense was \$67.5 million for the year ended December 31, 2024 compared to \$49.4 million for the year ended December 31, 2023, an increase of \$18.1 million or 36.7%. The increase was primarily associated with employee-related costs including salaries, benefits and non-cash equity-based compensation expense related to increased headcount, in addition to an increase in professional service fees. We expect general and administrative expense to increase as we continue to invest in building the infrastructure to support the commercialization of apitegromab.

Other Income (Expense), Net

The change in other income (expense), net was primarily attributable to an increase in interest income earned due to higher interest rates and higher average 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.

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 issuance of our common stock through our IPO in 2018, to Gilead in an exempt private placement, through multiple secondary public offerings, including our recent follow-on offering in October 2024 (see Note 9) and through at-the-market (“ATM”) sales, as well as payments from our research collaborations and the Loan and Security Agreement entered into in October 2020 and subsequently amended (see Note 13).

The following table provides information regarding our total cash, cash equivalents and marketable securities at December 31, 2024 and December 31, 2023 (in thousands):

	December 31, 2024	December 31, 2023
Cash and cash equivalents	\$ 177,878	\$ 101,855
Marketable securities	259,400	178,083
Total cash, cash equivalents and marketable securities	<u>\$ 437,278</u>	<u>\$ 279,938</u>

During the year ended December 31, 2024, our cash, cash equivalents and marketable securities balance increased by \$157.3 million. The change was primarily the result of proceeds from our equity offering completed in October 2024 and exercises of stock options and warrants, partially offset by 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 and made interest payments on our debt.

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. As of December 31, 2024, we sold 619,290 shares of our common stock, generating net proceeds of \$5.2 million, under the ATM program. No sales were made under the ATM program during the year ended December 31, 2024. 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.

We have had multiple equity offerings during the period 2019-2024. The most recent few are listed below:

In October 2024, we entered into an underwriting agreement with J.P. Morgan Securities LLC, Jefferies LLC and Piper Sandler & Co., as representatives of the several underwriters named therein, relating to the issuance and sale of an aggregate of 11,858,408 shares of our common stock and pre-funded warrants to purchase 353,983 shares of our common stock, which includes the exercise in full by the underwriters of their option to purchase an additional 1,592,920 shares. The offering price per share was \$28.25 and the offering price per pre-funded warrant was \$28.2499, which equals the per share public offering price for the common shares less the \$0.0001 exercise price for each such pre-funded warrant. The offering resulted in estimated proceeds of approximately \$324.4 million, net of underwriting discounts and estimated offering expenses (see Note 9).

In October 2023, we entered into an 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 14,270,074 shares of our common stock, which includes the exercise in full by the underwriters of their options to purchase an additional 1,861,314 shares. The offering price per share was \$6.85. The offering resulted in proceeds of approximately \$92.4 million, net of underwriting discounts and offering expenses.

On February 10, 2025, we entered into the Amended and Restated Loan and Security Agreement with Oxford for up to \$200 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 (see Note 13). The Amended and Restated Loan and Security Agreement consolidates the existing outstanding loan tranches solely with Oxford.

In December 2018, we entered into the Gilead Collaboration Agreement pursuant to which we conducted research and 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.

During the year ended December 31, 2024, 2,526,833 of the Company's pre-funded warrants were exercised. As of December 31, 2024, the Company had 17,362,147 pre-funded warrants outstanding.

During the year ended December 31, 2024, 1,309,492 of the Company's common warrants were exercised. As of December 31, 2024, the Company had 8,678,664 common warrants outstanding.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	\$ (200,949)	\$ (145,226)
Net cash (used in) provided by investing activities	(76,056)	41,141
Net cash provided by financing activities	353,028	102,574
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 76,023</u>	<u>\$ (1,511)</u>

Net Cash Used in Operating Activities

Net cash used in operating activities was \$200.9 million for the year ended December 31, 2024, and consisted of our net loss of \$246.3 million, changes in our assets and liabilities of \$6.6 million, partially offset by non-cash adjustments of \$38.8 million. The non-cash adjustments are primarily from equity-based compensation.

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) Provided by Investing Activities

Net cash used in investing activities was \$76.1 million for the year ended December 31, 2024, compared to net cash provided by investing activities of \$41.1 million for the year ended December 31, 2023. Net cash 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 \$353.0 million for the year ended December 31, 2024, compared to \$102.6 million for the year ended December 31, 2023. Net cash provided by financing activities for the year ended December 31, 2024 was primarily attributable to net proceeds from an equity offering completed in October 2024, in addition to stock option and warrant exercises. Net cash provided by financing activities for the year ended December 31, 2023 was primarily attributable to net proceeds from an equity offering completed in October 2023.

Funding Requirements

We expect our expenses to be substantial as we continue the research and development of apitegromab in SMA. In addition, we will seek marketing approval for apitegromab, and if we seek marketing approval for 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 clinical trial. We expect to incur costs to support our cardiometabolic program, including our Phase 2 EMBRAZE proof-of-concept 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, marketable securities and cash available to us will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2026. However, we will require additional capital in order to complete clinical development and commercialization for each of our current programs. We have based this estimate on 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 in our Phase 3 SAPPHIRE clinical trial in SMA and ONYX, our long-term extension study in SMA for patients from both the TOPAZ and SAPPHIRE studies, our Phase 2 EMBRAZE proof-of-concept trial for apitegromab in our cardiometabolic program, our Phase 1 DRAGON clinical trial for SRK-181, and the costs and timing of conducting future preclinical studies and clinical trials for SRK-439 or any other product candidates;
- the costs of future manufacturing of apitegromab, SRK-181, SRK-439, SRK-373, SRK-256 and any other future product candidates;
- 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, including apitegromab in SMA;
- 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;
- the costs of operating as a public 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. 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.

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 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 judgments 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 financial condition or result of operations.

Research and Development Expenses and related Accruals/Prepays

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 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 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 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.

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 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, 2024, 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 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 with respect to financial statement preparation and presentation. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. 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, 2024. This Annual Report on Form 10-K does not include an attestation report pursuant to the requirements of Section 404(b) of the 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, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.*Trading Plans*

During the quarter ended December 31, 2024, certain of our directors and officers adopted contracts, instructions or written plans for the purchase or sale of our securities as noted below:

Name and Title	Type of Trading Arrangement	Action Taken (Date of Action)	Duration or End Date	Aggregate Number of Securities to be Sold	Description of Trading Arrangement
Mo Qatanani, CSO	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (October 17, 2024)	February 19, 2026	68,510	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to the terms of the trading plan
Ted Myles, COO and CFO	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (November 19, 2024)	March 10, 2026	232,939 (1)	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to the terms of the trading plan
Katie Peng, Board Member	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (November 20, 2024)	March 17, 2026	6,049	Sale of the Company's common stock pursuant to the terms of the plan
Tracey Sacco, CCO	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (December 20, 2024)	March 25, 2026	43,000	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to the terms of the trading plan

Other than as disclosed above, no other officer or director adopted, modified or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K) during the quarter ended December 31, 2024.

- (1) These shares reflect the aggregate maximum number of Restricted Stock Units ("RSU") prior to any non-discretionary sell-to-cover transactions in addition to other shares eligible to be sold pursuant to the plan. The Company has a non-discretionary sell-to-cover requirement to satisfy tax withholding obligations associated with RSU vesting for employees.

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, 2024.

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, 2024.

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, 2024.

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, 2024.

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, 2024.

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, 2023 (and are numbered in accordance with Item 601 of Regulation S-K):

Number	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
3.2	Amendment to Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-224493	3.1.1	May 14, 2018
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-38501	3.1	June 28, 2024
3.4	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
4.2	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
4.4*	Description of Capital Stock				
4.5	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
4.7	Form of Pre-Funded Warrant	8-K	001-38501	4.1	October 10, 2024
10.1+	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
10.3+	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
10.5+	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

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
10.8+	Amendment No. 3 to Scholar Rock Holding Corporation 2022 Inducement Equity Plan, dated January 25, 2024	10-K	001-38501	10.8	March 19, 2024
10.9+	Amendment No. 4 to Scholar Rock Holding Corporation 2022 Inducement Equity Plan, dated November 9, 2024	S-8	333-283120	99.7	November 12, 2024
10.10+	Form of Indemnification Agreement	S-1/A	333-224493	10.5	May 14, 2018
10.11†	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
10.12	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
10.13+	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
10.14	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
10.15	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
10.16	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
10.17	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
10.18+	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
10.19+	Employment Agreement, by and between Scholar Rock, Inc. and Jing Marantz, dated November 7, 2022.	8-K	001-38501	10.1	November 9, 2022
10.20	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

10.21+	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
10.22+	Employment Agreement, by and between Scholar Rock, Inc. and Tracey Sacco, dated February 1, 2023.	10-K	001-38501	10.32	March 19, 2024
10.23+*	Amended and Restated Employment Agreement, by and between Scholar Rock, Inc. and Edward H. Myles dated December 8, 2024.				
10.24	Fourth Amendment to Loan and Security Agreement, dated May 27, 2024, by and among the Registrant, Scholar Rock, Inc., Oxford Finance LLC and Silicon Valley Bank.	10-Q	001-38501	10.2	August 8, 2024
10.25††*	Amended and Restated Loan and Security Agreement, dated February 10, 2025, by and among the Registrant, Scholar Rock, Inc., Oxford Finance LLC.				
10.26	Separation Agreement and Release by and between Scholar Rock, Inc. and Edward H. Myles, dated January 28, 2025.	8-K	001-38501	10.1	January 29, 2025
10.27*	Scholar Rock Holding Corporation Amended and Restated Non-employee Director Compensation Policy				
19*	Scholar Rock Holding Corporation Statement of Company Policy on Insider Trading and Disclosure				
21.1*	Subsidiaries of the Registrant				
23.1*	Consent of Independent Registered Public Accounting Firm.				
24.1*	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.				
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.				
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	10-K	001-38501	97	March 19, 2024
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
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 (indicated by asterisks) were omitted in accordance with the rules of the Securities and Exchange Commission.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

SCHOLAR ROCK HOLDING CORPORATION

Date: February 27, 2025

By: /s/ Jay T. Backstrom

Jay T. Backstrom
President and Chief Executive Officer (Principal
Executive Officer)

Date: February 27, 2025

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
<u>/s/ Jay T. Backstrom</u> Jay T. Backstrom	President and Chief Executive Officer <i>(Principal Executive Officer)</i>	February 27, 2025
<u>/s/ Edward H. Myles</u> Edward H. Myles	Chief Operating Officer & Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	February 27, 2025
<u>/s/ David Hallal</u> David Hallal	Chairman of the Board of Directors	February 27, 2025
<u>/s/ Srinivas Akkaraju</u> Srinivas Akkaraju	Director	February 27, 2025
<u>/s/ Richard Brudnick</u> Richard Brudnick	Director	February 27, 2025
<u>/s/ Kristina Burow</u> Kristina Burow	Director	February 27, 2025
<u>/s/ Jeffrey S. Flier</u> Jeffrey S. Flier	Director	February 27, 2025
<u>/s/ Michael Gilman</u> Michael Gilman	Director	February 27, 2025
<u>/s/ Katie Peng</u> Katie Peng	Director	February 27, 2025
<u>/s/ Joshua Reed</u> Joshua Reed	Director	February 27, 2025
<u>/s/ Akshay Vaishnaw</u> Akshay Vaishnaw	Director	February 27, 2025

SCHOLAR ROCK HOLDING CORPORATION
Index to Financial Statements

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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, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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 and accrued research and development expenses totaled \$7.7 million and \$12.1 million, respectively, at December 31, 2024. 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 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 in the context of our audit due to the estimation uncertainty associated with 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
February 27, 2025

SCHOLAR ROCK HOLDING CORPORATION
CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 177,878	\$ 101,855
Marketable securities	259,400	178,083
Prepaid expenses and other current assets	13,887	8,256
Total current assets	451,165	288,194
Property and equipment, net	2,761	4,600
Operating lease right-of-use asset	15,644	11,417
Restricted cash	2,407	2,407
Other long-term assets	2,945	4,417
Total assets	<u>\$ 474,922</u>	<u>\$ 311,035</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 10,095	\$ 3,465
Accrued expenses	31,067	20,449
Operating lease liability	5,774	7,408
Short-term debt	—	1,334
Other current liabilities	—	85
Total current liabilities	46,936	32,741
Long-term portion of operating lease liability	9,206	4,392
Long-term debt	50,146	48,684
Total liabilities	106,288	85,817
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value; 300,000,000 shares authorized; 93,823,678 and 75,979,495 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	94	76
Additional paid-in capital	1,291,095	901,471
Accumulated other comprehensive income	160	92
Accumulated deficit	(922,715)	(676,421)
Total stockholders' equity	368,634	225,218
Total liabilities and stockholders' equity	<u>\$ 474,922</u>	<u>\$ 311,035</u>

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

SCHOLAR ROCK HOLDING CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Year Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 184,550	\$ 121,900
General and administrative	67,504	49,395
Total operating expenses	252,054	171,295
Loss from operations	(252,054)	(171,295)
Other income (expense), net	5,760	5,506
Net loss	\$ (246,294)	\$ (165,789)
Net loss per share, basic and diluted	\$ (2.47)	\$ (1.99)
Weighted average common shares outstanding, basic and diluted	99,838,102	83,347,086
Comprehensive loss:		
Net loss	\$ (246,294)	\$ (165,789)
Other comprehensive income:		
Unrealized gain on marketable securities	68	976
Total other comprehensive income	68	976
Comprehensive loss	\$ (246,226)	\$ (164,813)

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

SCHOLAR ROCK HOLDING CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share data)

	Common Stock		Additional	Accumulated		Total
	Shares	Amount	Paid-in	Other	Accumulated	Stockholders'
			Capital	Comprehensive	Deficit	Equity
				Income (Loss)		
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
Unrealized gain on marketable securities	—	—	—	68	—	68
Sale of common shares, net of issuance costs	11,858,408	12	324,402	—	—	324,414
Exercise of stock options	1,469,756	1	18,974	—	—	18,975
Issuance of common shares upon RSU vesting	679,694	1	(1)	—	—	—
Exercise of pre-funded and common warrants	3,836,325	4	9,621	—	—	9,625
Equity-based compensation expense	—	—	36,628	—	—	36,628
Net loss	—	—	—	—	(246,294)	(246,294)
Balance at December 31, 2024	93,823,678	\$ 94	\$ 1,291,095	\$ 160	\$ (922,715)	\$ 368,634

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

SCHOLAR ROCK HOLDING CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (246,294)	\$ (165,789)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,937	2,844
Amortization of debt discount and debt issuance costs	253	274
Loss on disposal of property and equipment	—	11
Equity-based compensation	36,628	27,142
Amortization/accretion of investment securities	(5,291)	(6,220)
Non-cash operating lease expense	5,224	7,126
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,770)	4,530
Other assets	1,472	(2,698)
Accounts payable	6,630	(529)
Accrued expenses	10,647	(3,927)
Operating lease liabilities	(6,271)	(7,852)
Other liabilities	(114)	(138)
Net cash used in operating activities	(200,949)	(145,226)
Cash flows from investing activities:		
Purchases of property and equipment	(98)	(71)
Proceeds from sale of property and equipment	—	13
Purchases of marketable securities	(293,158)	(290,801)
Maturities of marketable securities	217,200	332,000
Net cash (used in) provided by investing activities	(76,056)	41,141
Cash flows from financing activities:		
Proceeds from sale of common shares and pre-funded warrants to purchase common shares, net of issuance costs	324,414	97,709
Proceeds from pre-funded and common warrant exercises	9,625	3,463
Proceeds from stock option exercises	19,114	1,399
Debt modification payment	(125)	—
Other	—	3
Net cash provided by financing activities	353,028	102,574
Net increase (decrease) in cash, cash equivalents and restricted cash	76,023	(1,511)
Cash, cash equivalents and restricted cash, beginning of period	104,262	105,773
Cash, cash equivalents and restricted cash, end of period	\$ 180,285	\$ 104,262
Supplemental disclosure for non-cash items:		
Offering costs in accrued expenses	\$ 314	\$ —
Operating lease liability adjustment from rent modification	\$ 9,451	\$ —
Supplemental cash flow information:		
Cash paid for interest	\$ 6,617	\$ 6,399

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

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 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. By targeting the signaling proteins at the cellular level and acting in the disease microenvironment, the Company believes that it may avoid the historical dose-limiting safety challenges associated with inhibiting growth factors for therapeutic effect.

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 completed SAPPHERE, a pivotal Phase 3 clinical trial to evaluate the efficacy and safety of apitegromab in patients with nonambulatory Type 2 and Type 3 SMA and announced positive top-line results in October 2024. The study achieved its primary endpoint. The Company submitted a U.S. Biologics License Application to the FDA in January 2025 and is planning to submit a European Union marketing authorization application to the European Medicines Agency (“EMA”) in the first quarter of 2025. If apitegromab is approved, the Company expects to initiate a commercial product launch in the fourth quarter of 2025 in the United States, with a commercial launch of apitegromab in Europe to follow. Additionally, in 2024, the Company announced data from the Phase 2 TOPAZ trial extension period which showed patient outcomes at 48 months of treatment with apitegromab. 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 Priority Medicines (“PRIME”) designation in March 2021 and the EC granted orphan medicinal product designation in December 2018 to apitegromab for the treatment of SMA.

In October 2023, the Company announced an expansion of its therapeutic focus into cardiometabolic disorders by advancing its anti-myostatin program with SRK-439, a novel, fully human anti-myostatin monoclonal antibody, for evaluation in cardiometabolic disorders, including obesity. The Company is developing SRK-439 towards a potential investigational new drug application (“IND”) submission in the third quarter of 2025. To inform the development of SRK-439, in May 2024 the Company initiated the Phase 2 EMBRAZE proof-of-concept trial, designed to assess the safety and efficacy of apitegromab to preserve muscle mass in individuals living with obesity and on background therapy of a GLP-1 receptor agonist (“GLP-1 RA”). In September 2024, the Company announced that it had completed enrollment in the Phase 2 EMRAZE proof-of-concept trial. Top-line results from this trial are expected in the second quarter of 2025.

The Company’s 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, such as anti-PD-1 or anti-PD-L1 antibody therapies (referred to together as anti-PD-(L)1 antibody therapies). SRK-181 is being 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 antibody therapies. The Company completed enrollment of the Phase 1 DRAGON trial in December 2023 and continues to treat patients who remain on study. 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, and head and neck squamous cell carcinoma. Safety, efficacy and biomarker data were presented in June 2024 at the American Society of Clinical Oncology annual meeting and in November 2024 at the Society for Immunotherapy of Cancer 39th 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 2024 (Note 9), as well as research and development collaboration agreements and the Company's debt facility (Note 13).

Revenue generation activities have been limited to two collaborations, both containing research services and the issuance of a license. 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, 2024 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.

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, 2024 and 2023, cash equivalents include money market funds that invest primarily in U.S. government-backed securities and treasuries.

At December 31, 2024 and 2023, restricted cash consists of letters of credit related to its leased facility. 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,	
	2024	2023
Cash and cash equivalents	\$ 177,878	\$ 101,855
Restricted cash	2,407	2,407
	<u>\$ 180,285</u>	<u>\$ 104,262</u>

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 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 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.

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.

The Company reviews its portfolio of available-for-sale debt securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost have resulted from a credit loss or other factors. If the decline in fair value is due to credit loss factors, a loss is recognized in net income. To date, the Company has not experienced any credit losses and does not believe it is exposed to 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 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, 2024 or 2023.

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.

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 (Note 16).

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.

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 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 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.

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.

Research and Development Expenses and Related Accruals/Prepays

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 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 reviews open contracts and purchase orders, the level of service performed, invoices received, contracted costs, and progress of studies, clinical trials or other 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, and payments for these activities are due based on the terms of individual arrangements, which may differ from the pattern of costs incurred.

Equity-Based Compensation

The Company accounts for equity awards, including 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 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. Through the second quarter of 2024, expected volatility was 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. As of the third quarter of 2024, the Company's own volatility data covered a period of time that was sufficient to meet the expected term of the granted awards and the blended approach was no longer needed. 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.

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 income (loss) consisted entirely of unrealized gains and losses on available-for-sale marketable securities during the period ending December 31, 2024 and 2023.

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 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 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, 2024. 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 Adopted 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 disclose significant segment expenses and other segment items on an annual and interim basis and 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 (see Note 16).

Recently Issued Accounting Pronouncements

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 in future years as a result of the adoption of ASU 2023-09.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, and in January 2025, the FASB issued ASU No. 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date*. ASU 2024-03 requires additional disclosure of the nature of expenses included in the income statement as well as disclosures about specific types of expenses included in the expense captions presented in the income statement. ASU 2024-03, as clarified by ASU 2025-01, is effective for public companies for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is still evaluating the impact on its disclosures in future years as a result of the adoption of ASU 2024-03.

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, 2024 and 2023 (in thousands):

	Fair Value Measurements at December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	\$ 97,290	\$ 97,290	\$ —	\$ —
U.S. treasury obligations, included in cash and cash equivalents	63,171	63,171	—	—
Marketable securities:				
U.S. treasury obligations and government agency securities	259,400	259,400	—	—
Total assets	<u>\$ 419,861</u>	<u>\$ 419,861</u>	<u>\$ —</u>	<u>\$ —</u>

	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	<u>\$ 270,612</u>	<u>\$ 270,612</u>	<u>\$ —</u>	<u>\$ —</u>

Cash, cash equivalents and marketable securities are Level 1 assets and include investments in money market funds, 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, 2024 and 2023. There were no transfers of assets between fair value measurement levels during the years ended December 31, 2024 and 2023.

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, 2024 and 2023, 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.

4. Marketable Securities

The following table summarizes the Company's investments as of December 31, 2024 (in thousands):

	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
Marketable securities available-for-sale:				
U.S. treasury obligations and government agency securities	\$ 259,240	\$ 180	\$ (20)	\$ 259,400
Total available-for-sale securities	<u>\$ 259,240</u>	<u>\$ 180</u>	<u>\$ (20)</u>	<u>\$ 259,400</u>

The following table summarizes the Company's investments as of December 31, 2023 (in thousands):

	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
Marketable securities available-for-sale:				
U.S. treasury obligations and government agency securities	\$ 177,991	\$ 93	\$ (1)	\$ 178,083
Total available-for-sale securities	<u>\$ 177,991</u>	<u>\$ 93</u>	<u>\$ (1)</u>	<u>\$ 178,083</u>

Amortized cost approximated fair value for money market funds and U.S. treasury obligations included in cash and cash equivalents. The aggregate fair value of marketable securities with unrealized losses was \$23.9 million and \$11.9 million at December 31, 2024 and 2023, respectively. At December 31, 2024 and 2023, 12 investments and three 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, 2024.

5. Prepaid Expenses and Other Assets

At December 31, 2024 and 2023, prepaid expenses and other current assets consist of the following (in thousands):

	As of	
	December 31, 2024	December 31, 2023
Prepaid external research and development expenses	\$ 7,716	\$ 4,059
Prepaid other	2,961	2,281
Receivables	2,151	1,076
Prepaid insurance	640	635
Prepaid professional and consulting expense	419	205
	<u>\$ 13,887</u>	<u>\$ 8,256</u>

At December 31, 2024 and 2023, other long-term assets consist of the following (in thousands):

	As of	
	December 31, 2024	December 31, 2023
Prepaid external research and development expenses	\$ 2,395	\$ 4,074
Prepaid other	536	312
Prepaid insurance	14	31
	<u>\$ 2,945</u>	<u>\$ 4,417</u>

6. Property and Equipment, Net

At December 31, 2024 and 2023, property and equipment consists of the following (in thousands):

	December 31, 2024	December 31, 2023
Laboratory equipment	\$ 10,305	\$ 10,270
Leasehold improvements	3,613	3,581
Computer equipment & software	1,059	1,029
Furniture & fixtures	1,002	1,002
Machinery & equipment	—	44
	15,979	15,926
Less: Accumulated depreciation and amortization	(13,218)	(11,326)
	\$ 2,761	\$ 4,600

Depreciation and amortization expense was \$1.9 million and \$2.8 million for the years ended December 31, 2024 and 2023, respectively.

7. Accrued Expenses

At December 31, 2024 and 2023, accrued expenses consist of the following (in thousands):

	As of	
	December 31, 2024	December 31, 2023
Accrued payroll and related expenses	\$ 14,776	\$ 10,591
Accrued external research and development expense	12,116	6,825
Accrued professional and consulting expense	3,296	2,267
Accrued other	879	766
	\$ 31,067	\$ 20,449

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.

9. Common Stock

In June 2024, the stockholders approved an amendment to the Company's amended and restated certificate of incorporation to increase the number of authorized shares of common stock from 150,000,000 to 300,000,000.

In October 2024, the Company entered into an underwriting agreement (the "Underwriting Agreement") with J.P. Morgan Securities LLC, Jefferies 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 10,265,488 shares of the Company's common stock at \$28.25 per share and pre-funded warrants to purchase 353,983 shares of its common stock. The offering price per pre-funded warrant was \$28.2499, which equals the per share 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. The offering closed on October 10, 2024. Pursuant to the Underwriting Agreement, the Underwriters were granted a 30-day option to purchase up to 1,592,920 additional shares (the "Option

Shares”) of common stock, which was exercised in full on October 16, 2024. Total proceeds of the transaction, including the Option Shares were approximately \$324.4 million, net of underwriting discounts and estimated offering expenses.

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, 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, 2024, the Company has sold 619,290 shares, generating net proceeds of \$5.2 million, under the ATM program. No sales were made under the ATM program during the year ended December 31, 2024.

The Company has issued pre-funded warrants to purchase common stock, as well as warrants to purchase common stock as part of its financing activities. Both the pre-funded warrants and warrants meet the conditions for equity classification and are recorded as a component of stockholders’ equity within additional paid-in capital. In October 2024, June 2022 and November 2020, the Company issued 353,983, 25,510,205 and 2,179,487 pre-funded warrants, respectively. During the years ended December 31, 2024 and 2023, 2,526,833 and 8,154,695, respectively of the Company’s pre-funded warrants were exercised. As of December 31, 2024, the Company has 17,362,147 pre-funded warrants outstanding. In June 2022, the Company also issued 10,459,181 warrants with an exercise price of \$7.35. During the years ended December 31, 2024 and 2023, 1,309,492 and 471,025, respectively of the Company’s warrants were exercised. As of December 31, 2024, the Company has 8,678,664 warrants outstanding.

Shares Reserved For Future Issuance

As of December 31, 2024, the Company had common shares reserved for issuance as follows:

	As of December 31, 2024
Common shares reserved for exercise of pre-funded warrants	17,362,147
Common shares reserved for issuance upon exercise of outstanding warrants	8,678,664
Common shares reserved for exercise of outstanding stock options and unvested restricted stock units under the 2017 and 2018 Plans	8,349,147
Common shares reserved for exercise of outstanding stock options and unvested restricted stock units under the 2022 Inducement Plan	3,607,447
Common shares reserved for future issuance under the 2018 Plan	1,814,874
Common shares reserved for future issuance under the 2022 Inducement Plan	1,117,137
Common shares reserved for future issuance under the 2018 ESPP	2,196,691
	<u>43,126,107</u>

10. Equity-Based Compensation

Equity Plans

As of December 31, 2024, 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”).

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 Initial Public Offering (“IPO”).

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.

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, 2024 there were 2,196,691 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. Since its inception and through December 31, 2024, an additional 4,000,000 shares of common stock have been added to the 2022 Inducement Plan.

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, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development expense	\$ 16,002	\$ 11,203
General and administrative expense	20,626	15,939
	<u>\$ 36,628</u>	<u>\$ 27,142</u>

The following table summarizes the Company's unrecognized equity-based compensation expense as of December 31, 2024:

	As of December 31, 2024	
	Unrecognized Expense (in thousands)	Weighted Average Remaining Period of Recognition (years)
Restricted Stock Units	\$ 36,249	2.6
Stock Options	41,141	2.5
	<u>\$ 77,390</u>	

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, 2023	2,089,552	\$ 11.92
Granted	2,269,450	\$ 15.13
Vested	(679,694)	\$ 12.50
Forfeited	(192,640)	\$ 12.64
Restricted stock units as of December 31, 2024	<u>3,486,668</u>	<u>\$ 13.86</u>

The total fair value of restricted stock units vested during the year ended December 31, 2024 was \$9.7 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)
Outstanding as of December 31, 2023	7,300,953	\$ 15.00	7.90	\$ 52,299
Granted	3,025,926	\$ 15.13		
Exercised	(1,469,756)	\$ 12.91		
Cancelled	(387,197)	\$ 26.60		
Outstanding as of December 31, 2024	8,469,926	\$ 15.19	7.83	\$ 244,677
Options exercisable as of December 31, 2024	3,904,470	\$ 17.40	6.82	\$ 107,399

Using the Black-Scholes option pricing model, the weighted average fair value of options granted during the year ended December 31, 2024 was \$11.79.

The following weighted average assumptions were used in determining the fair value of options granted in the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Risk-free interest rate	4.09 %	3.87 %
Expected dividend yield	0.0 %	0.0 %
Expected term (years to liquidity)	6.01	6.06
Expected volatility	92.30 %	89.67 %

11. Income Taxes

The Company has not recorded a current tax provision for the years ended December 31, 2024 and 2023.

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,	
	2024	2023
Tax effected at statutory rate	21.0 %	21.0 %
State taxes	5.9	6.3
Stock compensation	(0.5)	(2.3)
Non-deductible expenses	(0.3)	(0.3)
Federal research and development credits	5.8	4.9
Other	(0.8)	0.1
Change in valuation allowance	(31.1)	(29.7)
	<u>— %</u>	<u>— %</u>

Deferred tax assets (liabilities) consist of the following at December 31, 2024 and 2023 (in thousands):

	As of December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	\$ 139,160	\$ 110,120
Tax credits	61,027	45,621
Capitalized research & development	80,357	49,699
Stock based compensation	8,920	8,328
Operating lease liability	3,971	3,217
Reserve and accruals	4,139	3,294
Total gross deferred tax assets	297,574	220,279
Valuation allowance	(293,064)	(216,524)
Total deferred tax assets	4,510	3,755
Total deferred tax liabilities:		
Operating lease right-of-use asset	(4,148)	(3,113)
Fixed and intangible assets	(362)	(642)
Total deferred tax liabilities	(4,510)	(3,755)
Total net deferred tax assets	\$ —	\$ —

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, 2024 and 2023. The valuation allowance for deferred tax assets increased by \$76.5 million and \$49.2 million in 2024 and 2023, 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 \$121.5 million of R&D expenses, net of current and prior year amortization deductions. The corresponding deferred tax asset as of December 31, 2024 is \$80.4 million. As of December 31, 2024, the Company had approximately \$512.6 million and \$498.8 million of Federal and State operating loss carryforwards respectively, which begin to expire in 2032, except for \$462.1 million of the Company's federal net operating loss carryforwards, and \$0.2 million of state net operating losses 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, 2024, the Company also had federal and state credit carryovers of \$54.9 million and \$7.7 million, respectively, which begin to expire in 2034 and 2025, 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 and the indefinite state net operating losses 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, 2024 and 2023, 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.

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 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.

12. Commitments and Contingencies

Operating 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 Lease"). The expiration date of the Lease was originally in August 2025 and included an option to extend the term by two years. The base rent under the original Lease was \$6.9 million per year, subject to an annual increase of 3.5%. 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.

In May 2024, the Company entered into the First Amendment (the "Lease Amendment") to the Lease to extend the term for approximately two years, commencing on August 19, 2025 (the "First Extension Term") with the base rent to start at approximately \$6.2 million per year, followed by a 3% annual increase. Pursuant to the Lease Amendment, the Company also has an option to extend the term of the Lease by five years, upon the expiration of the First Extension Term.

Other information related to the Lease is as follows (in thousands, except lease term and discount rate):

	For Year Ended December 31, 2024
Lease Cost:	
Operating lease cost	\$ 7,004
Variable lease cost	1,449
Total lease cost	<u>\$ 8,453</u>
	For Year Ended December 31, 2024
Other information:	
Operating cash flows used for operating leases	\$ 8,051
Weighted average remaining lease term	2.7
Weighted average incremental borrowing rate	13.1 %

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, 2024 (in thousands):

Year Ending December 31,	
2025	7,368
2026	6,433
2027	3,818
Total lease payments	17,619
Less imputed interest	(2,639)
Total operating lease liability	<u>\$ 14,980</u>
Short-term portion of operating lease liability	5,774
Long-term portion of operating lease liability	9,206

The Company recorded approximately \$7.0 million and \$8.3 million in rent expense for the years ended December 31, 2024 and 2023, respectively.

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, 2024 and 2023.

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 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 to Loan and Security Agreement (“Amendment 2”) to increase the Company’s borrowing capacity under the Loan and Security 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 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. 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. The maturity of the loan was extended to November 2027.

Effective upon 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 Amendment 2, the Company was required to pay \$0.9 million for the accrued portion of the final payment on the previous outstanding balance.

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.

On May 17, 2024, the Company entered into the Fourth Amendment to the Loan and Security Agreement ("Amendment 4"). The Company currently has \$50.0 million outstanding under the Loan and Security Agreement, which was drawn down in two equal tranches. The third \$25.0 million tranche is available at the Company's discretion through December 2024, upon achievement of certain clinical and business milestones, which were amended under Amendment 4. The fourth \$25.0 million tranche may be available through June 1, 2025 (or through December 1, 2025, upon achievement of certain business milestones) upon the Company's request, at Oxford and SVB's discretion. Amendment 4 also extends the interest-only payment period for an additional six months through May 2025, with principal payments to commence in June 2025. Additionally, upon achievement of certain business performance milestones, which were achieved in October 2024, the interest-only payment period was extended through November 2025, with principal payments to commence in December 2025.

On February 10, 2025, the Company entered into an Amended and Restated Loan and Security Agreement (the "Amended and Restated Loan and Security Agreement") with Oxford. The Amended and Restated Loan and Security Agreement amends and restates in its entirety that certain Loan and Security Agreement, as amended.

The Amended and Restated Loan and Security Agreement provides for term loans in an aggregate principal amount of up to \$200.0 million (each, a "Term Loan" and together, the "Term Loans") subject to funding in four tranches. To date, the Company has received \$50.0 million of Term Loans. The remaining three tranches, each in an amount of \$50.0 million, are available to be borrowed (a) in the case of the second tranche, until December 31, 2025, (b) in the case of the third tranche, after the achievement of certain development and business performance milestones until September 30, 2026, and (c) in the case of the fourth tranche, after the achievement of certain development and business performance milestones until December 31, 2027. The Amended and Restated Loan and Security Agreement consolidates the existing outstanding loan tranches solely with Oxford and also extends the interest-only payment period through March 2029, with principal payments to commence in April 2029.

The outstanding principal of each Term Loan has an annual interest rate of (a) the greater of (i) the 1-Month CME Term SOFR on the last business day of the month that immediately precedes the month in which the interest will accrue and (ii) 3% , plus (b) 5.5%. Interest is payable on a monthly basis based on the principal amount outstanding during the preceding month. In addition, the Company is required to pay Oxford a final payment fee equal to 2.00% of the original principal amount of each Term Loan advanced to the Company.

Adjusted for the Amended and Restated Loan and Security Agreement entered into in February 2025, the following table shows required payments (excluding interest), during the next five years on debt outstanding at December 31, 2024 (in thousands):

Year Ending December 31,	Total future payments	
2025-2028	\$	—
2029		40,909
Total payments	\$	40,909

The Company incurred costs on behalf of the lender recorded as a debt discount of \$0.5 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, 2024 and 2023, the Company recorded total interest expense for the debt of \$6.6 million and \$6.5 million, respectively.

14. 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, June 2022 and October 2024 follow-on offerings as the pre-funded warrants are exercisable at any time for nominal cash consideration. As of December 31, 2024, 10,681,528 pre-funded warrants have been exercised and 17,362,147 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, 2024	Year Ended December 31, 2023
Net loss	\$ (246,294)	\$ (165,789)
Weighted average common shares outstanding, basic and diluted	99,838,102	83,347,086
Net loss per share, basic and diluted	\$ (2.47)	\$ (1.99)

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, 2024	2023
Restricted stock units	3,486,668	2,089,552
Stock options	8,469,926	7,300,953
Warrants	8,678,664	9,988,156
	<u>20,635,258</u>	<u>19,378,661</u>

15. 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 \$1.1 million and \$0.9 million in expense related to the match during the years ended December 31, 2024 and 2023, respectively.

16. Segment Reporting

The Company operates and manages its business as a single segment for the purposes of assessing performance and making operating decisions. The Company's president and chief executive officer, who is the chief operating decision maker ("CODM"), reviews the Company's financial information on a consolidated basis for purposes of evaluating financial performance and allocating resources and; therefore we have presented segment information on the same basis. When evaluating the Company's financial performance, the CODM regularly reviews net loss, non-operating expenses and operating expenses with non-cash expenses such as depreciation and equity-based compensation expense removed. The CODM considers net loss in making decisions on how to allocate resources. The measure of segment assets is

reported on the balance sheet as total consolidated assets. All of the Company's long-lived assets are held in the United States.

The following table presents significant expense information about the Company's operating segment:

	Year Ended December 31,	
	2024	2023
Operating expenses:		
Employee related expense	\$ 68,790	\$ 48,294
External R&D expense - SMA	68,076	40,141
External R&D expense - oncology	9,957	14,200
External R&D expense - cardiometabolic/obesity	21,843	1,914
External R&D expense - Early Research and other	3,055	4,464
External expense - G&A	22,384	13,973
Other segment related expense*	19,383	18,313
Employee related equity-based compensation expense	36,628	27,141
Depreciation and amortization expense	1,937	2,855
Interest income	(12,682)	(12,099)
Interest expense	6,837	6,738
Other non-operating income/(expense), net	86	(145)
Net loss	\$ 246,294	\$ 165,789

* Consists of other segment expenses related to supplies, corporate and facilities expenses.

17. Subsequent Events

On February 10, 2025, the Company entered into the Amended and Restated Loan and Security Agreement with Oxford for up to \$200.0 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. The Amended and Restated Loan and Security Agreement consolidates the existing outstanding loan tranches solely with Oxford and extends the interest-only payment period through March 2029, with principal payments to commence in April 2029. Additional details of the Amended and Restated Loan and Security Agreement can be found in Note 13 and as an exhibit to these financial statements.

DESCRIPTION OF CAPITAL STOCK

The following description of the capital stock of Scholar Rock Holding Corporation (“us,” “our,” “we” or the “Company”) is a summary of the rights of our common stock, par value \$0.001 per share (the “common stock”), and certain provisions of our amended and restated certificate of incorporation, as amended (the “charter”), and our amended and restated bylaws currently in effect (“bylaws”). This summary does not purport to be complete and is qualified in its entirety by the provisions of our charter and bylaws, each previously filed with the Securities and Exchange Commission and incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.4 is a part, as well as to the applicable provisions of the Delaware General Corporation Law (the “DGCL”). We encourage you to read our charter and bylaws, and the applicable portions of the DGCL carefully.

Authorized Capital Stock

Our authorized capital stock consists of 300,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share, all of which preferred stock is undesignated.

Dividend Rights

Holders of our common stock are entitled to receive ratably any dividends declared by the board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock.

Liquidation Rights

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Voting Rights

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights.

Other Matters

Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions. The shares to be issued by us will be, when issued and paid for, validly issued, fully paid and non-assessable. The rights, preferences, and privileges of our common shareholders are subject to the rights of the shareholders of any series of preferred stock that we may designate in the future. Our charter and bylaws do not restrict the ability of a holder of our common stock to transfer his, her or its shares of common stock.

Transfer Agent and Listing

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. Our common stock is listed on The Nasdaq Global Select Market under the symbol “SRRK.” The transfer agent and registrar’s address is P.O. Box 43006, Providence, Rhode Island 02940-3006, and its telephone number within the U.S. is (800) 736-3001 and outside the U.S. is (781) 575-3100.

Anti-Takeover Effects of Our Certificate of Incorporation and Our Bylaws

Our charter and bylaws contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of the company unless such takeover or change in control is approved by the board of directors.

These provisions include:

Classified Board. Our charter provides that our board of directors is divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors has the effect of making it more difficult for stockholders to change the composition of our board. Our charter provides that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors. Our board of directors has eight members. Our charter provides that the affirmative vote of at least two-thirds of the outstanding shares of capital stock entitled to vote, and the affirmative vote of at least two-thirds of the outstanding shares of each class entitled to vote as a class, is required to amend or repeal the foregoing provision. This requirement of a supermajority vote to amend or repeal that provision of our bylaws could enable a minority of our stockholders to prevent a declassification of our Board.

Action by Written Consent; Special Meetings of Stockholders. Our charter provides that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders. Our charter provides that the affirmative vote of at least two-

thirds of the outstanding shares of capital stock entitled to vote, and the affirmative vote of at least two-thirds of the outstanding shares of each class entitled to vote as a class, is required to amend or repeal the foregoing provision. Our charter and bylaws provide that, except as otherwise required by law, special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors, and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting. Stockholders are not permitted to call a special meeting or to require the board of directors to call a special meeting. Our bylaws provide that the affirmative vote of at least two thirds of the outstanding shares entitled to vote, and of each class entitled to vote, respectively, is required to amend or repeal the provision in our bylaws that provides that special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors, unless the Board first recommends such amendment or repeal to stockholders. This requirement of a supermajority vote to amend or repeal that provision of our bylaws could enable a minority of our stockholders to prevent a change to such provision and has the effect of making it more difficult for stockholders to call a special meeting of stockholders.

Removal of Directors. Our charter provides that our directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors, at a meeting of the stockholders called for that purpose. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board, and the treatment of vacancies also has the effect of making it more difficult for stockholders to change the composition of our board.

Advance Notice Procedures. Our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

Super Majority Approval Requirements and Amendment to Charter and Bylaws. Any amendment of our charter must first be approved by a majority of our board of directors, and if required by law or our charter, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our bylaws and charter must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws, and may also be amended by the affirmative vote of at least two-thirds of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Authorized but Unissued Shares. Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital and corporate acquisitions. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of convertible preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our charter grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of convertible preferred stock. The issuance of shares of convertible preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of Forum. Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on

our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our charter or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our charter or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine.

In addition, our bylaws contain a provision by virtue of which, unless we consent in writing to the selection of an alternative forum, the United States 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 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.

We have chosen the United States 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 have had such provisions challenged in legal proceedings by stockholders. While the Delaware Supreme Court ruled in March 2020 in *Salzburg et al. v. Sciabacucchi* 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.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the DGCL (“Section 203”). In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A “business combination” includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An “interested stockholder” is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation’s voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

SCHOLAR ROCK, INC.

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (“Agreement”) is made between Scholar Rock, Inc., a Delaware corporation (the “Company”), and Edward H. Myles (the “Employee”) and is effective as of December 8, 2024 (the “Effective Date”). Except with respect to the Equity Documents and the Restrictive Covenant Agreement (each as defined below) and subject to Section 10 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 July 16, 2020 (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 to be employed by the Company on the 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.

(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 Chief Operating Officer and Chief Financial Officer of the Company, and shall have such duties and authorities as may from time to time be prescribed by the Chief Executive Officer (“CEO”). The Employee shall devote 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 approval of the CEO (not to be unreasonably withheld and subject to any applicable Company policies), or engage in religious, charitable or other community activities as long as such services and activities do not interfere with the Employee’s performance of the Employee’s duties to the Company as provided in this Agreement.

(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 sometimes 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) Base Salary. During the Term, the Employee’s annual base salary shall be \$506,000. The Employee’s base salary shall be reviewed from time to time by the 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.

(b) Incentive Compensation. During the Term, the Employee shall be eligible to receive cash incentive compensation as determined by the Company from time to time. The Employee’s target annual

incentive compensation shall be 40% of the Employee's Base Salary. The target annual incentive compensation in effect at any given time is referred to herein as the "Target Annual Incentive Compensation". Except as otherwise provided herein, to 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 15 of the year following the applicable bonus year.

(c) Expenses. The Employee shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by 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) 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) Vacations. During the Term, the Employee shall be entitled to paid vacation in accordance with the Company's policies and 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) Equity. The equity awards held by the Employee shall continue to be governed by the terms and conditions of the applicable equity incentive plan(s) of Scholar Rock Holding Corporation ("SR Holding") and the applicable award agreement(s) (collectively, the "Equity Documents"). The Employee may also be eligible to receive future equity awards, in the sole discretion of the Board of Directors of SR Holding (the "Board") or the Compensation Committee of the Board. Notwithstanding anything to the contrary in the Equity Documents or any other applicable option agreement or stock-based award agreement, in the event that the Employee's employment is terminated by the Company without Cause or by the Employee for Good Reason, in either case during the Change in Control Period (as such terms are defined below), then all time-based stock options and other 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 Date of Termination (as defined below) or, if later, the Change in Control Date (as defined below); provided that, for the avoidance of doubt, in the event of a termination by the Company without Cause or by the Employee for Good Reason, in either case outside of the Change in Control Period, the termination or forfeiture of any unvested Time-Based Equity Awards that would otherwise occur on the Date of Termination will be delayed until the earlier of (i) the Change in Control Date (at which time acceleration will occur) or (ii) the date that is three (3) months after the Date of Termination (at which time the unvested portion of the Employee's Time-Based Equity Awards will terminate or be forfeited); provided further, that no additional vesting of the Time-Based Equity Awards shall occur after the Date of Termination unless the Change in Control Date occurs within three (3) months after the Date of Termination.

It is acknowledged and agreed that as of the effective date of the Prior Agreement, the Employee ceased vesting in the equity awards that the Employee received in connection with his prior Board service (the "Director Awards", together with the applicable underlying equity award agreements and equity plan(s), the "Director Award Documents"), notwithstanding anything to the contrary in the Director Award Documents. It is further acknowledged and agreed that, notwithstanding anything to the contrary in the Director Award Documents, the Company has extended the exercise period with respect to the vested portion of the Director Awards until the earlier of (i) three (3) months after the Employee's service relationship with the Company ends, or (ii) the expiration date for such vested stock options as provided in the applicable Director Award Documents (the "Extended Exercise Period"). Except as expressly stated herein, all other terms of the Director Award Documents remain in full force and effect.

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 Employee's employment hereunder shall terminate upon the Employee's death.

(b) Termination by Company for Cause. The Company may terminate the Employee's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean: (i) conduct by the Employee constituting a material act of misconduct in connection with the performance of 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 the Employee were retained in the Employee's position; (iii) continued non-performance by the Employee of 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 from the CEO; (iv) a material breach by the Employee of any of the Continuing Obligations (as defined below) which has not been cured (or is incapable of or otherwise cannot be cured) within 30 days after the CEO gives the Employee written notice regarding such breach; (v) a material violation by the Employee of the Company's written employment 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 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" shall mean that the Employee has complied with the Good Reason Process (hereinafter defined) following the occurrence of any of the following 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 applied equally, as a percentage of Base Salary, to all or substantially all senior management employees of the Company; (iii) a change of more than 30 miles in the geographic location at which the Employee is required to provide services to the Company, except for required travel for the Company's business; (iv) the material breach by the Company of this Agreement; or (v) any directive to the Employee by the Company to engage in a willful violation of law. "Good Reason Process" shall mean that (i) the Employee discovers and 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 Employee's discovery 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"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Employee terminates 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 of Termination” shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(f) Date of Termination. For purposes of this Agreement, “Date of Termination” shall mean: (i) if the Employee’s employment is terminated by the Employee’s death, the date of the Employee’s death; (ii) if the Employee’s employment is terminated by the Company for Cause under Section 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) other than for Good Reason, 14 days after the date on which a Notice of Termination is given, and (v) if the Employee’s employment is terminated by the Employee under Section 3(d) 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.

(g) Accrued Benefit. If the Employee’s employment with the Company is terminated for any reason, the Company shall pay or provide to the Employee (or to 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 (collectively, the “Accrued Benefit”).

4. Severance Pay and Benefits Upon Termination by the Company without Cause or by the Employee for Good Reason Outside the Change in Control Period. 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 the Employee’s employment for Good Reason as provided in Section 3(d), then the Company shall pay the Employee the Employee’s Accrued Benefit. In addition, subject to (i) 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, preservation of all of the Employee’s Continuing Obligations, and, in the Company’s sole discretion, a one-year post employment noncompetition agreement, and shall provide that if Employee breaches any of the Continuing Obligations, all payments of the Severance Amount shall immediately cease (the “Separation Agreement and Release”) and (ii) 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 seven (7) business day revocation period:

(a) the Company shall pay the Employee an amount equal to the sum of (i) nine (9) months of the Employee’s Base Salary (or the Employee’s Base Salary in effect before Good Reason existed under Section 3(d)(ii), if higher than the Employee’s then-current Base Salary) plus (ii) the Employee’s Prorated Incentive Compensation (the “Severance Amount”). For purposes of this Agreement, “Prorated Incentive Compensation” shall mean the Target Annual Incentive Compensation the Employee would have been entitled to receive in the fiscal year of the Date of Termination prorated by the number of days the Employee was employed by the Company during the fiscal year of the Date of Termination; for the avoidance of doubt, in no event shall “Prorated Incentive Compensation” include any sign-on bonus, retention bonus, or any other special bonus;

(b) if the Date of Termination occurs after the completion of a calendar year but prior to the payment of annual bonuses for such year, the Company will pay the Employee the bonus amount that the

Employee otherwise would have earned if the Employee remained employed on the date of payment, as determined in the sole discretion of the Company (the “Prior Year Bonus”); and

(c) 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, for the period of nine (9) months following the Date of Termination or the Employee’s COBRA health continuation period, whichever 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.

The amounts payable under Section 4(a) and (c), to the extent taxable, shall be paid out in substantially equal installments in accordance with the Company’s payroll practice over nine (9) months commencing 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, 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. If applicable, the Prior Year Bonus shall be paid to the Employee at the time that the Company’s other executives receive their annual bonuses, which shall be no later than March 15 of the calendar year in which the Date of Termination occurs. 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. Severance Pay and Benefits Upon Termination by the Company without Cause or by the Employee for Good Reason During the Change in Control Period. 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). These provisions are intended to assure and encourage in advance the Employee’s continued attention and dedication to the Employee’s assigned duties and 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 regarding the Severance Amount and other benefits upon a termination of employment, if such termination of employment occurs during the period beginning three (3) months immediately before the date of the first event constituting a Change in Control and ending on the 18 month anniversary of the first event constituting a Change in Control (such period, the “Change in Control Period”). These provisions shall terminate and be of no further force or effect after the Change in Control Period. For the avoidance of doubt, (i) in no event will the Employee be entitled to severance benefits under both Section 4 and Section 5 of this Agreement, and (ii) if the Company has commenced providing severance pay and benefits to the Employee under Section 4 prior to the date that the Employee becomes eligible to receive severance pay and benefits under this Section 5, the severance pay and benefits previously provided to the Employee under Section 4 shall reduce the severance pay and benefits to be provided under this Section 5.

(a) Change in Control. During the Term, if during the Change in Control Period, the Employee’s employment is terminated by the Company without Cause as provided in Section 3(c) or the Employee terminates 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 seven (7) business day revocation period:

(i) the Company shall pay the Employee a lump sum in cash in an amount equal to one (1) times the sum of (A) the Employee's Base Salary (or the Employee's Base Salary in effect immediately prior to the Change in Control or before Good Reason existed under Section 3(d)(ii), if higher than the Employee's then-current Base Salary) plus (B) the Employee's Annual Incentive Compensation (collectively, the "Change in Control Payment"). For purposes of this Agreement, "Annual Incentive Compensation" shall mean the Target Annual Incentive Compensation the Employee would have been entitled to receive in the fiscal year of 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). For the avoidance of doubt, in no event shall "Annual Incentive Compensation" include any sign-on bonus, retention bonus or any other special bonus;

(ii) if the Date of Termination occurs after the completion of a calendar year but prior to the payment of annual bonuses for such year, the Company will pay the Employee the Prior Year Bonus (if any); 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, for the period of 12 months following the Date of Termination or the Employee's COBRA health continuation period, whichever 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.

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 or, if later, the Change in Control Date; 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. If applicable, the Prior Year Bonus shall be paid to the Employee at the time that the Company's other executives receive their annual bonuses, which shall be no later than March 15 of the calendar year in which the Date of Termination occurs.

(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 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 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) or (c).

(ii) For purposes of this Section 5(b), the “After Tax 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 Agreement, the following terms shall have the following meanings:

“Change in 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 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 (“Voting Securities”) (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 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 in 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 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 or more of the combined voting power of all of the then outstanding Voting Securities, then a Change in Control shall be deemed to have occurred for purposes of the foregoing clause (i).

“Change in Control Date” shall mean, with respect to a Change in Control, the date of consummation of such Change in Control.

6. Section 409A.

(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 would be considered deferred compensation otherwise subject to the 20 percent 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. Continuing Obligations.

(a) Restrictive Covenant Agreement. The terms of the Amended and Restated Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement attached hereto as Exhibit A (the “Restrictive Covenant Agreement”) continue to be in full force and effect. For purposes of this Agreement, the obligations in this Section 7 and those that arise in the Restrictive Covenant Agreement and any other agreement related to confidentiality, assignment of inventions, or other restrictive covenants shall collectively be referred to as the “Continuing Obligations”. For the avoidance of doubt, all restrictive covenant obligations are supplemental to one another, and in the event of any conflict between restrictive covenant obligations, the most restrictive provision that is enforceable shall govern. In the event the Employee is entitled to both payments pursuant to the Restrictive Covenant Agreement and severance payments pursuant to Section 4 or Section 5 of this Agreement, then the severance payments pursuant to Section 4 or Section 5 of this Agreement 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.

(b) Third-Party Agreements and 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, 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 may have to 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 violation of any agreements with or rights of any such previous employer or other party, and 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.

(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(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 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.

(e) Protected Disclosures and Other Protected Action. 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. Arbitration of Disputes. 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 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. For the avoidance of doubt, nothing in this Agreement requires the Employee to arbitrate claims that cannot be arbitrated under applicable law, such as (i) claims under the Sarbanes-Oxley Act and (ii) claims constituting, relating to, and/or alleging sexual harassment or sexual assault based on conduct arising on or after March 3, 2022 (or earlier date, to the extent applicable state or local law provides for an earlier date), unless the Employee chooses to proceed with such claims in arbitration. 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. Consent to Jurisdiction. 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 Continuing Obligations, the Director Award Documents (subject to the terms of this Agreement), the Director Indemnification Agreement dated as of November 19, 2018, the Employee's indemnification agreement with the Company 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.

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 the Employee's termination of employment but prior to the completion by the Company of all payments due to the Employee under this Agreement, the Company shall continue such payments to the Employee's beneficiary designated in writing to the Company prior to the Employee's death (or to 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 Chief Executive Officer. Notices, requests, demands and other communications provided for by this Agreement shall also be sufficient if sent by email to the Company email address of the Employee or, in the case of Company, the Company email address of the Chief Executive Officer, with confirmation of receipt.

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. Effects on Other Plans and Agreements. An election by the Employee to resign for Good Reason under the provisions of this Agreement shall not be deemed a voluntary termination of employment by the Employee for the purpose of interpreting the provisions of any of the Company's benefit plans, programs or policies. Nothing in this Agreement shall be construed to limit the rights of the Employee under the Company's benefit plans, programs or policies except that the Employee shall have no rights to any severance benefits under any Company severance pay plan, offer letter or otherwise. Notwithstanding anything to the contrary in this Agreement, all severance pay and benefits provided to the Employee pursuant to Section 4 or Section 5 of this Agreement (as applicable) shall be reduced and/or offset by any amounts or benefits paid to the Employee to satisfy the federal Worker Adjustment and Retraining Notification (WARN) Act, 29 U.S.C. § 2101 et seq., as amended, and any applicable state plant or facility closing or mass layoff law (whether as damages, as payment of salary or other wages during an applicable notice period or otherwise).

19. Governing Law. 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.

20. 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.

21. Successor to Company. 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.

22. Clawback Acknowledgement. The Employee acknowledges that the Employee may become subject to the Scholar Rock Holding Corporation Compensation Recovery Policy adopted pursuant to Rule 10D-1 promulgated under the Securities Exchange Act of 1934 and Nasdaq Rule 5608, or any successor rule (the “Clawback Policy”). The Employee understands that if the Employee is or becomes subject to the Clawback Policy, the Company and/or the Board shall be entitled to recover all Erroneously Awarded Compensation (as defined in the Clawback Policy) from the Employee pursuant to such means as the Company and/or the Board may elect. The Employee agrees that the Employee shall take all required action to enable such recovery. The Employee understands that such recovery may be sought and occur after the Employee’s employment or service with the Company terminates. The Employee further agrees that the Employee is not entitled to indemnification for any Erroneously Awarded Compensation or for any claim or losses arising out of or in any way related to Erroneously Awarded Compensation recovered pursuant to the Clawback Policy and, to the extent any agreement or organizational document purports to provide otherwise, the Employee hereby irrevocably agrees to forego such indemnification. The Employee acknowledges and agrees that the Employee has received and has had an opportunity to review the Clawback Policy. Any action by the Company to recover Erroneously Awarded Compensation under the Clawback Policy from the Employee shall not, whether alone or in combination with any other action, event or condition, be deemed (i) a Good Reason condition or serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to the Employee, or (ii) to constitute a breach of a contract or other arrangement to which the Employee is a party. This Section 22 is a material term of this Agreement.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK. SIGNATURE PAGES FOLLOW.]

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the Effective Date.

SCHOLAR ROCK, INC.

/s/ Caryn Parlavecchio

By: Caryn Parlavecchio

Its: CHRO

EMPLOYEE

/s/ Edward H. Myles

Edward H. Myles

Exhibit A

**Amended and Restated Employee Non-Competition, Non-Solicitation,
Confidentiality and Assignment Agreement**

**CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT
BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS
AS PRIVATE OR CONFIDENTIAL. INFORMATION THAT WAS OMITTED HAS BEEN NOTED
IN THIS DOCUMENT WITH A PLACEHOLDER IDENTIFIED BY THE MARK “[***]”.**

AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT

THIS AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT (as the same may from time to time be amended, modified, supplemented or restated, this “**Agreement**”) dated as of February 10, 2025 (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, OXFORD FINANCE CREDIT FUND II LP, by its manager Oxford Finance Advisors, LLC, and OXFORD FINANCE CREDIT FUND III LP, by its manager Oxford Finance Advisors, LLC, each with an office located at 115 South Union Street, Suite 300, Alexandria, Virginia 22314 (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, and amends and restates in its entirety that certain Loan and Security Agreement dated as of October 16, 2020, as the same may from time to time be amended, modified, supplemented or restated, including without limitation, by that certain First Amendment to Loan and Security Agreement dated as of November 16, 2021, that certain Second Amendment to Loan and Security Agreement dated as of November 10, 2022, that certain Third Amendment to Loan and Security Agreement dated as of April 18, 2023 and that certain Fourth Amendment to Loan and Security Agreement dated as of May 17, 2024) among the Collateral Agent, the Lenders and Borrower (as amended prior to the Effective Date, the “**Prior Agreement**”), and provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

1. ACCOUNTING AND OTHER TERMS

1.1 Accounting terms not defined in this Agreement shall be construed in accordance with GAAP; provided that if at any time any change in GAAP would require that operating leases entered into in the ordinary course of business be treated in a manner similar to capital leases under GAAP, all financial covenants, requirements and terms in this Agreement shall continue to be calculated or construed as if such change in GAAP had not occurred and no operating lease in effect at the time of such change, or new lease entered into after such change that would have been treated as an operating lease before such change, shall be treated as a capital lease for any purpose hereunder. Calculations and determinations must be made in accordance with GAAP. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to “**Dollars**” or “**\$**” are United States Dollars, unless otherwise noted.

2. LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay each Lender the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans.

(a) Availability.

(i) Subject to the terms and conditions of the Prior Agreement, the Lenders (as defined in the Prior Agreement), severally and not jointly, made term loans to Borrower in an aggregate amount of Fifty Million Dollars (\$50,000,000.00) according to each Lender’s Term Loan Commitment as set forth on Schedule 1.1 of the Prior Agreement (such term loans are hereinafter referred to singly as an “**Original Term Loan**”, and collectively as the

“Original Term Loans”). SVB made Original Term Loans in an aggregate amount of Twenty-Five Million Dollars (\$25,000,000.00) and Oxford made Original Term Loans in an aggregate amount of Twenty-Five Million Dollars (\$25,000,000.00). Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, on the Effective Date, (A) to amend and restate the secured promissory notes that evidence the Original Term Loans made by Oxford and subsequently assigned to Oxford Finance Funding XIII, LLC, Oxford Finance Funding IX, LLC and Oxford Finance Funding 2023-1, LLC in an aggregate amount equal to Twenty-Five Million Dollars (\$25,000,000.00) and according to each Lender’s Term A-1 Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a **“Term A-1 Loans”**, and collectively as the **“Term A-1 Loans”**); and (B) to make term loans to Borrower on the Effective Date in an aggregate amount equal to Twenty-Five Million Dollars (\$25,000,000.00) according to each Lender’s Term A-2 Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a **“Term A-2 Loan”**, and collectively as the **“Term A-2 Loans”**; each Term A-1 Loan and Term A-2 is hereinafter referred to singly as a **“Term A Loan”** and the Term A-1 Loans and Term A-2 Loans are hereinafter referred to collectively as the **“Term A Loans”**). Borrower shall use the proceeds of the Term A-2 Loans to fully repay the Original Term Loans held by SVB in the original principal amount of Twenty-Five Million Dollars (\$25,000,000.00) on the Effective Date. After repayment, no Term A Loan may be re-borrowed.

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Term B Draw Period, to make term loans to Borrower (but in a single disbursement) in an aggregate amount equal to Fifty Million Dollars (\$50,000,000.00) 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, the Lenders agree, severally and not jointly, during the Term C Draw Period, to make term loans to Borrower (but in a single disbursement) in an aggregate amount equal to Fifty Million Dollars (\$50,000,000.00) according to each Lender’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”**). 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 equal to Fifty Million Dollars (\$50,000,000.00) 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”**; each Term A Loan, Term B Loan, Term C Loan or Term D Loan is hereinafter referred to singly as a **“Term Loan”** and the Term A Loans, the Term B Loans, Term C Loans and the Term D Loans are hereinafter referred to collectively as the **“Term Loans”**). After repayment, no Term D Loan may be re-borrowed.

(b) Repayment. Borrower shall make monthly payments in arrears of interest only commencing on the first (1st) Payment Date following the first full calendar month to occur after 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 last calendar day of the month in which such Term Loan funds. 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 eleven (11) months. 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).

(c) Mandatory Prepayments. If the Term Loans are accelerated following the occurrence and during the continuance of an Event of Default (unless such Event of Default has been waived in writing by Collateral Agent or the Lenders in its (or their, as applicable) sole discretion), Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of, without duplication: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Payment, (iii) the Prepayment Fee, if applicable, plus (iv) all other Obligations that are due and payable,

including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Payment had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to Collateral Agent, for payment to each Lender in accordance with its respective Pro Rata Share, the Final Payment in respect of the Term Loan(s).

(d) Permitted Prepayment of Term Loans. Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of, without duplication: (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Payment, (C) the Prepayment Fee, plus (D) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts.

2.3 Payment of Interest on the Credit Extensions.

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent on the Funding Date of the applicable Term Loan and monthly thereafter, which interest, in each case, shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus four percentage points (4.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 360-Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year, and the actual number of days elapsed.

(d) Debit of Accounts. Collateral Agent and each Lender may debit (or ACH) any deposit accounts (other than deposit accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's employees), maintained by Borrower or any other Loan Party, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes Collateral Agent or the Lenders under the Loan Documents when due hereunder. Any such debits (or ACH activity) shall not constitute a set-off.

(e) Payments. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to Collateral Agent (and Collateral Agent shall then make payments to the respective Lender to which such payments are owed), at Collateral Agent's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 2:00 P.M. Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

2.4 Secured Promissory Notes. The Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit D hereto (each a "**Secured Promissory Note**"), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender's Secured Promissory Note, an appropriate notation on such Lender's Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set

forth on such Lender's Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender's Secured Promissory Note Record shall not limit or otherwise affect Borrower's obligations under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

2.5 Fees. Borrower shall pay to Collateral Agent:

(a) Facility Fee. A fully earned, non-refundable facility fee of Two Hundred Fifty Thousand Dollars (\$250,000.00) was paid to the Lenders pursuant to their respective Commitment Percentages on the Original Closing Date;

(b) Final Payment. The Final Payment, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(c) Prepayment Fee. The Prepayment Fee, if and when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(d) Lenders' Expenses. All Lenders' Expenses (including reasonable and documented out-of-pocket attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due;

(e) Second Amendment Accrued Final Payment. The Second Amendment Accrued Final Payment (as defined in the Prior Agreement) was paid to the Lenders on the Second Amendment Effective Date in accordance with their respective Pro Rata Shares; and

(f) First Interest-Only Extension Milestone Fee. The First Interest-Only Extension Milestone Fee (as defined in the Prior Agreement) was paid to the Lenders on the Fourth Amendment Effective Date in accordance with their respective Pro Rata Shares.

(g) Second Interest-Only Extension Milestone Fee. The Second Interest-Only Extension Milestone Fee (as defined in the Prior Agreement) due to Lenders who are Affiliates of Oxford is hereby waived and is no longer due and payable to such Lenders.

(h) Effective Date Accrued Final Payment. A fully-earned, non-refundable Final Payment in the aggregate amount of One Hundred Fifty Thousand Dollars (\$150,000.00) in respect of the Original Term Loans made by Oxford (the "**Effective Date Accrued Final Payment**") to be shared between the Lenders that are Affiliates of Oxford and held the Original Term Loans immediately prior the Effective Date in accordance with their Pro Rata Shares due and payable on the Effective Date. The Effective Date Accrued Final Payment shall not reduce the Final Payment otherwise due pursuant to Section 2.5(b) hereof. From and after the Effective Date, the Final Payment in respect of the Term A Loans shall accrue from the Effective Date.

2.6 Withholding. Payments received by the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto) ("**Taxes**"). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority; provided, that Borrower shall not be required to make such increased payment to a Lender who is not a United States Person (as defined in Section 7701(a)(30) of the

IRC) or who has not provided a duly executed original IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement.

3. CONDITIONS OF LOANS

3.1 Conditions Precedent to Initial Credit Extension. Each Lender's obligation to make a Term A-2 Loan is subject only to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance reasonably satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may have reasonably requested, including, without limitation:

(a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;

(b) duly executed original Control Agreements with respect to any Collateral Accounts maintained by Borrower or any of its Subsidiaries as required pursuant to Section 6.6;

(c) (i) duly executed original Secured Promissory Notes in favor of each Lender according to its Term A-2 Loan Commitment Percentage; and (ii) duly executed original Amended and Restated Secured Promissory Notes in favor of each Lender according to its Term A-1 Loan Commitment Percentage;

(d) with respect to the Shares, the Assignments Separate from Certificate, duly executed in blank;

(e) 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 (in each case to the extent applicable in the relevant jurisdiction(s) of such Subsidiary), each as of a date no earlier than thirty (30) days prior to the Effective Date;

(f) a completed Perfection Certificate for Borrower;

(g) the Annual Projections, for the current calendar year;

(h) duly executed original officer's certificate for Borrower and each Subsidiary that is a party to the Loan Documents, in a form reasonably acceptable to Collateral Agent and the Lenders;

(i) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall reasonably request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;

(j) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;

(k) evidence reasonably satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect; and

(l) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

3.2 Conditions Precedent to all Credit Extensions. The obligation of each Lender to make each Credit Extension, including the initial Credit Extension, is subject only to the following conditions precedent:

(a) receipt by the Lenders of an executed Disbursement Letter substantially in the form of Exhibit B attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of the Disbursement Letter and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in Section 5 hereof are true, accurate and complete in all material respects as of such date; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;

(c) in such Lender's sole but reasonable discretion, there has not been any Material Adverse Change;

(d) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes, in number, form and content reasonably acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date; and

(e) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

3.3 Covenant to Deliver. Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension.

Notwithstanding the foregoing, Borrower shall not be required to make duplicative payments to the Lenders if Borrower has already paid Collateral Agent for fees and/or expenses incurred by or on behalf of Collateral Agent pursuant to any Loan Documents, but, for the avoidance of doubt, Borrower shall continue to be responsible for the payment of all fees and Lenders' Expenses in accordance with the terms of this Agreement and the other Loan Documents. Borrower expressly agrees that a Credit Extension made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in each Lender's sole discretion.

3.4 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 2:00 P.M. Eastern time ten (10) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter executed by a Responsible Officer or his or her designee. The Lenders may rely on any telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its Term Loan Commitment.

4. CREATION OF SECURITY INTEREST

4.1 Grant of Security Interest. Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof; provided, however, that solely with respect to Borrower's Intellectual Property, such security interest shall only become effective on the date on which the IP Trigger Event occurs and shall remain effective at all times thereafter. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral (other than with respect to perfection of the security interest on the Shares of any Foreign Subsidiary, which are governed by local law share pledges (if any)), subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent's Lien. If Borrower shall acquire a commercial tort claim (as defined

in the Code), Borrower, shall promptly notify Collateral Agent in a writing signed by Borrower, as the case may be, of the general details thereof (and further details as may be required by Collateral Agent) and grant to Collateral Agent, for the ratable benefit of the Lenders, in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to make Credit Extensions has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower.

4.2 Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.

4.3 Pledge of Collateral. Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within ten (10) days of the certification of any Shares of any Domestic Subsidiary, the certificate or certificates for such Shares will be delivered to Collateral Agent, accompanied by an instrument of assignment duly executed in blank by Borrower, and the Perfection Certificates delivered on the Effective Date describe the certificated Shares as of the Effective Date. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each Subsidiary whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, upon written notice by Collateral Agent to Borrower, Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent or its transferee. Borrower will execute and deliver such documents, and take or cause to be taken such actions, as Collateral Agent may reasonably request to perfect or continue the perfection of Collateral Agent's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing and Collateral Agent has provided written notice thereof, Borrower shall be entitled to exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default after Collateral Agent has provided Borrower written notice thereof.

5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

5.1 Due Organization, Authorization: Power and Authority. Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower has delivered to Collateral Agent a completed perfection certificate for Borrower, prepared on a consolidating basis, and signed by an officer of Borrower (each a "**Perfection Certificate**" and collectively, the "**Perfection Certificates**"). Borrower represents and warrants that (a) Borrower and each of its Subsidiaries' exact legal name is that which is indicated on its respective Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on its respective Perfection Certificate; (c) each Perfection Certificate accurately sets forth each

of Borrower's and its Subsidiaries' organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) each Perfection Certificate accurately sets forth Borrower's and each other Loan Party's (and, as of the Effective Date and as of the date of any Perfection Certificate delivered after the Effective Date, each of its Subsidiaries' that are not Loan Parties) place of business, or, if more than one, its chief executive office as well as Borrower's and each of its Subsidiaries' mailing address (if different than its chief executive office); (e) except as may be set forth on its respective Perfection Certificate, Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years, changed its jurisdiction of organization, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries, is accurate and complete (it being understood and agreed that Borrower may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent Borrower is permitted to take such action resulting in the applicable update by one or more specific provisions in this Agreement, and any notices delivered in accordance with the provisions in this Agreement shall be deemed to be updates to such information (subject to the review and approval of Collateral Agent as provided below) without any further requirement of Borrower to make such updates until the next Perfection Certificate is delivered); such updated Perfection Certificates subject to the review and approval of Collateral Agent unless such facts, events or circumstances being updated first arose or occurred after the Effective Date and do not constitute a breach, default, or Event of Default under this Agreement or any other Loan Document. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, Borrower shall notify Collateral Agent of such occurrence and provide Collateral Agent with such Person's organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except for (A) a filing by Borrower on Form 8-K with the Securities and Exchange Commission promptly following the Effective Date with respect to Borrower's execution and delivery of this Agreement and (B) such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

5.2 Collateral.

(a) Borrower and each other Loan Party have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith (as may be updated from time to time in accordance with the terms hereof) with respect of which Borrower or such Loan Party has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein unless otherwise provided pursuant to Section 6.6. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee (such as a warehouse), and (ii) no such third party bailee possesses components of the Collateral in excess of One Million Dollars (\$1,000,000.00). None of the components of the Collateral shall be maintained at locations other than as disclosed in the Perfection Certificates on the Effective Date or as permitted pursuant to Section 6.11.

(c) All Inventory (other than raw materials, parts, supplies, packing and shipping materials and work in process) is in all material respects of good and marketable quality, free from material defects.

(d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to solely own, and is the joint owner of the Intellectual Property each respectively purports to own jointly, in each case free and clear of all Liens other than Permitted Liens. From and after the IP Trigger Event occurs, (i) each of Borrower's and its Subsidiaries' Patents that is material to its business is valid and enforceable and no part of Borrower's or its Subsidiaries' Intellectual Property that is material to its business has been judged invalid or unenforceable, in whole or in part, and (ii) to the Borrower's knowledge, no claim has been made that any part of the Intellectual Property or any practice by Borrower or its Subsidiaries violates the rights of any third party except to the extent such claim could not reasonably be expected to have a Material Adverse Change. Except as noted on the Perfection Certificates (as may be updated from time to time in accordance with the terms hereof), neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Subsidiary is the licensee that (i) prohibits or otherwise restricts Borrower or its Subsidiaries from granting a security interest in Borrower's or such Subsidiary's interest in such material license or material agreement or any other property, or (ii) for which a default under or termination of could interfere with Collateral Agent's or any Lender's right to sell any Collateral. Borrower shall provide written notice to Collateral Agent and each Lender with the next Compliance Certificate due to be delivered to Lenders pursuant to Section 6.2(b) of Borrower or any other Loan Party entering into or becoming bound by any license or agreement with respect to which Borrower or such Loan Party is the licensee (other than (y) over-the-counter software that is commercially available to the public and (z) non-exclusive licenses from or to contract manufacturers, clinical research organizations, clinical trial or research sites, and service providers and other entities, in each case, (A) entered into in the ordinary course of business, (B) the principal purpose of which does not include the acquisition of licensing rights, but which contain such non-exclusive licenses merely ancillary to, and for the limited purpose of, facilitating the principal purposes of the agreement and (C) so long as Borrower has complied with all other applicable terms of the Loan Documents applicable thereto).

5.3 Litigation. Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with Section 6.9 hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than One Million Dollars (\$1,000,000.00).

5.4 No Material Deterioration in Financial Condition; Financial Statements. All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Borrower and its Subsidiaries, and the consolidated results of operations of Borrower and its Subsidiaries as of the date of such financial statements. There has not been any material deterioration in the consolidated financial condition of Borrower and its Subsidiaries, taken as a whole, since the date of the most recent financial statements submitted to any Lender.

5.5 Solvency. Borrower is Solvent and Borrower and its Subsidiaries, on a consolidated basis, are Solvent.

5.6 Regulatory Compliance. Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all material consents, approvals and authorizations of, made all material declarations or filings with, and given all material notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction

that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

5.7 Investments. Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed (or timely filed extensions to file) all required tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid all federal, material foreign, material state, and material local taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries, in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless (i) such taxes are being contested in accordance with the following sentence or (ii) in the case of material foreign, material state and material local taxes, assessments, deposits and contributions owed, such taxes, assessments, deposits and contributions do not, individually or in the aggregate, exceed Two Hundred Fifty Thousand Dollars (\$250,000.00). Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the taxes by appropriate proceedings instituted and conducted with reasonable promptness and diligence, (b) notifies Collateral Agent in writing of the commencement of, and any material development in, the proceedings, and (c) posts bonds or takes any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a “**Permitted Lien.**” Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower’s or such Subsidiaries’, prior tax years which could result in additional taxes, in excess of Twenty-Five Thousand Dollars (\$25,000.00) in the aggregate, becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

5.9 Use of Proceeds. Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes. Additionally, Borrower will be permitted to use the proceeds of the Credit Extensions of the Term A-2 Loan to repay all outstanding Credit Extensions made by SVB pursuant to the Prior Agreement.

5.10 Shares. Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower’s knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower’s knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

5.11 Full Disclosure. No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender in connection with the Loan Documents or the transactions contemplated thereby, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading in light of the circumstances in which they were made (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon reasonable

assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

5.12 “Know Your Customer” Information. All materials and information provided to Collateral Agent and Lenders in connection with applicable “know your customer” and Anti-Terrorism Legislation are true and correct.

5.13 Definition of “Knowledge.” For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower’s knowledge or awareness, to the “best of” Borrower’s knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

6.1 Government Compliance.

(a) Maintain its and (except as permitted by the second sentence of Section 7.3) all its Subsidiaries’ legal existence and good standing (to the extent applicable in the relevant jurisdiction(s) of such Subsidiary) in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral. Borrower shall promptly provide copies to Collateral Agent of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries.

6.2 Financial Statements, Reports, Certificates.

(a) Deliver to Collateral Agent:

(i) as soon as available, but no later than forty-five (45) days after the last day of each fiscal quarter, a company prepared consolidated and consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its Subsidiaries for such quarter certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;

(ii) as soon as available, but no later than the earlier of (A) ninety (90) days after the last day of Borrower’s fiscal year or (B) within five (5) days of filing with the SEC, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on the financial statements (other than any qualification that is with respect to, or resulting from an upcoming maturity date of any Term Loan or any other material Indebtedness) from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion (each of the “Big Four” accounting firms and Borrower’s existing accounting firm are acceptable to Collateral Agent);

(iii) as soon as available after approval thereof by Parent’s Board of Directors, but no later than sixty (60) days after the last day of each of Borrower’s fiscal years, Borrower’s annual financial projections for the entire current fiscal year as most recently approved by Parent’s Board of Directors, which such annual financial projections shall be set forth in a quarter-by-quarter format (such annual financial projections as originally delivered to Collateral Agent are referred to herein as the “**Annual Projections**”; provided that, any revisions of the Annual Projections approved by Parent’s Board of Directors shall be delivered to Collateral Agent no later than seven (7) days after such approval);

(iv) within five (5) days of delivery, copies of all statements, reports and notices made available to Borrower's security holders or holders of Subordinated Debt;

(v) within five (5) days of filing, all reports on Form 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission;

(vi) prompt notice of any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto;

(vii) (A) prompt notice of any event that could reasonably be expected to materially and adversely affect the value of the Intellectual Property, and (B) at all times after the IP Trigger Event occurs, (1) each of the following on each Certificate of Compliance: (y) a summary of any material change in the composition of the Intellectual Property, and (z) a report of the registered patents, trademarks, service marks, copyrights, mask works, or any pending applications for any of the foregoing, whether as owner, licensee or otherwise, by Borrower or any of its Subsidiaries, and noting any changes from the report provided for the prior fiscal quarter, and (2) at least fifteen (15) days prior written notice of Borrower's or any other Loan Party's intent to register such copyrights or mask works together with a copy of the application it intends to file with the United States Copyright Office (excluding exhibits thereto);

(viii) as soon as available, but no later than thirty (30) days after the last day of each fiscal quarter, copies of the month-end account statements for the month-end of such fiscal quarter for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s); and

(ix) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the Securities and Exchange Commission or posted on Borrower's website) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) No later than forty-five (45) days after the last day of each fiscal quarter, deliver to each Lender, a duly completed Compliance Certificate signed by a Responsible Officer.

(c) Keep proper books of record and account in accordance with GAAP in all material respects, in which full, true and correct entries shall be made of all dealings and transactions in relation to its business and activities. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than once every year unless (and more frequently if) an Event of Default has occurred and is continuing.

6.3 Inventory; Returns. Keep all Inventory in good and marketable condition (ordinary wear and tear excepted), free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist at the Effective Date. Borrower must promptly notify Collateral Agent and the Lenders of all returns, recoveries, disputes and claims that involve more than Two Hundred Fifty Thousand Dollars (\$250,000.00) individually or in the aggregate in any calendar year.

6.4 Taxes; Pensions. Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely file, all federal, material foreign, material state, and material local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries,

except (a) in the case of material foreign, material state and material local taxes, assessments, deposits and contributions owed do not, individually or in the aggregate, exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) or (b) for deferred payment of any taxes contested pursuant to the terms of Section 5.8 hereof, and shall deliver to the Collateral Agent, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

6.5 Insurance. Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to One Million Dollars (\$1,000,000.00) with respect to any loss, but not exceeding One Million Dollars (\$1,000,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of better, equal or like value or usefulness as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest (subject only to Permitted Liens that are permitted pursuant to the terms of this Agreement to have superior priority to Collateral Agent's Lien), and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make, at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

6.6 Operating Accounts.

(a) Maintain all of Borrower's and its Subsidiaries Collateral Accounts at the banks and financial institutions as disclosed in the Perfection Certificates delivered on the Effective Date, or such other Collateral Accounts as to which Borrower provided notice pursuant to Section 6.6(b), which are subject to a Control Agreement in favor of Collateral Agent (other than any Collateral Account that is not required to constitute Collateral). Borrower shall at all times have on deposit in Collateral Accounts that are subject to a Control Agreement in favor of Collateral Agent cash in an amount equal to the lesser of (i) one hundred percent (100.00%) of the Dollar value of all of Borrower's consolidated cash, including any Subsidiaries', in the aggregate, at all financial institutions, and (ii) one hundred five percent (105.00%) of the Dollar amount of the then-outstanding Obligations. Clause (i) of the previous sentence shall not be applicable to (and no additional amounts need to be maintained to cover the amounts in) deposit accounts exclusively used for (x) payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees identified to Collateral Agent by Borrower as such in the Perfection Certificates (as may be updated from time to time in accordance with the terms hereof) so long as the amounts in such deposit accounts do not exceed one month of payroll at any time and (y) cash collateral purposes to secure obligations for the Indebtedness permitted by clause (g) of the defined term "Permitted Indebtedness".

(b) Borrower shall provide Collateral Agent five (5) days' prior written notice before Borrower or any of its Subsidiaries establishes any Collateral Account. In addition, for each Collateral Account that Borrower or such other Loan Party at any time opens or maintains, to the extent constituting Collateral, Borrower or such other Loan Party shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account of Borrower or such other Loan Party to perfect Collateral Agent's Lien in such Collateral Account in

accordance with the terms hereunder prior to the establishment of such Collateral Account, which Control Agreement may not be terminated without the prior written consent of Collateral Agent or by such bank or financial institution in accordance with its terms. The provisions of the previous sentence shall not apply to deposit accounts exclusively used for (i) payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees so long as the amounts in such deposit accounts do not exceed one month of payroll at any time and (ii) cash collateral purposes to secure obligations for the Indebtedness permitted by clause (g) of the defined term "Permitted Indebtedness", in each case identified to Collateral Agent by Borrower as such in the Perfection Certificates (as may be updated from time to time in accordance with the terms hereof).

(c) Neither Borrower nor any other Loan Party shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Sections 6.6(a) and (b).

6.7 Protection of Intellectual Property Rights. Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to Borrower's business; (b) promptly advise Collateral Agent in writing of infringement by a third party of its Intellectual Property if such Intellectual Property has material value; and (c) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent. At all times after the IP Trigger Event occurs, if Borrower or any other Loan Party (i) obtains any patent, registered trademark or servicemark, registered copyright, registered mask work, or any pending application for any of the foregoing, whether as owner, licensee or otherwise, or (ii) applies for any patent or the registration of any trademark or servicemark, then Borrower or such Loan Party shall execute such intellectual property security agreements and other documents and take such other actions as Collateral Agent shall reasonably request in its good faith business judgment to perfect and maintain a first priority (subject only to Permitted Liens that are permitted pursuant to the terms of this Agreement to have superior priority to Collateral Agent's Lien) perfected security interest in favor of Collateral Agent, for the ratable benefit of the Lenders, in such Intellectual Property. At all times after the IP Trigger Event occurs, if Borrower or any other Loan Party decides to register any copyrights or mask works in the United States Copyright Office, Borrower or such Loan Party shall: (y) execute an intellectual property security agreement and such other documents and take such other actions as Collateral Agent may reasonably request in its good faith business judgment to perfect and maintain a first priority (subject only to Permitted Liens that are permitted pursuant to the terms of this Agreement to have superior priority to Collateral Agent's Lien) perfected security interest in favor of Collateral Agent, for the ratable benefit of the Lenders, in the copyrights or mask works intended to be registered with the United States Copyright Office; and (z) record such intellectual property security agreement with the United States Copyright Office contemporaneously with filing the copyright or mask work application(s) with the United States Copyright Office. Notwithstanding anything to the contrary in this Section 7.7, within thirty (30) days after the occurrence of the IP Trigger Event, Borrower and each other Loan Party, as applicable, shall execute such intellectual property security agreements and other documents and take such other actions as Collateral Agent shall reasonably request in its good faith business judgment to perfect and maintain a first priority (subject only to Permitted Liens that are permitted pursuant to the terms of this Agreement to have superior priority to Collateral Agent's Lien) perfected security interest in favor of Collateral Agent, for the ratable benefit of the Lenders, in the Intellectual Property.

6.8 Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders and, provided no Event of Default has occurred, upon reasonable written prior notice, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

6.9 Notices of Litigation and Default. Borrower will give prompt written notice to Collateral Agent and the Lenders of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of One Million Dollars (\$1,000,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within three (3) Business Days) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to Collateral Agent and the Lenders of such occurrence, which such notice shall

include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default.

6.10 Financial Covenant. Commencing on March 31, 2027 and on the last day of each fiscal quarter thereafter (each, a “**Testing Date**”) if (a) at any time during the fiscal quarter of such Testing Date the aggregate amount of Borrower’s unrestricted (other than Permitted Liens) cash, Cash Equivalents and other marketable securities is less than [***] of the outstanding principal balance of the Term Loans as of such Testing Date and (b) at any time during such fiscal quarter the Market Capitalization is less than [***], then as of such Testing Date, Borrower shall have Net Product Revenue (calculated on a trailing six (6) month basis), of at least the amount set forth on Annex A for such Testing Date.

6.11 Landlord Waivers; Bailee Waivers. In the event that Borrower or any other Loan Party, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower or such other Loan Party will first provide written notice to Collateral Agent to the extent such location is not already set forth on a Perfection Certificate and, in the event that the new location is the chief executive office of the Borrower or such other Loan Party or the Collateral at any such new location is valued in excess of [***] in the aggregate, such Loan Party shall use commercially reasonable efforts to cause such bailee or landlord, as applicable, to execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of such new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

6.12 Creation/Acquisition of Subsidiaries. In the event Borrower or any of its Subsidiaries creates or acquires any Subsidiary (including, without limitation, pursuant to a Division) after the Effective Date, Borrower shall provide prior written notice to Collateral Agent of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Collateral Agent or any Lender to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to Collateral Agent, for the ratable benefit of the Lenders, a perfected security interest in the Shares of each such newly created Subsidiary; provided, however, that solely in the circumstance in which Borrower or any Subsidiary creates or acquires a Foreign Subsidiary in an acquisition approved by the Required Lenders, (i) such Foreign Subsidiary shall not be required to guarantee the Obligations of Borrower under the Loan Documents and grant a continuing pledge and security interest in and to the assets of such Foreign Subsidiary, and (ii) Borrower shall not be required to grant and pledge to Collateral Agent, for the ratable benefit of Lenders, a perfected security interest in more than sixty-five percent (65%) of the Shares of such Foreign Subsidiary, if Borrower demonstrates to the reasonable satisfaction of Collateral Agent that such Foreign Subsidiary providing such guarantee or pledge and security interest or Borrower providing a perfected security interest in more than sixty-five percent (65%) of the Shares would create a present and existing adverse tax consequence to Borrower under the IRC. For the avoidance of doubt, neither Scholar Rock Netherlands, nor any Subsidiary of Scholar Rock Netherlands that is a Foreign Subsidiary, shall be required to become a Loan Party until sixty (60) days after the occurrence of the Foreign Subsidiary Trigger Event.

6.13 Further Assurances.

(a) Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent’s Lien in the Collateral or to effect the purposes of this Agreement.

(b) Deliver to Collateral Agent, within five (5) days after the same are sent or received, copies of all material written correspondence, reports, documents and other filings of Borrower or any Subsidiary with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower’s business or otherwise could reasonably be expected to have a Material Adverse Change.

7. **NEGATIVE COVENANTS**

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

7.1 Dispositions. Convey, sell, lease, transfer, assign, or otherwise dispose of (including, without limitation, pursuant to a Division) (collectively, “**Transfer**”), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out, obsolete or surplus Equipment or other Equipment which is being replaced by Equipment of reasonably equivalent or better value or usefulness; (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses; (d) pursuant to the Permitted Royalty Transaction; (e) of cash and Cash Equivalents in connection with transactions not prohibited hereunder to the extent such transactions are in the ordinary course of business and consistent with the then applicable Annual Projections most recently approved by Borrower’s Board of Directors; and (f) of other assets (excluding Intellectual Property) having a book value not exceeding One Million Dollars (\$1,000,000.00) during any fiscal year.

7.2 Changes in Business, Management, Ownership, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) any Key Person shall cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent within five (5) Business Days of such change, or (ii) enter into any transaction or series of related transactions in which the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than forty nine percent (49.00%) of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Borrower’s equity securities in a public offering, a private placement of public equity or to venture capital investors so long as Borrower identifies to Collateral Agent the venture capital investors prior to the closing of the transaction) (an “**Acquisition of Borrower**”). Borrower shall not, without at least thirty (30) days’ prior written notice to Collateral Agent: (A) add any new office or business location, including a warehouse (unless such new office or business location (i) contains assets or property of Borrower or any other Loan Party with a value of less than One Million Dollars (\$1,000,000.00) and (ii) is not Borrower’s or any other Loan Party’s chief executive office (it being understood that any such locations set forth on a Perfection Certificate shall not require such prior written notice)); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

7.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person (including, without limitation, pursuant to a Division). A Subsidiary may merge or consolidate into another Subsidiary (provided that if either Subsidiary is a Loan Party, the surviving Subsidiary of such consolidation or merger shall be a Loan Party) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom.

7.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

7.5 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens that are permitted by the terms of this Agreement to have superior priority over Collateral Agent’s Lien or to the extent Collateral Agent has not perfected its security interest with respect to the Shares of any Foreign Subsidiary), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from collaterally assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower’s or such Subsidiary’s Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of “**Permitted Liens**” herein.

7.6 Maintenance of Collateral Accounts. Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

7.7 Distributions; Investments. (a) Except for any Tax Distributions, pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock (other than repurchases pursuant to the terms of stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, or repurchases from current or former employees, officers, consultants or directors pursuant to stock repurchase agreements or similar by the cancellation of indebtedness owed by such employees, officers, consultants or directors to Borrower, provided such repurchases do not exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate per fiscal year), provided that (i) Borrower may convert any of its convertible securities into equity securities of Borrower (which equity securities do not have a put or redemption right) pursuant to the terms of such convertible securities or otherwise in exchange thereof, (ii) Borrower's or its Subsidiaries may make distributions and pay dividends to Borrower, and (iii) Borrower may make cash payments in lieu of the issuance of fractional shares upon conversion of convertible securities in an aggregate amount not to exceed Fifty Thousand Dollars (\$50,000.00) during the term of this Agreement, or (b) directly or indirectly make any Investment other than Permitted Investments.

7.8 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries, (c) customary compensation and other benefits arrangements (including retirement, health, stock option, and other benefit plans and indemnification arrangements) with Borrower's or its Subsidiaries' employees, officers, directors and managers approved by Borrower's or such Subsidiary's board of directors consistent with the industry practices in Borrower's or such Subsidiary's industry, and (d) transactions permitted pursuant to Section 7.3, 7.4 or 7.7 to be carried out with Affiliates.

7.9 Subordinated Debt. (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

7.10 Compliance. Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

7.11 Compliance with Anti-Terrorism Laws. Collateral Agent hereby notifies Borrower and each of its Subsidiaries that pursuant to the requirements of Anti-Terrorism Laws, and Collateral Agent's policies and practices, Collateral Agent is required to obtain, verify and record certain information and documentation that identifies Borrower and each of its Subsidiaries and their principals, which information includes the name and address of Borrower and each of its Subsidiaries and their principals and such other information that will allow Collateral Agent to identify such party in accordance with Anti-Terrorism Laws. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Borrower and each of its Subsidiaries shall immediately notify Collateral Agent if Borrower or such Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for

the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

7.12 MSC Subsidiary. Cause or permit (i) MSC Subsidiary to incur any Indebtedness, (ii) any Lien on any assets of MSC Subsidiary, and (iii) any transfers from any deposit or securities account maintained by MSC Subsidiary other than to accounts of Borrower which are subject to a Control Agreement in favor of Collateral Agent. Borrower shall not permit MSC Subsidiary to engage in any business, make any Investments or hold any assets that would cause MSC Subsidiary to fail to qualify as a Massachusetts security corporation under 830 CMR 63.38B.1 of the Massachusetts tax code and applicable regulations (as the same may be amended, modified or replaced from time to time).

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an “**Event of Default**”) under this Agreement:

8.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period);

8.2 Covenant Default.

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Notice of Litigation and Default), 6.10 (Financial Covenant), 6.11 (Landlord Waivers; Bailee Waivers), 6.12 (Creation/Acquisition of Subsidiaries) or 6.13 (Further Assurances) or Borrower violates any covenant in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section 8.2(b) shall not apply, among other things, to financial covenants, if any, or any other covenants set forth in subsection (a) above;

8.3 Material Adverse Change. A Material Adverse Change occurs;

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any Lender or any Lender's Affiliate or any bank or other institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

8.5 Insolvency. (a) Borrower is or becomes Insolvent or Borrower and its Subsidiaries, on a consolidated basis, are or become Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

8.6 Other Agreements. There is a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of One Million Dollars (\$1,000,000.00) or that could reasonably be expected to have a Material Adverse Change; provided, however, that the Event of Default under this Section 8.6 caused by the occurrence of a breach or default under such other agreement shall be cured or waived for purposes of this Agreement upon Collateral Agent receiving written notice from the party asserting such breach or default of such cure or waiver of the breach or default under such other agreement, if at the time of such cure or waiver under such other agreement (x) Collateral Agent or any Lender has not declared an Event of Default under this Agreement and/or exercised any rights with respect thereto; (y) any such cure or waiver does not result in an Event of Default under any other provision of this Agreement or any Loan Document; and (z) in connection with any such cure or waiver under such other agreement, the terms of any agreement with such third party are not modified or amended in any manner which could in the good faith business judgment of Collateral Agent be materially less advantageous to Borrower;

8.7 Judgments. One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least One Million Dollars (\$1,000,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree);

8.8 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

8.9 Subordinated Debt. A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

8.10 Guaranty. (a) Any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor, or (d) the liquidation, winding up, or termination of existence of any Guarantor;

8.11 Governmental Approvals. Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or

8.12 Lien Priority. Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected (other than with respect to perfection of the security interest on the Shares of any Foreign Subsidiary to the extent Collateral Agent has not perfected its security interest with respect to such Shares)

Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens which are permitted to have priority in accordance with the terms of this Agreement.

8.13 Delisting. The shares of common stock of Borrower are delisted from The NASDAQ Global Select Market because of failure to comply with continued listing standards thereof or due to a voluntary delisting which results in such shares not being listed on any other nationally recognized stock exchange in the United States having listing standards at least as restrictive as The NASDAQ Global Select Market.

9. RIGHTS AND REMEDIES

9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, or (b) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or

(iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use

of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any account (other than deposit accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's employees) maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance. As used in the immediately preceding sentence, "**Exigent Circumstance**" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of the other Loan Parties after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

9.2 Power of Attorney. Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of the other Loan Parties' name on any checks or other forms of payment or security; (b) sign Borrower's or any of the other Loan Parties' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of the other Loan Parties' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make Credit Extensions hereunder. Collateral Agent's foregoing appointment as Borrower's or any of the other Loan Parties' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Credit Extensions terminates.

9.3 Protective Payments. If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such

payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

9.4 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of the other Loan Parties of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise.

Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's portion of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent.

If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender's ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent's security interest therein.

9.5 Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

9.6 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 Demand Waiver. Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any the other Loan Party is liable.

10. NOTICES

All notices, consents, requests, approvals, demands, or other communication (collectively, “**Communication**”) by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:	SCHOLAR ROCK HOLDING CORPORATION 301 Binney Street, 3rd Floor Cambridge, MA 02142 Attn: [***] Email: [***]
with a copy (which shall not constitute notice) to:	GOODWIN PROCTER LLP 520 Broadway, Suite 500 Santa Monica, CA 90401 Attn: [***] Email: [***]
If to Collateral Agent:	OXFORD FINANCE LLC 115 South Union Street, Suite 300 Alexandria, Virginia 22314 Attention: [***] Fax: [***] Email: [***]
with a copy to:	OXFORD FINANCE CREDIT FUND II LP c/o Oxford Finance Advisors, LLC, its manager 115 South Union Street Suite 300 Alexandria, VA 22314 Attention: [***] Fax: [***] Email: [***]
with a copy to:	OXFORD FINANCE CREDIT FUND III LP c/o Oxford Finance Advisors, LLC, its manager 115 South Union Street Suite 300 Alexandria, VA 22314 Attention: [***] Fax: [***] Email: [***]

with a copy (which shall not constitute notice) to:

DLA PIPER LLP (US)
500 8th Street, NW
Washington, DC 20004
Attn: Eric Eisenberg
Fax: [***]
Email: [***]

11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

New York law governs the Loan Documents without regard to principles of conflicts of law. Borrower, Lenders and Collateral Agent each submit to the exclusive jurisdiction of the State and Federal courts in the City of New York, Borough of Manhattan. NOTWITHSTANDING THE FOREGOING, COLLATERAL AGENT AND THE LENDERS SHALL HAVE THE RIGHT TO BRING ANY ACTION OR PROCEEDING AGAINST BORROWER OR ITS PROPERTY IN THE COURTS OF ANY OTHER JURISDICTION WHICH COLLATERAL AGENT AND THE LENDERS (IN ACCORDANCE WITH THE PROVISIONS OF SECTION 9.1) DEEM NECESSARY OR APPROPRIATE TO REALIZE ON THE COLLATERAL OR TO OTHERWISE ENFORCE COLLATERAL AGENT'S AND THE LENDERS' RIGHTS AGAINST BORROWER OR ITS PROPERTY. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court.

Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, first class, registered or certified mail return receipt requested, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER, COLLATERAL AGENT, AND THE LENDERS EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

12. GENERAL PROVISIONS

12.1 Successors and Assigns.

(a) This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's and each Lender's prior written consent (which may be granted or withheld in Collateral Agent's and each Lender's discretion, subject to Section 12.6). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "**Lender Transfer**") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; *provided, however*, that any such Lender Transfer (other than a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Required Lenders (such approved assignee, an "**Approved Lender**"). Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence

with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent.

(b) Collateral Agent, acting solely for this purpose as a non-fiduciary agent of Borrower (solely for tax purposes), shall maintain at one of its U.S. offices a copy of each assignment and a register for the recordation of the name and address of, and the principal amounts (and stated interest) of the obligations owing to, each lender or assignee pursuant to the terms hereof from time to time (the "**Register**"). The entries in the Register shall be conclusive absent manifest error, and the parties shall treat each person whose name is recorded in the Register pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement. The Register shall be available for inspection by Borrower at any reasonable time and from time to time upon reasonable prior notice. Any Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of Borrower (solely for tax purposes), maintain a register on which it enters the name and address of each participant and the principal amounts (and stated interest) of each participant's interest in the obligations under the Loan Documents (the "**Participant Register**"). The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. This requirement to maintain the Register and Participant Register shall be construed so that such obligations are at all times maintained in "registered form" within the meaning of Sections 163(f), 871(h)(2) and 881(c)(2) of the IRC and any related Treasury Regulations (and any other relevant or successor provisions of the IRC or such Treasury Regulations).

12.2 Indemnification. Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an "**Indemnified Person**") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "**Claims**") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable and documented out-of-pocket attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct. This Section 12.2 shall not apply with respect to Taxes other than any Taxes that represent losses, claims, damages or liability arising from any non-Tax claim.

12.3 Time of Essence. Time is of the essence for the performance of all Obligations in this Agreement.

12.4 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.5 Correction of Loan Documents. Collateral Agent and the Lenders may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties so long as Collateral Agent and the Lenders provide Borrower with written notice of such correction and allows Borrower at least ten (10) days to object to such correction. In the event of such objection, such correction shall not be made except by an amendment signed by Collateral Agent, the Lenders, and Borrower.

12.6 Amendments in Writing; Integration. (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature;

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "**Required Lenders**" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.6 or the definitions of the terms used in this Section 12.6 insofar as the definitions affect the substance of this Section 12.6; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.10. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the preceding sentence;

(iv) the provisions of the foregoing clauses (i), (ii) and (iii) are subject to the provisions of any interlender or agency agreement among the Lenders and Collateral Agent pursuant to which any Lender may agree to give its consent in connection with any amendment, waiver or modification of the Loan Documents only in the event of the unanimous agreement of all Lenders.

(b) Other than as expressly provided for in Section 12.6(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

12.7 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

12.8 Survival. All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as

well as the confidentiality provisions in Section 12.9 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

12.9 Confidentiality. In handling any confidential information of Borrower and its Subsidiaries, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates that are subject to confidentiality provisions that are similar to the provisions of this Section 12.9, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Credit Extensions (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms no less restrictive than those contained herein); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent (other than due to the fault of the Lenders and/or Collateral Agent in violation of this Section 12.9); or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information relating to the administration of this Agreement and for the development of client databases, reporting purposes required by law or by Governmental Authorities, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.9 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.9.

12.10 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmaturing and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

12.11 Cooperation of Borrower. If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Term Loan to an assignee in accordance with Section 12.1(a), (ii) make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments or Credit Extensions (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request. Subject to the provisions of Section 12.9, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement.

12.12 Borrower Liability. Either Borrower may, acting singly, request Credit Extensions hereunder. Each Borrower hereby appoints the other as agent for the other for all purposes hereunder, including with respect to requesting Credit Extensions hereunder. Each Borrower hereunder shall be jointly and severally obligated to repay all Credit Extensions made hereunder, regardless of which Borrower actually receives said Credit Extension, as if each Borrower hereunder directly received all Credit Extensions. Each Borrower waives (a) any suretyship defenses available to it under the Code or any other applicable law, and (b) any right to require Collateral Agent or any Lender to: (i) proceed against any Borrower or any other person; (ii) proceed against or exhaust any security; or (iii) pursue any other remedy. Collateral Agent and or any Lender may exercise or not exercise any right or remedy it has against any Borrower or any security it holds (including the right to foreclose by judicial or non-judicial sale) without affecting any Borrower's liability. Notwithstanding any other provision of this Agreement or other related document, each Borrower irrevocably waives all rights that it may have at law or in equity (including, without limitation, any law subrogating Borrower to the rights of Collateral Agent and the Lenders under this Agreement) to seek contribution, indemnification or any other form of reimbursement from any other Borrower, or any other Person now or hereafter primarily or secondarily liable for any of the Obligations, for any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise and all rights that it might have to benefit from, or to participate in, any security for the Obligations as a result of any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise. Any agreement providing for indemnification, reimbursement or any other arrangement prohibited under this Section shall be null and void. If any payment is made to a Borrower in contravention of this Section, such Borrower shall hold such payment in trust for Collateral Agent and the Lenders and such payment shall be promptly delivered to Collateral Agent for application to the Obligations, whether matured or unmatured.

13. DEFINITIONS

13.1 Definitions. As used in this Agreement, the following terms have the following meanings:

"1-Month CME Term SOFR" is the 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website.

"Acceptable Intercreditor Agreement" means, with respect to any Permitted Royalty Transaction that is a synthetic royalty transaction, an intercreditor or other agreement among the Collateral Agent, the applicable synthetic royalty financier (or agent of such applicable synthetic royalty financier) of such Permitted Royalty Transaction (the **"Applicable Synthetic Royalty Financier"**) and Borrower (and/or any Subsidiary of Borrower party thereto) providing (i) at the sole option of Borrower, a first priority security interest and Lien (or, solely, with respect to clause (B) below, a second priority interest and Lien subject only to the priority of the security interest and Lien of the Collateral Agent under the Loan Documents in a manner consistent with such intercreditor or other agreement) granted to the Applicable Synthetic Royalty Financier in (A) the applicable percentage of (and/or the applicable rights, benefits and/or interests in) the royalty interest or revenue interest and payment intangibles related to the Applicable Product, (B) any intellectual property (including, without limitation, any Intellectual Property) solely underlying the Applicable Product, (C) any proceeds or product of any of the foregoing, and (D) a deposit account of Borrower solely holding royalty proceeds due to the Applicable Synthetic Royalty Financier in an amount not to exceed the percentage of revenues and royalty amounts due to the Applicable Synthetic Royalty Financier, (ii) that (A) the governing law thereof is New York and (B) submission of jurisdiction and venue is the State of New York (or some customary subset thereof) and the appellate courts thereof, and (iii) for such other provisions that are reasonably satisfactory to the Collateral Agent that are consistent with clause (i) and clause (ii) above.

"Account" is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"Account Debtor" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

"Acquisition of Borrower" is defined in Section 7.2.

“**Affiliate**” of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person’s senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person’s managers and members.

“**Agreement**” is defined in the preamble hereof.

“**Amortization Date**” is April 1, 2029; provided, however, if Borrower achieves the Interest-Only Extension Milestone, then the Amortization Date with respect to all Term Loans shall automatically be extended to April 1, 2030.

“**Annual Projections**” is defined in Section 6.2(a).

“**Anti-Terrorism Laws**” are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

“**Applicable Product**” is defined in the definition of “Permitted Royalty Transaction”.

“**Applicable Synthetic Royalty Financer**” is defined in the definition of “Acceptable Intercreditor Agreement”.

“**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).

“**Approved Lender**” is defined in Section 12.1(a).

“**Basic Rate**” is with respect to each Term Loan, the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to (a) the greater of (i) the 1-Month CME Term SOFR on the last Business Day of the month that immediately precedes the month in which the interest will accrue and (ii) three percent (3.00%), plus (b) five and one half of one percent (5.50%). Notwithstanding the foregoing, (i) in no event shall the Basic Rate for any Term Loan be less than eight and one half of one percent (8.50%), (ii) upon the occurrence of a Benchmark Transition Event, Collateral Agent may, in good faith and with reference to the margin above such interest rate in this definition, amend this Agreement to replace the Benchmark with a replacement interest rate and replacement margin above such interest rate that results in a substantially similar interest rate floor and total rate in effect immediately prior to the effectiveness of such replacement interest rate and replacement margin, and any such amendment shall become effective at 5:00 p.m. Eastern time on the third Business Day after Collateral Agent has notified Borrower of such amendment, and (iii) the Basic Rate for the Term A Loan for the period from the Effective Date through and including February 28, 2025 shall be 9.81308%. Any determination, decision or election that may be made by Collateral Agent pursuant hereto will be conclusive and binding absent manifest error and may be made in Collateral Agent’s sole discretion in good faith and without consent from any other party.

“**Benchmark**” is, initially, the 1-Month CME Term SOFR; provided, that if a Benchmark Transition Event has occurred with respect to the 1-Month CME Term SOFR or the then-current Benchmark, then “Benchmark” means the applicable replacement rate that has replaced the immediately preceding benchmark rate pursuant to the defined term “Basic Rate”.

“**Benchmark Transition Event**” means the occurrence of one or more of the following events with respect to the then-current Benchmark:

(a) a public statement or publication of information by or on behalf of the administrator for such Benchmark announcing that such Person has ceased or will cease to provide such Benchmark, permanently or

indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide such Benchmark;

(b) a public statement or publication of information by the regulatory supervisor for the administrator for such Benchmark, the U.S. Federal Reserve System, an insolvency official with jurisdiction over the administrator for such Benchmark, a resolution authority with jurisdiction over the administrator for such Benchmark or a court or an entity with similar insolvency or resolution authority over the administrator for such Benchmark, which states that the administrator for such Benchmark has ceased or will cease to provide such Benchmark permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide such Benchmark; or

(c) a public statement or publication of information by the regulatory supervisor for the administrator for such Benchmark announcing that such Benchmark is no longer representative or in compliance with the International Organization of Securities Commissions Principles for Financial Benchmarks.

“Biologics License Application” means an application for licensure of a biological product submitted to the FDA under 42 U.S.C. § 262(a) for permission to introduce, or deliver for introduction, a biological product into interstate commerce.

“Blocked Person” is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports “terrorism” as defined in Executive Order No. 13224, or (e) a Person that is named a “specially designated national” or “blocked person” on the most current list published by OFAC or other similar list.

“Borrower” is defined in the preamble hereof.

“Borrower’s Books” are Borrower’s or any of its Subsidiaries’ books and records including ledgers, federal, and state tax returns, records regarding Borrower’s or its Subsidiaries’ assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

“Business Day” is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed.

“Cash Equivalents” are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor’s Ratings Group or Moody’s Investors Service, Inc., (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent, and (d) money market funds at least ninety-five percent (95.00%) of the assets of which constitute Cash Equivalents of the kinds described in clauses (a) through (c) of this definition. For the avoidance of doubt, the direct purchase by Borrower or any of its Subsidiaries of any Auction Rate Securities, or purchasing participations in, or entering into any type of swap or other derivative transaction, or otherwise holding or engaging in any ownership interest in any type of Auction Rate Security by Borrower or any of its Subsidiaries shall be conclusively determined by the Lenders as an ineligible Cash Equivalent, and any such transaction shall expressly violate each other provision of this Agreement governing Permitted Investments. Notwithstanding the foregoing, Cash Equivalents does not include and Borrower, and each of its Subsidiaries, are prohibited from purchasing, purchasing participations in, entering into any type of swap or other equivalent derivative transaction, or otherwise holding or engaging in any ownership interest in any type of debt instrument, including, without limitation, any corporate or municipal bonds with a long-term nominal maturity for which the interest rate is reset through a Dutch auction and more commonly referred to as an auction rate security (each, an **“Auction Rate Security”**).

“Claims” are defined in Section 12.2.

“**CME Term SOFR Administrator**” is CME Group Benchmark Administration Limited, as administrator of the forward-looking term SOFR, or any successor administrator.

“**CME Term SOFR Administrator’s Website**” is the website of the CME Group Benchmark Administrator at <http://www.cmegroup.com>, or any successor source.

“**Code**” is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles of the Code, the definition of such term contained in Article 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent’s Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term “Code” shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

“**Collateral**” is any and all properties, rights and assets of Borrower described on Exhibit A.

“**Collateral Account**” is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

“**Collateral Agent**” is, Oxford, not in its individual capacity, but solely in its capacity as agent on behalf of and for the benefit of the Lenders.

“**Commitment Percentage**” is set forth in Schedule 1.1, as amended from time to time.

“**Commodity Account**” is any “commodity account” as defined in the Code with such additions to such term as may hereafter be made.

“**Communication**” is defined in Section 10.

“**Compliance Certificate**” is that certain certificate in the form attached hereto as Exhibit C.

“**Contingent Obligation**” is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but “Contingent Obligation” does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

“**Control Agreement**” is any control agreement entered into among the depository institution at which Borrower or any other Loan Party maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or such Loan Party maintains a Securities Account or a Commodity Account, Borrower or such Loan Party, and Collateral Agent pursuant to which Collateral Agent obtains control (within the meaning of the Code) for the benefit of the Lenders over such Deposit Account, Securities Account, or Commodity Account; provided that in the case of any Foreign Subsidiary that is a Loan Party, “Control Agreement” shall mean such other appropriate instrument with respect to such Collateral Account to the extent necessary under applicable law to perfect the Collateral Agent’s Lien in such Collateral Account.

“Copyrights” are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

“Credit Extension” is any Term Loan or any other extension of credit by Collateral Agent or Lenders for Borrower’s benefit.

“Declined Royalty Transaction” means a proposed Permitted Royalty Transaction that (i) is structured as a true sale royalty transaction, (ii) satisfies the conditions of clauses (i) through (iv) of the definition of Permitted Royalty Transaction, and (iii) (A) unless Collateral Agent has previously notified Borrower in writing that Collateral Agent or a Lender will not agree to the terms of such Permitted Royalty Transaction, does not satisfy the condition of clause (v) of the definition of Permitted Royalty Transaction as confirmed by Collateral Agent to Borrower in writing within five (5) Business Days after Borrower requests such confirmation so long as Borrower has provided final transaction documents with respect to such Permitted Royalty Transaction between Borrower and the acquiror or financier to such Permitted Royalty Transaction to Collateral Agent, and Borrower certifies to Collateral Agent that such acquiror or financier to such Permitted Royalty Transaction has considered Collateral Agent’s comments (if any) to such Permitted Royalty Transaction, and (B) is consummated within thirty (30) days (or such longer period as consented to by Collateral Agent in its sole discretion) after Borrower’s receipt of such confirmation from Collateral Agent.

“Default Rate” is defined in Section 2.3(b).

“Deposit Account” is any “deposit account” as defined in the Code with such additions to such term as may hereafter be made.

“Designated Deposit Account” is Borrower’s deposit account, account number ending in 5801, maintained with SVB, or such other deposit account of Borrower designated as such to the Collateral Agent in writing after the Effective Date.

“Disbursement Letter” is that certain form attached hereto as Exhibit B.

“Division” means, in reference to any Person which is an entity, the division of such Person into two (2) or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, or any analogous action taken pursuant to any other applicable law with respect to any corporation, limited liability company, partnership or other entity.

“Dollars,” “dollars” and **“\$”** each mean lawful money of the United States.

“Effective Date” is defined in the preamble of this Agreement.

“Effective Date Accrued Final Payment” is defined in Section 2.5(h).

“Eligible Assignee” is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an “accredited investor” (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor’s Rating Group and a rating of Baa2 or higher from Moody’s Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Five Billion Dollars (\$5,000,000,000.00), and in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar taxes; provided that notwithstanding the foregoing, “Eligible Assignee” shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower’s Affiliates or Subsidiaries or (ii) a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent. Notwithstanding the foregoing, (x) in connection with assignments by a Lender due to a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection

with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

"Equipment" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"ERISA" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"Excluded Assets" means the assets of Borrower that will no longer remain Collateral upon the consummation of a Permitted Royalty Transaction, which, for the avoidance of doubt, shall not include Intellectual Property except to the extent provided in the definition of Acceptable Intercreditor Agreement.

"Event of Default" is defined in Section 8.

"FDA" means the U.S. Food and Drug Administration or any successor thereto.

"Final Payment" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d), equal to the original principal amount of such Term Loan advanced to Borrower multiplied by the Final Payment Percentage, payable to Lenders in accordance with their respective Pro Rata Shares.

"Final Payment Percentage" is two percent (2.00%).

"First Interest-Only Extension Milestone Fee" is a fee, due and payable to the Lenders in accordance with their respective Pro Rata Shares, in an aggregate amount equal to Thirty Thousand Dollars (\$30,000.00), which was paid on the Fourth Amendment Effective Date.

"Foreign Subsidiary" is a Subsidiary that is not an entity organized under the laws of the United States or any territory thereof.

"Foreign Subsidiary Trigger Event" means the occurrence of either of the following:

(a) as of the end of any fiscal quarter of Borrower that ends after [***], if Net Product Revenue (as determined in accordance with GAAP) of Borrower and its Subsidiaries generated, sourced and received by such Persons in the United States of America for the four fiscal quarter period ending as of such date is less than [***], the Net Product Revenue (as determined in accordance with GAAP) of Borrower and its Subsidiaries generated, sourced and received by such Persons from countries outside of the United States of America for such four fiscal quarter period exceed [***] of the worldwide Net Product Revenue (as determined in accordance with GAAP) of Borrower and its Subsidiaries for such four fiscal quarter period; or

(b) as of the end of any fiscal quarter of Borrower that ends after [***], if Net Product Revenue (as determined in accordance with GAAP) of Borrower and its Subsidiaries generated, sourced and received by such Persons in the United States of America for the four fiscal quarter period ending as of such date is greater than or equal to [***], the Net Product Revenue (as determined in accordance with GAAP) of Borrower and its Subsidiaries generated, sourced and received by such Persons from countries outside of the United States of America for such four fiscal quarter period exceed [***] of the worldwide Net Product Revenue (as determined in accordance with GAAP)

of Borrower and its Subsidiaries for such four fiscal quarter period.

“**Fourth Amendment**” means that certain Fourth Amendment to Loan and Security Agreement, dated as of the Fourth Amendment Effective Date, by and among Borrower, Parent, Oxford as a lender and Collateral Agent, SVB as a lender and the other Lenders party thereto.

“**Fourth Amendment Effective Date**” is May 17, 2024.

“**Funding Date**” is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

“**GAAP**” is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

“**General Intangibles**” are all “general intangibles” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

“**Governmental Approval**” is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

“**Governmental Authority**” is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

“**Guarantor**” is any Person providing a Guaranty in favor of Collateral Agent.

“**Guaranty**” is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

“**Indebtedness**” is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

“**Indemnified Person**” is defined in Section 12.2.

“**Insolvency Proceeding**” is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

“**Insolvent**” means not Solvent.

“Intellectual Property” means all of Borrower’s or any Subsidiary’s right, title and interest in and to the following:

- (a) its Copyrights, Trademarks and Patents;
- (b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;
- (c) any and all source code;
- (d) any and all design rights which may be available to Borrower;
- (e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and
- (f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

“Interest-Only Extension Milestone” is Borrower’s delivery to Collateral Agent of [***], that is equal to or greater than [***].

“Inventory” is all “inventory” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person’s custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

“Investment” is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance, payment or capital contribution to any Person.

“IP Agreement” is any Intellectual Property Security Agreement entered into by and between Borrower and Collateral Agent, as such may be amended from time to time.

“IP Trigger Event” means the earlier to occur of (a) the outstanding principal balance of the Term Loans exceeds One Hundred One Million Dollars (\$101,000,000.00) and (b) Borrower enters into a binding and enforceable Permitted Royalty Financing Transaction; provided, however, for the avoidance of doubt, that no IP Trigger Event shall occur under clause (a) of this definition as a result of any accrual or capitalization of any interest, fees or other amounts with respect to any Term Loan.

“IRC” means the Internal Revenue Code of 1986, as amended, and Treasury Regulations thereunder.

“Key Person” is each of Borrower’s (i) President and Chief Executive Officer, (ii) Chief Financial Officer, and (iii) Chief Medical Officer.

“Lender” is any one of the Lenders.

“Lender Transfer” is defined in Section 12.1(a).

“Lenders” are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1(a).

“Lenders’ Expenses” are all audit fees and expenses, costs, and expenses (including reasonable attorneys’ fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without

limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

“**Lien**” is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

“**Loan Documents**” are, collectively, this Agreement, the Perfection Certificates, each Compliance Certificate, each Disbursement Letter, each Guaranty, each IP Agreement, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

“**Loan Party**” means any Borrower and any Guarantor.

“**Market Capitalization**” means, as of any date of determination, the product of (a) the number of Parent’s shares of common stock outstanding on such date of determination and (b) the closing price of one share of Parent’s common stock as quoted on www.nasdaq.com or, if such page is not available, any other commercially available source providing quotations of such closing price as reasonably selected by Parent, on such date of determination.

“**Material Adverse Change**” is (a) a material impairment in the perfection or priority of Collateral Agent’s Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or financial condition of Borrower or Borrower and its Subsidiaries (taken as a whole); or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

“**Maturity Date**” is, for each Term Loan, February 1, 2030; provided, however, if Borrower achieves the Interest-Only Extension Milestone, then the Maturity Date is automatically extended to February 1, 2031.

“**MSC Subsidiary**” means Scholar Rock Securities Corporation, a Subsidiary of Parent that is a corporation that qualifies as a Massachusetts securities corporation by meeting the requirements of Chapter 63, Section 38B of the Massachusetts General Laws.

“**Net Product Revenue**” means net product revenue (as determined in accordance with GAAP) from the sale of any products or services of Borrower or its Subsidiaries, including sales-based royalty revenue (regardless of whether such payments are included as product revenue as determined in accordance with GAAP) but excluding any upfront or milestone payments under royalty, profit sharing, business development or licensing transactions.

“**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, the First Interest-Only Extension Milestone Fee 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.

“**OFAC**” is the U.S. Department of Treasury Office of Foreign Assets Control.

“**OFAC Lists**” are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

“**Operating Documents**” are, for any Person, such Person’s formation documents, as certified by the Secretary of State (or equivalent agency) of such Person’s jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if

such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

“Original Closing Date” is October 16, 2020.

“Original Term Loan” is defined in Section 2.2(a)(i) hereof.

“Parent” is defined in the preamble hereof.

“Participant Register” is defined in Section 12.1(b).

“Patents” means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

“Payment Date” is the first (1st) calendar day of each calendar month, commencing on April 1, 2025.

“Perfection Certificate” and **“Perfection Certificates”** is defined in Section 5.1.

“Permitted Indebtedness” is:

(a) Borrower’s Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificates;

(c) Subordinated Debt;

(d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Five Hundred Thousand Dollars (\$500,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower’s business;

(g) Indebtedness in respect of letters of credit and similar obligations related to real estate leases in the ordinary course of business in an aggregate amount not to exceed Two Million Seven Hundred Thousand Dollars (\$2,700,000.00) at any time;

(h) other unsecured Indebtedness in an aggregate amount outstanding at any time not to exceed Five Hundred Thousand Dollars (\$500,000.00);

(i) Indebtedness incurred in the Permitted Royalty Transaction that is if a synthetic royalty, (i) subject to an Acceptable Intercreditor Agreement and (ii) solely to the extent structured to have a maturity date, does not have a scheduled maturity date earlier than ninety-one (91) days after the Maturity Date;

(j) to the extent constituting Indebtedness, Permitted Investments; and

(k) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (j) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

“Permitted Investments” are:

- (a) Investments disclosed on the Perfection Certificates and existing on the Effective Date;
- (b) (i) Investments consisting of cash and Cash Equivalents, and (ii) any other Investments permitted by Borrower’s investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;
- (c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower’s business;
- (d) Investments consisting of deposit accounts in which Collateral Agent has a perfected security interest or which are otherwise maintained in compliance with Section 6.6;
- (e) Investments in connection with Transfers permitted by Section 7.1;
- (f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Parent’s Board of Directors; not to exceed One Hundred Thousand Dollars (\$100,000.00) in the aggregate for (i) and (ii) in any fiscal year;
- (g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;
- (h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary;
- (i) non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower’s business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support;
- (j) Investments in MSC Subsidiary;
- (k) Investments by (i) Borrower in any Subsidiary which is a Borrower hereunder or a Guarantor and (ii) any Subsidiary in Borrower or a Guarantor;
- (l) prior to the Foreign Subsidiary Trigger Event and so long as Borrower is in compliance with Section 6.6(a), Investments (including, for the avoidance of doubt, transfer pricing, cost plus or similar arrangements with Foreign Subsidiaries in the ordinary course of business to the extent constituting Investments) by Borrower or its Subsidiaries in Foreign Subsidiaries; and
- (m) to the extent more than one of the Borrowers and any of their Subsidiaries holds the assets related to any Permitted Royalty Transaction, Investments by such Persons in connection therewith.

“Permitted Licenses” are (A) licenses of over-the-counter software that is commercially available to the public, (B) non-exclusive and exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described

in clause (B), (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face (in each case, other than non-exclusive licenses from or to contract manufacturers, clinical research organizations, clinical trial or research sites, service providers and other entities (A) entered into in the ordinary course of business, (B) the principal purpose of which does not include the acquisition of licensing rights, but which contain such non-exclusive licenses merely ancillary to, and for the limited purpose of, facilitating the principal purposes of the agreement and (C) so long as Borrower has complied with all other applicable terms of the Loan Documents applicable thereto), do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; (iii) in the case of any exclusive license, (x) Borrower delivers ten (10) days' prior written notice and a brief summary of the terms of the proposed license to Collateral Agent and the Lenders and delivers copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, and (y) any such license could not result in a legal transfer of title of the licensed property but may be exclusive in respects other than territory and may be exclusive as to territory only as to discrete geographical areas outside of the United States; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower are paid to a Deposit Account that is governed by a Control Agreement (except in connection with a Permitted Royalty Transaction that is not otherwise restricted by any applicable Acceptable Intercreditor Agreement), and (C) any other ancillary license provided in connection with a Permitted Royalty Transaction structured as a synthetic royalty transaction that is in form and substance reasonably satisfactory to the Collateral Agent and otherwise satisfies the conditions of clauses (B)(i) through (iii) hereof (unless otherwise reasonably agreed by the Collateral Agent with respect to clause (B)(ii) in connection with any negative lien covenant provided in any such synthetic royalty transaction (subject to such covenant expressly permitted the Collateral Agent's Liens under the Loan Documents)).

"Permitted Liens" are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the IRC;

(c) liens securing Indebtedness permitted under clause (e) of the definition of **"Permitted Indebtedness,"** provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such Liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed One Hundred Thousand Dollars (\$100,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if

the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(b) hereof;

(i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;

(j) Liens securing Indebtedness permitted under clause (g) of the definition of "Permitted Indebtedness";

(k) Liens consisting of landlord liens, so long as each such landlord is party to a landlord agreement in favor of Collateral Agent, in form and substance reasonably satisfactory to Collateral Agent;

(l) Liens consisting of Permitted Licenses;

(m) Liens (including priority Liens) provided in connection with a Permitted Royalty Transaction; provided that no Liens shall be granted with respect to any Intellectual Property of Borrower or its Subsidiaries except in the case of a Permitted Royalty Transaction structured as a synthetic royalty transaction that is subject to an Acceptable Intercreditor Agreement; and

(n) to the extent constituting Liens, the ownership interest of any joint owners in any patents listed in a Perfection Certificate as being jointly owned or co-owned.

"Permitted Royalty Transaction" means the purchase of (or a financing with respect to) a royalty interest, or a revenue interest financing of, the Borrower's rights in Apitegromab in spinal muscular atrophy (the **"Applicable Product"**), provided that (i) such transaction constitutes an arms-length transaction (the terms of which, on their face, do not provide for a sale or collateral assignment of any Intellectual Property other than (A) a second priority Lien and collateral assignment of Intellectual Property solely underlying the Applicable Product may be provided in connection with such transaction that is structured as a synthetic royalty transaction to the extent such transaction is subject to an Acceptable Intercreditor Agreement and (B) any Permitted License, (ii) Borrower receives upfront and unrestricted (including, not subject to any redemption, clawback, escrow or similar encumbrance or restriction) gross cash payments of at least One Hundred Fifty Million Dollars (\$150,000,000.00), (iii) such transaction encumbers (with respect to a synthetic royalty transaction) or sells (with respect to a true sale royalty transaction) not more than ten percent (10.00%) of Borrower's projected revenues from the Applicable Product, (iv) no Event of Default has occurred and is continuing at the time of entering such transaction, and (v) the royalty or revenue interest agreement and related material documents, including the assets that comprise the Excluded Assets, are otherwise in form and substance reasonably satisfactory to the Collateral Agent (it being understood, for the avoidance of doubt, that an Acceptable Intercreditor Agreement shall only be required with respect to such transaction that is structured as a synthetic royalty transaction).

"Person" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"Post Closing Letter" is that certain Post Closing Letter dated as of the Effective Date by and between Collateral Agent and Borrower.

"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) for a prepayment made on or after the Funding Date of such Term Loan through and including the first anniversary of the Funding Date of such Term Loan, one and one half of one percent (1.50%) of the principal amount of such Term Loan prepaid; provided, however, (A) if such prepayment is made immediately prior to and concurrently with an Acquisition of Borrower or an acquisition of all or substantially all of the assets of Borrower or (B) if such prepayment is made immediately prior to, substantially concurrently with (not to exceed five (5) Business Days) or concurrently with the consummation of a Declined Royalty Transaction, such Prepayment Fee shall be one percent (1.00%) 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 Funding Date of such Term Loan through and including the second anniversary of the Funding Date of such Term Loan, one percent (1.00%) of the principal amount of such Term Loan prepaid; provided, however, if such prepayment is made immediately prior to, substantially concurrently with (not to exceed five (5) Business Days) or concurrently with the consummation of a Declined Royalty Transaction, such Prepayment Fee shall be one half of one percent (0.50%) of the principal amount of such Term Loan prepaid;

(iii) for a prepayment made after the date which is after the second anniversary of the Funding Date of such Term Loan through and including the third anniversary of the Funding Date of such Term Loan, one half of one percent (0.50%) of the principal amount of such Term Loan prepaid; provided, however, if such prepayment is made immediately prior to, substantially concurrently with (not to exceed five (5) Business Days) or concurrently with the consummation of a Declined Royalty Transaction, such Prepayment Fee shall be zero percent (0.00%) of the principal amount of such Term Loan prepaid; and

(iv) for a prepayment made after the date which is after the third anniversary of the Funding of such Term Loan, zero percent (0.00%) of the principal amount of such Term Loan prepaid.

“**Prior Agreement**” is defined in the preamble hereof.

“**Pro Rata Share**” is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

“**Register**” is defined in Section 12.1(b).

“**Registered Organization**” is any “registered organization” as defined in the Code with such additions to such term as may hereafter be made.

“**Required Lenders**” means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an “**Original Lender**”) have not assigned or transferred any of their interests in their Term Loan, Lenders holding one hundred percent (100.00%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66.00%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender’s interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

“**Requirement of Law**” is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

“**Responsible Officer**” is any of the President, Chief Executive Officer, Chief Financial Officer or General Counsel of Borrower acting alone.

“**Scholar Rock Netherlands**” means Scholar Rock Netherlands B.V., a private limited company incorporated under the laws of the Netherlands.

“**Second Amendment Effective Date**” is November 10, 2022.

“**Secured Promissory Note**” is defined in Section 2.4.

“**Secured Promissory Note Record**” is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

“**Securities Account**” is any “securities account” as defined in the Code with such additions to such term as may hereafter be made.

“**Shares**” is one hundred percent (100.00%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or Borrower’s Subsidiary, in any Subsidiary; provided that, in the event Borrower demonstrates to Collateral Agent’s reasonable satisfaction that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary which is a Foreign Subsidiary creates a present and existing adverse tax consequence to Borrower under the IRC, “Shares” shall mean sixty-five percent (65%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or its Subsidiary in such Foreign Subsidiary.

“**Solvent**” is, with respect to any Person: the fair salable value of such Person’s consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person’s liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

“**Subordinated Debt**” is indebtedness for borrowed money incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance reasonably satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms reasonably acceptable to Collateral Agent and the Lenders; provided that, notwithstanding anything to the contrary in this Agreement or any other Loan Document, no Permitted Royalty Transaction (or any obligations or liabilities with respect thereto) shall be deemed to be Subordinated Debt.

“**Subsidiary**” is, with respect to any Person, any Person of which more than fifty percent (50.00%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

“**SVB**” is Silicon Valley Bank, a division of First-Citizens Bank & Trust Company.

“**Taxes**” is defined in Section 2.6.

“**Tax Distributions**” means for any taxable period in which Borrower is a member of a consolidated, combined, unitary or similar group for U.S. federal and applicable state and local income Tax purposes, distributions to the common parent of such consolidated, combined, unitary or similar group to permit such common parent to pay (a) Taxes then due and owing by such common parent on behalf of such consolidated, combined, unitary or similar group and (b) franchise Taxes and other similar fees, Taxes (other than income Taxes) imposed on it and expenses required to maintain the corporate existence such common parent and any intermediate holding companies in the chain of ownership between Borrower and such common parent.

“**Term A-1 Loan**” is defined in Section 2.2(a)(i).

“**Term A-2 Loan**” is defined in Section 2.2(a)(i).

“**Term A Loan**” is defined in Section 2.2(a)(i).

“**Term B Draw Period**” is the period commencing on the Effective Date and ending on the earlier of (i) December 31, 2025 and (ii) the occurrence of an Event of Default.

“**Term B Loan**” is defined in Section 2.2(a)(ii).

“**Term C Draw Period**” is the period commencing on the date of the occurrence of the Term C Milestone and ending on the earliest of (i) September 30, 2026, (ii) the date that is ninety (90) days after the achievement of the Term C Milestone and (iii) the occurrence of an Event of Default; provided, however, that the Term C Draw Period shall not commence if on the date of the occurrence of the Term C Milestone an Event of Default has occurred and is continuing.

“**Term C Loan**” is defined in Section 2.2(a)(iii).

“**Term C Milestone**” is Borrower’s delivery to Collateral Agent and Lenders of evidence reasonably satisfactory to Collateral Agent and the Lenders that Borrower has received a Biologics License Application approval of Apatemab in spinal muscular atrophy.

“**Term D Draw Period**” is the period commencing on the date of the occurrence of the Interest-Only Extension Milestone and ending on the earliest of (i) December 31, 2027, (ii) the date that is ninety (90) days after the achievement of the Interest-Only Extension 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 Interest-Only Extension Milestone an Event of Default has occurred and is continuing.

“**Term D Loan**” is defined in Section 2.2(a)(iv).

“**Term Loan**” is defined in Section 2.2(a)(iv).

“**Term Loan Commitment**” is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on Schedule 1.1. “**Term Loan Commitments**” means the aggregate amount of such commitments of all Lenders.

“**Testing Date**” is defined in Section 6.10.

“**Trademarks**” means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

“**Transfer**” is defined in Section 7.1.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

SCHOLAR ROCK HOLDING CORPORATION

By _____
Name: _____
Title: _____

SCHOLAR ROCK, INC.

By _____
Name: _____
Title: _____

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By _____
Name: _____
Title: _____

LENDERS:

OXFORD FINANCE FUNDING XIII, LLC

By: Oxford Finance LLC, as servicer

By _____
Name: _____
Title: _____

OXFORD FINANCE FUNDING IX, LLC

By: Oxford Finance LLC, as servicer

By _____
Name: _____
Title: _____

OXFORD FINANCE FUNDING 2023-1, LLC

By: Oxford Finance LLC, as servicer

By _____
Name: _____
Title: _____

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LENDERS:

OXFORD FINANCE CREDIT FUND II LP

By: Oxford Finance Advisors, LLC, as manager

By _____

Name: _____

Title: _____

OXFORD FINANCE CREDIT FUND III LP

By: Oxford Finance Advisors, LLC, as manager

By _____

Name: _____

Title: _____

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SCHEDULE 1.1

Lenders and Commitments**Term A-1 Loans**

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE FUNDING XIII, LLC	\$12,500,000.00	50.00%
OXFORD FINANCE FUNDING IX, LLC	\$6,500,000.00	26.00%
OXFORD FINANCE FUNDING 2023-1, LLC	\$6,000,000.00	24.00%
TOTAL	\$25,000,000.00	100.00%

Term A-2 Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$19,375,000.00	77.50%
OXFORD FINANCE CREDIT FUND II LP	\$1,875,000.00	7.50%
OXFORD FINANCE CREDIT FUND III LP	\$3,750,000.00	15.00%
TOTAL	\$25,000,000.00	100.00%

Term B Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$50,000,000.00	100.00%
TOTAL	\$50,000,000.00	100.00%

Term C Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$50,000,000.00	100.00%
TOTAL	\$50,000,000.00	100.00%

Term D Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$50,000,000.00	100.00%
TOTAL	\$50,000,000.00	100.00%

Aggregate (all Term Loans)

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE FUNDING XIII, LLC	\$12,500,000.00	6.2500%
OXFORD FINANCE FUNDING IX, LLC	\$6,500,000.00	3.2500%
OXFORD FINANCE FUNDING 2023-1, LLC	\$6,000,000.00	3.0000%
OXFORD FINANCE LLC	\$169,375,000.00	84.6875%
OXFORD FINANCE CREDIT FUND II LP	\$1,875,000.00	0.9375%
OXFORD FINANCE CREDIT FUND III LP	\$3,750,000.00	1.8750%
TOTAL	\$200,000,000.00	100.00%

EXHIBIT A

Description of Collateral

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (including Intellectual Property from and after the date on which the IP Trigger Event occurs), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (a)(i) any Equipment or other property financed by a third party, provided that such third party's Liens are Liens of the type described in subsection (c) of the definition of Permitted Liens if the granting of a Lien in such Equipment or other property financed is prohibited by or would constitute a default under any agreement or document governing such Equipment or property financed; provided that the aggregate value of all such Equipment or property financed does not exceed Five Hundred Thousand Dollars (\$500,000.00); provided further that upon the termination, lapsing or expiration of any such prohibition, such Equipment or other property financed, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral"; (ii) any lease, license or contract, in each case if the granting of a Lien in such lease, license or contract is prohibited by or would constitute a default under the agreement governing such lease, license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Article 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such lease, license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral"; and (iii) until the date on which an IP Trigger Event occurs, any Intellectual Property; provided, however, (A) the Collateral shall include all Accounts (other than as set forth in clause (b) directly below) and all proceeds of Intellectual Property and (B) if a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; and (b) from and after the date that any Permitted Royalty Transaction is consummated, the Excluded Assets with respect to such Permitted Royalty Transaction.

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Borrower has agreed not to encumber any of its Intellectual Property except in connection with any Permitted Royalty Transaction to the extent permitted by the A&R Loan Agreement (as defined below) and, if applicable, the Acceptable Intercreditor Agreement with respect to such Permitted Royalty Transaction.

Capitalized terms used herein without definition shall have the meaning set forth in that certain Amended and Restated Loan and Security Agreement (the "A&R Loan Agreement") to which this Exhibit A is attached.

EXHIBIT B

Form of Disbursement Letter

[see attached]

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DISBURSEMENT LETTER

February 10, 2025

The undersigned, being the duly elected and acting _____ of 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 does hereby certify to OXFORD FINANCE LLC (as collateral agent acting on behalf of the Lenders (as defined in the Loan Agreement) from time to time party to the Loan Agreement (as defined below), the "**Collateral Agent**") in connection with that certain Amended and Restated Loan and Security Agreement dated as of February 10, 2025, by and among Borrower, Collateral Agent and the Lenders from time to time party thereto (the "**Loan Agreement**"; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof.
2. No event or condition has occurred and is continuing that would constitute an Event of Default under the Loan Agreement or any other Loan Document.
3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.
4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.
5. No Material Adverse Change has occurred.
6. The undersigned is a Responsible Officer.

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7. The proceeds of the Term [A-2][B][C][D] Loan shall be disbursed as follows:

Disbursement from Collateral Agent:

Loan Amount \$ _____

Plus:

Less:

--Interim Interest (\$ _____)

--Lender's Legal Fees (\$ _____)*

Net Proceeds due from Collateral Agent: \$ _____

**TOTAL TERM [A-2][B][C][D] LOAN NET
PROCEEDS FROM COLLATERAL AGENT** \$ _____

8. The Term [A-2][B][C][D] Loan shall amortize in accordance with the Amortization Table attached hereto.

9. The aggregate net proceeds of the Term Loans shall be transferred to the Designated Deposit Account as follows:

Account Name: SCHOLAR ROCK, INC.
Bank Name: Silicon Valley Bank, a division of First-Citizens Bank
& Trust Company
Bank Address: 3003 Tasman Drive
Santa Clara, California 95054
Beneficiary Address: 301 Binney Street, 3rd Floor, Cambridge, MA 02142
Account Number: 3301055801
ABA Number: 121140399

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* Legal fees and costs are through the Effective Date. Post-closing legal fees and costs, payable after the Effective Date, to be invoiced and paid post-closing.

Dated as of the date first set forth above.

BORROWER:

SCHOLAR ROCK HOLDING CORPORATION

By _____
Name: _____
Title: _____

SCHOLAR ROCK, INC.

By _____
Name: _____
Title: _____

**COLLATERAL AGENT ON BEHALF OF
LENDERS:**

OXFORD FINANCE LLC

By _____
Name: _____
Title: _____

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AMORTIZATION TABLE
(Term [A-2][B][C][D] Loan)

[see attached]

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EXHIBIT C

Compliance Certificate

TO: OXFORD FINANCE LLC, as Collateral Agent and Lender
OXFORD FINANCE CREDIT FUND II LP, as Lender
OXFORD FINANCE CREDIT FUND III LP, as Lender

FROM: SCHOLAR ROCK HOLDING CORPORATION and SCHOLAR ROCK, INC.

The undersigned authorized officer (“**Officer**”) of SCHOLAR ROCK HOLDING CORPORATION (“**Parent**”) and SCHOLAR ROCK, INC. (together with Parent, individually and collectively, jointly and severally, “**Borrower**”), hereby certifies (in such officer capacity and not in an individual capacity) that in accordance with the terms and conditions of the Amended and Restated Loan and Security Agreement, dated as of February 10, 2025, by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the “**Loan Agreement**,” capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

(a) Borrower is in compliance for the period ending _____ with all required covenants except as noted below;

(b) There are no Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

(d) Borrower, and each of Borrower’s Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower’s Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except, in each case, as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under “Complies” column.

	Reporting Covenant	Requirement	Actual	Complies		
1)	Financial statements	Quarterly within 45 days	Yes	No	N/A	
2)	Annual (CPA Audited) statements	Within earlier of (i) 90 days after FYE and (ii) 5 days of filing with SEC	Yes	No	N/A	

3)	Annual Financial Projections/Budget (prepared on a quarterly basis)	Annually (within 60 days of FYE), and when revised	Yes	No	N/A
4)	A/R & A/P agings	If applicable	Yes	No	N/A
5)	8-K, 10-K and 10-Q Filings	If applicable, within 5 days of filing	Yes	No	N/A
6)	Compliance Certificate	Quarterly within 45 days	Yes	No	N/A
7)	IP Report	When required	Yes	No	N/A
8)	Total amount of Borrower's cash and Cash Equivalents at the last day of the measurement period	\$ _____	Yes	No	N/A
9)	Total amount of Borrower's Subsidiaries' cash and Cash Equivalents at the last day of the measurement period	\$ _____	Yes	No	N/A

Deposit and Securities Accounts

(Please list all accounts; attach separate sheet if additional space needed)

	Institution Name	Account Number	New Account?		Account Control Agreement in place?	
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No

Financial Covenant (Section 6.10)¹

(Please attach a separate sheet with supporting detail)

- 1) Was the aggregate amount of Borrower's unrestricted (other than Permitted Liens) cash, Cash Equivalents and marketable securities maintained in Collateral Accounts subject to a Control Agreement in favor of Collateral Agent less than 75.00% of the outstanding principal balance of the Term Loans at any time during the applicable fiscal quarter?

	Yes	No
--	-----	----
- 2) Was the Market Capitalization less than \$800,000,000.00 at any time during the applicable fiscal quarter?

	Yes	No
--	-----	----
- 3) If you did not answer yes to both Question 1 and Question 2, then the financial covenant for such Testing Date is **waived** and you do not need to answer this Question 3 or Question 4. If you answered yes to both Question 1 and Question 2, the Net Product Revenue of Borrower (calculated on a trailing six (6) month basis) as of such Testing Date is \$ _____ and the Net Product Revenue set forth in Annex A for such Testing Date is \$ _____.
- 4) If you did not answer yes to both Question 1 and Question 2, then the financial covenant for such Testing Date is **waived** and you do not need to answer Question 3 above or this Question 4. If you answered yes to both Question 1 and Question 2 above, did Borrower have Net Product Revenue (calculated on a trailing six (6) month basis) as of such Testing

	Yes	No
--	-----	----

¹ To be completed in the Compliance Certificate for the month ending March 31, 2027 and on the last day of the month of each fiscal quarter thereafter.

Date of at least the amount set forth in Annex A for such Testing Date and therefore Borrower is in compliance with Section 6.10?

Other Matters

- | | | | |
|----|---|-----|----|
| 1) | Have there been any changes in management since the last Compliance Certificate? | Yes | No |
| 2) | Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement? | Yes | No |
| 3) | Have there been any new or pending claims or causes of action against Borrower that involve more than One Million Dollars (\$1,000,000.00)? | Yes | No |
| 4) | Have there been any material changes to the capitalization table of Borrower or any amendments of the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate. | Yes | No |
| 5) | Have there been any new licenses or agreements pursuant to which Borrower or any Subsidiary is the licensee as required by Section 5.2(d)? | Yes | No |
| 6) | Has the Foreign Subsidiary Trigger Event occurred? ² Please attach a separate sheet with supporting detail. | Yes | No |
| 7) | From and after the IP Trigger Event, please provide (a) a summary of any material change in the composition of the Intellectual Property, and (b) a report of the registered patents, trademarks, service marks, copyrights, mask works, or any pending applications for any of the foregoing, whether as owner, licensee or otherwise, by Borrower or any of its Subsidiaries, and noting any changes from the report provided for the prior fiscal quarter. | | |

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

SCHOLAR ROCK HOLDING CORPORATION

By _____
Name: _____
Title: _____

SCHOLAR ROCK, INC.

By _____
Name: _____
Title: _____

Date: _____

LENDER USE ONLY

Received by: _____ Date: ____

2 To be completed in the Compliance Certificate for the month ending March 31, 2027 and on the last day of the month of each fiscal quarter thereafter.

Verified by: _____

Date: ____

Compliance Status:
No

Yes

1615764111.13

EXHIBIT D

Form of Secured Promissory Note

[see attached]

1615764111.13

SECURED PROMISSORY NOTE
(Term [A][B][C][D] Loan)

\$ _____

Dated: [_____] [____], 20[____]

FOR VALUE RECEIVED, the undersigned, 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 (“**Borrower**”) HEREBY PROMISES TO PAY [OXFORD FINANCE LLC] [OXFORD FINANCE CREDIT FUND II LP] [OXFORD FINANCE CREDIT FUND III LP] (“**Lender**”) the principal amount of [_____] MILLION DOLLARS (\$_____) or such lesser amount as shall equal the outstanding principal balance of the Term [A][B][C][D] Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term [A][B][C][D] Loan, at the rates and in accordance with the terms of the Amended and Restated Loan and Security Agreement dated as of February 10, 2025 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the “**Loan Agreement**”). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term [A][B][C][D] Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this “**Note**”). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term [A][B][C][D] Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term [A][B][C][D] Loan, interest on the Term [A][B][C][D] Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable and documented out-of-pocket attorneys’ fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower’s obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

SCHOLAR ROCK HOLDING CORPORATION

By _____
Name: _____
Title: _____

SCHOLAR ROCK, INC.

By _____
Name: _____
Title: _____

1615764111.13

LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

<u>Date</u>	<u>Principal Amount</u>	<u>Interest Rate</u>	<u>Scheduled Payment Amount</u>	<u>Notation By</u>
-------------	-----------------------------	----------------------	-------------------------------------	--------------------

1615764111.13

CORPORATE BORROWING CERTIFICATE

BORROWER: SCHOLAR ROCK HOLDING CORPORATION

DATE: [_____]

LENDERS: OXFORD FINANCE LLC, as Collateral Agent and Lender
OXFORD FINANCE CREDIT FUND II LP, as Lender
OXFORD FINANCE CREDIT FUND III LP, as Lender

I hereby certify solely in my officer capacity and not any individual capacity as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.
2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.
3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Articles/Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.
4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

[Balance of Page Intentionally Left Blank]

1615764111.13

RESOLVED, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

<u>Name</u>	<u>Title</u>	<u>Signature</u>	Authorized to Add or Remove <u>Signatories</u>
			☐
			☐
			☐
			☐

RESOLVED FURTHER, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER, that such individuals may, on behalf of Borrower:

- Borrow Money.** Borrow money from the Lenders.
- Execute Loan Documents.** Execute any loan documents any Lender requires.
- Grant Security.** Grant Collateral Agent a security interest in any of Borrower’s assets.
- Negotiate Items.** Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.
- Further Acts.** Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower’s right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[Balance of Page Intentionally Left Blank]

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By:_____

Name:_____

Title: Secretary

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as
[print title]
of the date set forth above.

By:_____

Name:_____

Title:_____

1615764111.13

EXHIBIT A

Certificate of Incorporation (including amendments)

[see attached]

1615764111.13

EXHIBIT B

Bylaws

[see attached]

1615764111.13

CORPORATE BORROWING CERTIFICATE

BORROWER: SCHOLAR ROCK, INC.

DATE: [_____]

LENDERS: OXFORD FINANCE LLC, as Collateral Agent and Lender
OXFORD FINANCE CREDIT FUND II LP, as Lender
OXFORD FINANCE CREDIT FUND III LP, as Lender

I hereby certify solely in my officer capacity and not any individual capacity as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.
2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.
3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Articles/Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.
4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

[Balance of Page Intentionally Left Blank]

1615764111.13

RESOLVED, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

<u>Name</u>	<u>Title</u>	<u>Signature</u>	Authorized to Add or Remove <u>Signatories</u>
			☐
			☐
			☐
			☐

RESOLVED FURTHER, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.

Execute Loan Documents. Execute any loan documents any Lender requires.

Grant Security. Grant Collateral Agent a security interest in any of Borrower’s assets.

Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower’s right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[Balance of Page Intentionally Left Blank]

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By:_____

Name:_____

Title: Secretary

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as
[print title]
of the date set forth above.

By:_____

Name:_____

Title:_____

1615764111.13

EXHIBIT A

Certificate of Incorporation (including amendments)

[see attached]

1615764111.13

EXHIBIT B

Bylaws

[see attached]

1615764111.13

DEBTOR: SCHOLAR ROCK HOLDING CORPORATION and SCHOLAR ROCK, INC.
SECURED PARTY: OXFORD FINANCE LLC, as Collateral Agent

EXHIBIT A TO UCC FINANCING STATEMENT

Description of Collateral

The collateral consists of all of Debtor's right, title and interest in and to the following personal property (the "Collateral"):

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, general intangibles (including Intellectual Property from and after the date on which the IP Trigger Event occurs), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts, securities accounts, commodity accounts and any other bank account maintained by Debtor at any time, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Debtor's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (a)(i) any equipment or other property financed by a third party, provided that such third party's Liens are Liens securing Capital Leases and Purchase Money Debt if the granting of a Lien in such Equipment or other property financed is prohibited by or would constitute a default under any agreement or document governing such Equipment or property financed; provided that the aggregate value of all such Equipment or property financed does not exceed Five Hundred Thousand Dollars (\$500,000.00); provided, further, that (A) such Liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness, (B) such Liens do not extend to any property of Debtor other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness, and (C) upon the termination, lapsing or expiration of any such prohibition, such Equipment or other property financed, as applicable, shall automatically be subject to the security interest granted in favor of Secured Party hereunder and become part of the "Collateral"; (ii) any lease, license or contract, in each case if the granting of a Lien in such lease, license or contract is prohibited by or would constitute a default under the agreement governing such lease, license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Article 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such lease, license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Secured Party hereunder and become part of the "Collateral"; and (iii) until the date on which an IP Trigger Event occurs, any Intellectual Property; provided, however, (A) the Collateral shall include all Accounts (other than as set forth in clause (b) directly below) and all proceeds of Intellectual Property and (B) if a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically and effective as of the Effective Date include the Intellectual Property to the extent necessary to permit perfection of Secured Party's security interest in such Accounts and such other property of Debtor that are proceeds of the Intellectual Property; and (b) from and after the date that any Permitted Royalty Transaction is consummated, the Excluded Assets with respect to such Permitted Royalty Transaction.

Pursuant to the terms of a certain negative pledge arrangement under the A&R LSA, Debtor has agreed not to encumber any of its Intellectual Property except in connection with any Permitted Royalty Transaction to the extent permitted by the A&R LSA and, if applicable, the Acceptable Intercreditor Agreement with respect to such Permitted Royalty Transaction.

Capitalized terms used herein without definition shall have the meaning set forth below. Any uncanceled

terms used herein that are defined in the Code (as defined below) shall have the meaning set forth in the Code.

“**A&R LSA**” is that certain Amended and Restated Loan and Security Agreement dated as of February 10, 2025, by and among Debtor, Secured Party, the other loan parties from time to time party thereto, and the lenders from time to time party thereto, as modified, amended and/or restated from time to time.

“**Acceptable Intercreditor Agreement**” means, with respect to any Permitted Royalty Transaction that is a synthetic royalty transaction, an intercreditor or other agreement among the Secured Party, the applicable synthetic royalty financier (or agent of such applicable synthetic royalty financier) of such Permitted Royalty Transaction (the “**Applicable Synthetic Royalty Financier**”) and Debtor (and/or any subsidiary of Debtor party thereto) providing (i) at the sole option of Debtor, a first priority security interest and Lien (or, solely, with respect to clause (B) below, a second priority interest and Lien subject only to the priority of the security interest and Lien of the Secured Party under the A&R LSA or related loan documents in a manner consistent with such intercreditor or other agreement) granted to the Applicable Synthetic Royalty Financier in (A) the applicable percentage of (and/or the applicable rights, benefits and/or interests in) the royalty interest or revenue interest and payment intangibles related to the Applicable Product, (B) any intellectual property (including, without limitation, any Intellectual Property) solely underlying the Applicable Product, (C) any proceeds or product of any of the foregoing, and (D) a deposit account of Debtor solely holding royalty proceeds due to the Applicable Synthetic Royalty Financier in an amount not to exceed the percentage of revenues and royalty amounts due to the Applicable Synthetic Royalty Financier, (ii) that (A) the governing law thereof is New York and (B) submission of jurisdiction and venue is the State of New York (or some customary subset thereof) and the appellate courts thereof, and (iii) for such other provisions that are reasonably satisfactory to the Secured Party that are consistent with clause (i) and clause (ii) above.

“**Account**” is any “account” as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Debtor.

“**Applicable Product**” is Apatemab in spinal muscular atrophy.

“**Applicable Synthetic Royalty Financier**” is defined in the definition of “Acceptable Intercreditor Agreement”.

“**Capital Leases and Purchase Money Debt**” is Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Debtor or any of its subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person; provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Five Hundred Thousand Dollars (\$500,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made).

“**Code**” is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein and such term is defined differently in different Articles of the Code, the definition of such term contained in Article 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Secured Party’s Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term “Code” shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

“**Contingent Obligation**” is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but “Contingent Obligation” does not include endorsements in the ordinary course of business.

The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it

determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

“Copyrights” are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

“Debtor’s Books” are Debtor’s books and records including ledgers, federal, and state tax returns, records regarding Debtor’s assets or liabilities, the collateral under the A&R LSA or any related loan documents, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

“Division” means, in reference to any Person which is an entity, the division of such Person into two or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, or any analogous action taken pursuant to any other applicable law with respect to any corporation, limited liability company, partnership or other entity.

“Effective Date” is February 10, 2025

“Equipment” is all “equipment” as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

“Excluded Assets” means the assets of Debtor that will no longer remain Collateral upon the consummation of a Permitted Royalty Transaction, which, for the avoidance of doubt, shall not include Intellectual Property except to the extent provided in the definition of Acceptable Intercreditor Agreement.

“Indebtedness” is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

“Intellectual Property” means all of Debtor’s right, title and interest in and to the following:

- (a) its Copyrights, Trademarks and Patents;
- (b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;
- (c) any and all source code;
- (d) any and all design rights which may be available to Debtor;
- (e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and
- (f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

“Inventory” is all “inventory” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person’s custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

“IP Trigger Event” means the earlier to occur of (a) the outstanding principal balance of the term loans made by the lenders pursuant to the A&R LSA exceeds One Hundred One Million Dollars (\$101,000,000.00) and (b) Debtor enters

into a binding and enforceable Permitted Royalty Financing Transaction; provided, however, for the avoidance of doubt, that no IP Trigger Event shall occur under clause (a) of this definition as a result of any accrual or capitalization of any interest, fees or other amounts with respect to any term loan made by the lenders pursuant to the A&R LSA.

“**Lien**” is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

“**Person**” is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

“**Patents**” means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

“**Permitted Licenses**” are (A) licenses of over-the-counter software that is commercially available to the public, (B) non-exclusive and exclusive licenses for the use of the Intellectual Property of Debtor or any of its subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), (i) no event of default under the A&R LSA has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face (in each case, other than non-exclusive licenses from or to contract manufacturers, clinical research organizations, clinical trial or research sites, service providers and other entities (A) entered into in the ordinary course of business, (B) the principal purpose of which does not include the acquisition of licensing rights, but which contain such non-exclusive licenses merely ancillary to, and for the limited purpose of, facilitating the principal purposes of the agreement and (C) so long as Debtor has complied with all other applicable terms of the A&R LSA and other related loan documents applicable thereto), do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Debtor or any of its subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; (iii) in the case of any exclusive license, (x) Debtor delivers ten (10) days’ prior written notice and a brief summary of the terms of the proposed license to Secured Party and the lenders under the A&R LSA and delivers copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, and (y) any such license could not result in a legal transfer of title of the licensed property but may be exclusive in respects other than territory and may be exclusive as to territory only as to discrete geographical areas outside of the United States; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Debtor are paid to a deposit account that is governed by a deposit account control agreement in favor of Secured Party (except in connection with a Permitted Royalty Transaction that is not otherwise restricted by any applicable Acceptable Intercreditor Agreement), and (C) any other ancillary license provided in connection with a Permitted Royalty Transaction structured as a synthetic royalty transaction that is in form and substance reasonably satisfactory to Secured Party and otherwise satisfies the conditions of clauses (B)(i) through (iii) hereof (unless otherwise reasonably agreed by the Secured Party with respect to clause (B)(ii) in connection with any negative lien covenant provided in any such synthetic royalty transaction (subject to such covenant expressly permitted the Secured Party’s Liens under the A&R LSA and related loan documents)).

“**Permitted Royalty Transaction**” means the purchase of (or a financing with respect to) a royalty interest, or a revenue interest financing of, Debtor’s rights in the Applicable Product, provided that (i) such transaction constitutes an arms-length transaction (the terms of which, on their face, do not provide for a sale or collateral assignment of any Intellectual Property other than (A) a second priority Lien and collateral assignment of Intellectual Property solely underlying the Applicable Product may be provided in connection with such transaction that is structured as a synthetic royalty transaction to the extent such transaction is subject to an Acceptable Intercreditor Agreement and (B) any Permitted License, (ii) Debtor receives upfront and unrestricted (including, not subject to any redemption, clawback, escrow or similar encumbrance or restriction) gross cash payments of at least One Hundred Fifty Million Dollars (\$150,000,000.00), (iii) such transaction encumbers (with respect to a synthetic royalty transaction) or sells (with respect to a true sale royalty transaction) not more than ten percent (10.00%) of Debtor’s projected revenues from the Applicable Product, (iv) no event of default under the A&R LSA has occurred and is continuing at the time of entering such transaction, and (v) the royalty or revenue interest agreement and related material documents, including the assets that comprise the Excluded Assets, are otherwise in form and substance reasonably satisfactory to Secured Party (it being understood, for the avoidance of doubt, that an Acceptable Intercreditor Agreement shall only be required with respect to such transaction that is structured as a synthetic royalty transaction).

“Trademarks” means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Debtor connected with and symbolized by such trademarks.

“Transfer” means to convey, sell, lease, transfer, assign, or otherwise dispose of (including, without limitation, pursuant to a Division).

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ANNEX A

Net Product Revenue Covenant

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SCHOLAR ROCK HOLDING CORPORATION
AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR
COMPENSATION POLICY

The purpose of this Amended and Restated Non-Employee Director Compensation Policy of Scholar Rock Holding Corporation (the “Company”), is to provide a total compensation package that enables the Company to attract and retain, on a long- term basis, high-caliber directors who are not employees or officers of the Company or its subsidiaries. In furtherance of the purpose stated above, all non-employee directors shall be paid compensation for services provided to the Company as set forth below:

Cash Retainers

Annual Retainer for Board Membership: \$45,000 for general availability and participation in meetings and conference calls of our Board of Directors, to be paid quarterly in arrears, pro-rated based on the number of actual days served by the director during such calendar quarter.

Additional Annual Retainer for Non-Executive Chair of the Board: \$115,000 Additional

Retainers for Committee Membership:

Audit Committee Chair:	\$20,000
Audit Committee member:	\$10,000
Compensation Committee Chair:	\$15,000
Compensation Committee member:	\$7,500
Nominating and Corporate Governance Committee Chair:	\$10,000
Nominating and Corporate Governance Committee member:	\$5,000
Science, Innovation and Technology Committee Chair:	\$15,000
Science, Innovation and Technology Committee member:	\$7,500

Note: Chair and committee member retainers are in addition to retainers for members of the Board of Directors.

Equity Retainers

Initial Award: An initial, one-time equity award (the “Initial Award”) of (i) an option to purchase 36,000 shares of the Company’s common stock and (ii) 27,000 restricted stock units (or, if less, the number of aggregate shares underlying the Initial Award with a Value that does not exceed \$800,000), to each new non-employee director upon his or her election to the Board

of Directors, which option and restricted stock units shall vest monthly over three years, provided, however, that all vesting shall cease if the director resigns from the Board of

Directors or otherwise ceases to serve as a director of the Company. If the Initial Award is in the form of a stock option, such stock option shall have a per share exercise price equal to the Fair Market Value (as defined in the Company's 2018 Stock Option and Incentive Plan, as may be amended from time to time) of the Company's common stock on the date of grant.

Annual Award: On or after each date of the Company's Annual Meeting of Stockholders (the "Annual Meeting"), each continuing non-employee member of the Board of Directors other than a director receiving an Initial Award less than three (3) months prior to such Annual Meeting, will receive an annual equity award (the "Annual Award") as follows:

- (i) for any non-employee director who has served as a member of the Board of Directors for at least nine (9) months, (i) an option to purchase 18,000 shares of the Company's common stock and (ii) 13,500 restricted stock units (or, if less, the number of aggregate shares underlying the Annual Award with a Value that does not exceed \$400,000); and
- (ii) for any non-employee director who has served as a member of the Board of Directors for less than nine (9) months but at least three (3) months, (i) an option to purchase that number of shares of the Company's common stock equal to the number of full months served by such non-employee director as of such Annual Meeting divided by 12 (the "Applicable Fraction") and multiplied by 18,000 and (ii) restricted stock units equal to the Applicable Fraction multiplied by 13,500 (or, if less, the number of aggregate shares underlying the Annual Award with a Value that does not exceed the product of the Applicable Fraction multiplied by \$400,000),

such option and restricted stock units shall vest on the earlier of the first anniversary following the date of grant or the next scheduled Annual Meeting; provided, however, that all vesting shall cease if the director resigns from the Board of Directors or otherwise ceases to serve as a director, unless the Board of Directors determines that the circumstances warrant continuation of vesting. If the Annual Award is in the form of a stock option, such stock option shall have a per share exercise price equal to the Fair Market Value (as defined in the Company's 2018 Stock Option and Incentive Plan) of the Company's common stock on the date of grant.

Value: For purposes of this Policy, "Value" means the grant date fair value of the option (i.e., Black-Scholes Value) determined in accordance with the reasonable assumptions and methodologies employed by the Company for calculating the fair value of options under Financial Accounting Standard Board ("FASB") Accounting Standards Codification ("ASC") Topic 718.

Expenses

The Company will reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending meetings of the Board or any Committee.

Amended and Restated version, adopted June 16, 2020, as amended on March 16, 2021, May 26, 2022, June 21, 2023 and April 9, 2024.

**SCHOLAR ROCK HOLDING CORPORATION
STATEMENT OF COMPANY POLICY ON INSIDER
TRADING AND DISCLOSURE**

This Insider Trading Policy (the “Insider Trading Policy”) is designed to prevent insider trading or the appearance of impropriety, to satisfy Scholar Rock Holding Corporation and its subsidiaries (collectively, the “Company”) obligation to reasonably supervise the activities of Company personnel, and to help Company personnel avoid the severe consequences associated with violations of insider trading laws.

It is your obligation to understand and comply with this Insider Trading Policy. Please contact the General Counsel at legal@scholarrock.com, if you have any questions regarding the policy.

PART I. OVERVIEW

To Whom does this Insider Trading Policy Apply?

This Insider Trading Policy is applicable to the Company’s directors, officers, and employees and designated consultants and contractors and applies to any and all transactions by such persons and their affiliates (as defined below) in the Company’s securities, including its common stock, options to purchase common stock, any other type of securities that the Company may issue (such as preferred stock, convertible debentures, warrants, exchange-traded options or other derivative securities), and any derivative securities that provide the economic equivalent of ownership of any of the Company’s securities or an opportunity, direct or indirect, to profit from any change in the value of the Company’s securities.

In addition, all directors, all officers and all employees and certain designated consultants and contractors also must comply with the Trading Procedures set forth in Part II of this Insider Trading Policy (the “Trading Procedures”) (collectively, and solely for the purposes of this Insider Trading Policy, these persons are referred to as “Insiders”). Generally, the Trading Procedures establish trading windows outside of which the persons covered by the Trading Procedures will be restricted from trading in the Company’s securities and also require the pre- clearance of all transactions in the Company’s securities by such persons. You will be notified if you are required to comply with the Company’s Trading Procedures.

This Insider Trading Policy, including, if applicable, the Trading Procedures contained herein, also applies to the following persons (collectively, these persons and entities are referred to as “Affiliated Persons”):

- your spouse, child, parent, significant other or other family member, in each case, living in the same household;
 - all trusts, family partnerships and other types of entities formed for your benefit or for the benefit of a member of your family over which you have the ability to influence or direct investment decisions concerning securities;
 - all persons who execute trades on your behalf; and
 - all investment funds, trusts, retirement plans, partnerships, corporations and other types of entities over which you have the ability to influence or direct investment decisions concerning securities; provided, however, that the Trading Procedures shall not apply to any such entity that engages in the investment of securities in the ordinary course of its business (e.g., an investment fund or partnership) if such entity has established its own insider trading controls and procedures in compliance with applicable securities laws and an Insider has included such entity on that Insider’s signed acknowledgment in the attached form.
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You are responsible for ensuring compliance with this Insider Trading Policy, including the Trading Procedures contained herein, by all of your Affiliated Persons.

In the event that you leave the Company for any reason, this Insider Trading Policy, including, if applicable, the Trading Procedures contained herein, will continue to apply to you and your Affiliated Persons until the first trading day after any material nonpublic information known to you has become public or is no longer material.

What is Prohibited by this Insider Trading Policy?

It is generally illegal for you to trade in the securities of the Company, whether for your account or for the account of another, while in the possession of material, nonpublic information about the Company. It is also generally illegal for you to disclose material, nonpublic information about the Company to others who may trade on the basis of that information. These illegal activities are commonly referred to as “insider trading.”

Prohibited Activities

When you know or are in possession of material, nonpublic information about the Company, whether positive or negative, you are prohibited from the following activities:

- trading (whether for your account or for the account of another) in the Company’s securities, which includes common stock, options to purchase common stock, any other type of securities that the Company may issue (such as preferred stock, convertible debentures, warrants, exchange-traded options or other derivative securities), and any derivative securities that provide the economic equivalent of ownership of any of the Company’s securities or an opportunity, direct or indirect, to profit from any change in the value of the Company’s securities, except for trades made in compliance with the affirmative defense of Rule 10b5-1 under the Exchange Act, such as when trades are made pursuant to a written plan that was adopted, or trading instructions that were given, before you knew or had possession of such material, nonpublic information and certain other conditions are satisfied;
- having others trade for you in the Company’s securities;
- giving trading advice of any kind about the Company; and
- disclosing such material, nonpublic information about the Company, whether positive or negative, to anyone else (commonly known as “*tipping*”).

This Insider Trading Policy does not apply to an exercise of an employee stock option when payment of the exercise price is made in cash. The policy does apply, however, to the use of outstanding Company securities to constitute part or all of the exercise price of an option, any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

These prohibitions continue whenever and for as long as you know or are in possession of material, nonpublic information. Remember, anyone scrutinizing your transactions will be doing so after the fact, with the benefit of hindsight. As a practical matter, before engaging in any transaction, you should carefully consider how enforcement authorities and others might view the transaction in hindsight.

Definition of Material, Nonpublic Information

This Insider Trading Policy prohibits you from trading in the Company’s securities if you are in possession of information about the Company that is both “*material*” and “*nonpublic*.” If you have a question whether certain information you are aware of is material or has been made public, you are encouraged to consult with the General Counsel.

What is “Material” Information?

Information about the Company is “material” if it could reasonably be expected to affect the investment or voting decisions of a stockholder or investor, or if the disclosure of the information could reasonably be expected to significantly alter the total mix of information in the marketplace about the Company. In simple terms, material information is any type of information that could reasonably be expected to affect the market price of the Company’s securities. Both positive and negative information may be material. While it is not possible to identify all information that would be deemed “material,” the following items are types of information that should be considered carefully to determine whether they are material:

- developments regarding any programs in clinical development or subject to regulatory approval, including recent regulatory interaction and/or data that have been recently generated from ongoing or recently completed clinical trials;
- developments regarding the intellectual property and/or freedom to operate for any of the current programs or product candidates under development;
- projections of future earnings or losses, or other earnings guidance;
- earnings or revenue that are inconsistent with the consensus expectations of the investment community;
- potential restatements of the Company’s financial statements, changes in auditors or auditor notification that the Company may no longer rely on an auditor’s audit report;
- pending or proposed corporate mergers, acquisitions, tender offers, joint ventures or dispositions of significant assets;
- changes in management or the Board of Directors;
- significant actual or threatened litigation or governmental investigations or major developments in such matters;
- a cybersecurity incident;
- significant developments regarding products, customers, suppliers, orders, contracts or financing sources (e.g., the acquisition or loss of a contract);
- changes in dividend policy, declarations of stock splits, or public or private sales of additional securities;
- potential defaults under the Company’s credit agreements or indentures, or the existence of material liquidity deficiencies; and
- bankruptcies or receiverships.

By including the list above, the Company does not mean to imply that each of these items above is per se material. The information and events on this list still require determinations as to their materiality (although some determinations will be reached more easily than others). For example, some new products or contracts may clearly be material to an issuer; yet that does not mean that all product developments or contracts will be material. This demonstrates, in our view, why no “bright-line” standard or list of items can adequately address the range of situations that may arise. Furthermore, the Company cannot create an exclusive list of events and information that have a higher probability of being considered material.

The Securities and Exchange Commission (the “SEC”) has stated that there is no fixed quantitative threshold amount for determining materiality, and that even very small quantitative changes can be qualitatively material if they would result in a movement in the price of the Company’s securities.

What is “Nonpublic” Information?

Material information is “nonpublic” if it has not been disseminated in a manner making it available to investors generally. To show that information is public, it is necessary to point to some fact that establishes that the information has become publicly available, such as the filing of a report with the SEC, the distribution of a press release through a widely disseminated news or wire service, or by other means that

are reasonably designed to provide broad public access. Before a person who possesses material, nonpublic information can trade, there also must be adequate time for the market as a whole to absorb the information that has been disclosed. For the purposes of this Insider Trading Policy, information will be considered public after the close of trading on the first full trading day following the Company's public release of the information.

For example, if the Company announces material nonpublic information of which you are aware before trading begins on a Tuesday, the first time you can buy or sell Company securities is the opening of the market on Wednesday. However, if the Company announces this material information after trading begins on that Tuesday, the first time that you can buy or sell Company securities is the opening of the market on Thursday.

What are the Penalties for Insider Trading and Noncompliance with this Insider Trading Policy?

Both the SEC and the national securities exchanges, through the Financial Industry Regulatory Authority ("FINRA"), investigate and are very effective at detecting insider trading. The SEC, together with the U.S. Attorneys, pursue insider trading violations vigorously. For instance, cases have been successfully prosecuted against trading by employees in foreign accounts, trading by family members and friends, and trading involving only a small number of shares.

The penalties for violating insider trading or tipping rules can be severe and include:

- disgorgement of the profit gained or loss avoided by the trading;
- payment of the loss suffered by the persons who, contemporaneously with the purchase or sale of securities that are subject of such violation, have purchased or sold, as applicable, securities of the same class;
- payment of criminal penalties of up to \$5,000,000;
- payment of civil penalties of up to three times the profit made or loss avoided; and
- imprisonment for up to 20 years.

The Company and/or the supervisors of the person engaged in insider trading may also be required to pay civil penalties of up to the greater of \$1,275,000 or three times the profit made or loss avoided, as well as criminal penalties of up to \$25,000,000, and could under certain circumstances be subject to private lawsuits.

Violation of this Insider Trading Policy or any federal or state insider trading laws may subject the person violating such policy or laws to disciplinary action by the Company up to and including termination. The Company reserves the right to determine, in its own discretion and on the basis of the information available to it, whether this Insider Trading Policy has been violated. The Company may determine that specific conduct violates this Insider Trading Policy, whether or not the conduct also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against the alleged violator before taking disciplinary action.

How Do You Report a Violation of this Insider Trading Policy?

If you have a question about this Insider Trading Policy, including whether certain information you are aware of is material or has been made public, you are encouraged to consult with the General Counsel. In addition, if you violate this Insider Trading Policy or any federal or state laws governing insider trading, or know of any such violation by any director, officer or employee of the Company, you must report the violation immediately to the General Counsel.

PART II. TRADING PROCEDURES

Special Trading Restrictions Applicable to Insiders

In addition to the restrictions on trading in Company securities set forth above, Insiders and their Affiliated Persons are subject to the following special trading restrictions:

1. No Trading Except During Trading Windows.

Subject to limited exceptions described herein, Insiders may trade in Company securities only during certain trading windows established by the Company from time to time in its sole discretion, and then only after obtaining pre-clearance from the General Counsel in accordance with the procedures set forth below.

The General Counsel shall advise insiders upon the Company's decision to establish a trading window, including the dates upon which the window will open and close. Insiders may be allowed to trade outside of a trading window only (a) pursuant to a pre-approved Rule 10b5-1 Plan as described below or (b) in accordance with the procedure for waivers as described below.

2. Prohibited Transactions

- No Short Sales. No Insider may at any time sell any securities of the Company that are not owned by such Insider at the time of the sale (a "short sale").
- No Purchases or Sales of Derivative Securities or Hedging Transactions. No Insider may buy or sell puts, calls, other derivative securities of the Company or any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities or engage in any other hedging transaction with respect to the Company's securities, at any time.
- No Company Securities Subject to Margin Calls. No Insider may use the Company's securities as collateral in a margin account.
- No Pledges. No Insider may pledge Company securities as collateral for a loan (or modify an existing pledge).

3. Distributions, Gifts and Other Transfers for No Consideration are Subject to Same Restrictions as All Other Securities Trades.

No Insider may give or make any other transfer of Company securities without consideration (e.g., a partnership distribution or gift) during a period when the Insider is not permitted to trade.

Pre-Clearance Procedures

No Insider may trade in Company securities unless the trade has been approved by the Compliance Officer in accordance with the procedures set forth below. The General Counsel will review and either approve or prohibit all proposed trades by Insiders in accordance with the procedures set forth below. The General Counsel may consult with the Company's other officers and/or outside legal counsel and will receive approval for his/her own trades from the Chief Financial Officer.

Procedures. No Insider may trade in Company securities until:

- The Insider has notified the General Counsel of the amount and nature of the proposed trade(s) using the Stock Transaction Request form attached to this Insider Trading Policy. In order to provide adequate time for the preparation of any required reports under Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), a Stock Transaction Request form should, if practicable, be received by the General Counsel at least two (2) business days prior to the intended trade date;
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- The Insider has certified to the General Counsel in writing prior to the proposed trade(s) that the Insider is not in possession of material, nonpublic information concerning the Company;
- The Insider has informed the General Counsel, using the Stock Transaction Request form attached hereto, whether, to the Insider's best knowledge, (a) the Insider has (or is deemed to have) engaged in any opposite way transactions within the previous six months that were not exempt from Section 16(b) of the Exchange Act and (b) if the transaction involves a sale by an "affiliate" of the Company or of "restricted securities" (as such terms are defined under Rule 144 under the Securities Act of 1933, as amended ("Rule 144")), whether the transaction meets all of the applicable conditions of Rule 144; and
- The General Counsel or his or her designee has approved the trade(s) and has certified such approval in writing. Such certification may be made via digitally-signed electronic mail.

The General Counsel does not assume the responsibility for, and approval from the General Counsel does not protect the Insider from, the consequences of prohibited insider trading.

Additional Information. Insiders shall provide to the General Counsel any documentation reasonably requested by him or her in furtherance of the foregoing procedures. Any failure to provide such requested information will be grounds for denial of approval by the General Counsel.

No Obligation to Approve Trades. The existence of the foregoing approval procedures does not in any way obligate the General Counsel to approve any trade requested by an Insider. The General Counsel may reject any trading request at his or her sole discretion.

From time to time, an event may occur that is material to the Company and is known by only a few directors or executives. Insiders may not trade in Company securities if they are notified by the General Counsel that a proposed trade has been cleared because of the existence of a material, nonpublic development. Even if that particular Insider is not aware of the material, nonpublic development involving the Company, if any Insider engages in a trade before a material, nonpublic development is disclosed to the public or resolved, the Insider and the Company might be exposed to a charge of insider trading that could be costly and difficult to refute even if the Insider was unaware of the development. So long as the event remains material and nonpublic, the General Counsel may determine not to approve any transactions in the Company's securities. The General Counsel will subsequently notify the Insider once the material, nonpublic development is disclosed to the public or resolved. If an Insider requests clearance to trade in the Company's securities during the pendency of such an event, the General Counsel may reject the trading request without disclosing the reason.

Completion of Trades. After receiving written clearance to engage in a trade signed by the General Counsel, an Insider must complete the proposed trade within two (2) business days or make a new trading request.

Post-Trade Reporting. Any transactions in the Company's securities by an Insider (including transactions effected pursuant to a Rule 10b5-1 Plan) must be reported to the General Counsel by completing the "Confirmation of Transaction" section of the Stock Transaction Request form attached to this Insider Trading Policy on the same day in which such a transaction occurs. Each report an Insider makes to the General Counsel should include the date of the transaction, quantity of shares, price and broker-dealer through which the transaction was effected. This reporting requirement may be satisfied by sending (or having such Insider's broker send) duplicate confirmations of trades to the General Counsel if such information is received by the General Counsel on or before the required date. Compliance by directors and executive officers with this provision is imperative given the requirement of Section 16 of the Exchange Act that these persons generally must report changes in ownership of Company securities within two (2) business

days. The sanctions for noncompliance with this reporting deadline include mandatory disclosure in the Company's proxy statement for the next annual meeting of stockholders, as well as possible civil or criminal sanctions for chronic or egregious violators.

Exemptions

Pre-Approved Rule 10b5-1 Plan. Transactions effected pursuant to a Rule 10b5-1 Plan (as defined below) will not be subject to the Company's trading windows, retirement plan blackout periods or pre-clearance procedures, and Insiders are not required to complete a Stock Transaction Request form for such transactions. Rule 10b5-1 of the Exchange Act provides an affirmative defense from insider trading liability under the federal securities laws for trading plans, arrangements or instructions that meet certain requirements. A trading plan, arrangement or instruction that meets the requirements of Rule 10b5-1 (a "Rule 10b5-1 Plan") enables Insiders to establish arrangements to trade in Company securities outside of the Company's trading windows, even when in possession of material, nonpublic information.

If an Insider intends to trade pursuant to a Rule 10b5-1 Plan, such plan, arrangement or instruction must:

- satisfy the requirements of Rule 10b5-1;
- be documented in writing;
- be established during a trading window when such Insider does not possess material, nonpublic information; and
- be pre-approved by the General Counsel.

Any deviation from, or alteration to, the specifications of an approved Rule 10b5-1 Plan (including, without limitation, the amount, price or timing of a purchase or sale) must be reported immediately to the General Counsel. Any transaction pursuant to a Rule 10b5-1 Plan must be timely reported following the transaction in accordance with the procedures set forth above.

The General Counsel may refuse to approve a Rule 10b5-1 Plan as he or she deems appropriate including, without limitation, if he or she determines that such plan does not satisfy the requirements of Rule 10b5-1.

Any modification of an Insider's prior Rule 10b5-1 Plan requires pre-approval by the General Counsel. A modification must occur during a trading window and while such Insider is not aware of material, nonpublic information.

Employee Benefit Plans

1. **Exercise of Stock Options.** The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to the exercise of an option to purchase securities of the Company when payment of the exercise price is made in cash. However, the exercise of an option to purchase securities of the Company is subject to the current reporting requirements of Section 16 of the Exchange Act and, therefore, Insiders must comply with the post-trade reporting requirement described in Section C above for any such transaction. In addition, the securities acquired upon the exercise of an option to purchase Company securities are subject to all of the requirements of this Insider Trading Policy, including the Trading Procedures contained herein. Moreover, the Trading Procedures apply to the use of outstanding Company securities to constitute part or all of the exercise price of an option, any net option exercise, any exercise of a stock appreciation right, share withholding, any sale of stock as part of a broker- assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.
 2. **Tax Withholding on Restricted Stock/Units.** The trading prohibitions and restrictions set
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forth in the Trading Procedures do not apply to the withholding by the Company of shares of stock upon vesting of restricted stock or upon settlement of restricted stock units to satisfy applicable tax withholding requirements if (a) such withholding is required by the applicable plan or award agreement or (b) the election to exercise such tax withholding right was made by the Insider in compliance with the Trading Procedures.

3. **Employee Stock Purchase Plan.** The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to periodic wage withholding contributions by the Company or employees of the Company which are used to purchase the Company's securities pursuant to the employees' advance instructions under the Company's 2018 Employee Stock Purchase Plan. However, no Insider may: (a) elect to participate in the plan or alter his or her instructions regarding the level of withholding or purchase by the Insider of Company securities under such plan; or (b) make cash contributions to such plan (other than through periodic wage withholding) without complying with the Trading Procedures. Any sale of securities acquired under such plan is subject to the prohibitions and restrictions of the Trading Procedures.

WAIVERS

A waiver of any provision of this Insider Trading Policy, or the Trading Procedures contained herein, in a specific instance may be authorized in writing by the General Counsel, his or her designee or the Audit Committee of the Board of Directors, and to the extent authorized in writing by the General Counsel or his or her designee, any such waiver shall be reported to the Company's Audit Committee of the Board of Directors.

ACKNOWLEDGMENT

This Insider Trading Policy will be delivered to all current Insiders and to all directors, officers, employees, and designated consultants and contractors at the start of their employment or relationship with the Company. Upon first receiving a copy of this Insider Trading Policy, as amended from time to time, each individual must acknowledge that he or she has received a copy and agrees to comply with the terms of this Insider Trading Policy, and, if applicable, the Trading Procedures contained herein.

This acknowledgment will constitute consent for the Company to impose sanctions for violation of the Insider Trading Policy, including the Trading Procedures, and to issue any necessary stop-transfer orders to the Company's transfer agent to ensure compliance.

All directors, officers and employees and designated consultants and contractors will be required upon the Company's request to re-acknowledge and agree to comply with the Insider Trading Policy (including any amendments or modifications). For such purpose, an individual will be deemed to have acknowledged and agreed to comply with the Insider Trading Policy when copies of such items have been delivered by regular or electronic mail (or other delivery option used by the Company) by the General Counsel or his or her designee.

Question regarding this Insider Trading Policy are encouraged and may be directed to the General Counsel. _____

Adopted May 8, 2018, subject to effectiveness of the Company's Registration Statement on Form S-1.
Updated on March 12, 2021, June 15, 2021, and January 31, 2024.

STOCK TRANSACTION REQUEST

Pursuant to Scholar Rock Holding Corporation's Statement of Company Policy on Insider Trading and Disclosure (the "Trading Procedures"), I hereby notify Scholar Rock Holding Corporation (the "Company") of my intent to trade the securities of the Company as indicated below:

REQUESTER INFORMATION

Insider's Name: _____

INTENT TO PURCHASE

Number of shares: _____

Intended trade date: _____

Means of acquiring shares:

- ☐ Acquisition through employee benefit plan (please specify): _____
- ☐ Purchase through a broker on the open market
- ☐ Other (please specify): _____

INTENT TO SELL

Number of shares: _____

Intended trade date: _____

Means of selling shares:

- ☐ Sale through employee benefit plan (please specify): _____
- ☐ Sale through a broker on the open market
- ☐ Other (please specify): _____

CERTIFICATION

I hereby certify that (1) I am not in possession of any material, nonpublic information concerning the Company, as defined in the Company's Statement of Company Policy on Insider Trading and Disclosure, (2) to the best of my knowledge, the proposed trade(s) listed above does not violate the trading restrictions of Section 16 of the Securities Exchange Act of 1934, as amended, or Rule 144 under the Securities Act of 1933, as amended, and (3) I am not purchasing any securities of the Company on margin in contravention of the Company's Trading Procedures. I understand that, if I trade while possessing such information or in violation of such trading restrictions, I may be subject to severe civil and/or criminal penalties, and may be subject to discipline by the Company including termination.

Insider's Signature

Date

AUTHORIZED APPROVAL

Signature of Compliance Officer (or designee)

Date

CONFIRMATION OF TRANSACTION

I hereby confirm that the transaction(s) requested above was (were) executed as follows:

- ☐ Purchase of shares: _____ Price per share: _____ Date and approximate time of purchase: _____
*Number of shares: _____
- ☐ Sale of shares: _____ Date and approximate time of sale: _____
*Number of shares: _____ Price per share: _____

Insider's Signature

Date

SUBSIDIARIES OF SCHOLAR ROCK HOLDING CORPORATION

Subsidiary

Scholar Rock, Inc.

Scholar Rock Netherlands B.V.

Scholar Rock Securities Corporation

Jurisdiction

Delaware

The Netherlands

Massachusetts

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, 333-268329, and 333-282530) 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,
- (4) Registration Statement (Form S-8 Nos. 333-266658, 333-268327, and 333-283120) pertaining to the 2022 Inducement Equity Plan, of Scholar Rock Holding Corporation, and
- (5) Registration Statement (Form S-8 No. 333-270318 and 333-278049) 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 February 27, 2025, 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, 2024.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 27, 2025

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: February 27, 2025

/s/ Jay T. Backstrom

Jay T. Backstrom
President and Chief Executive Officer
(Principal Executive Officer)

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: February 27, 2025

/s/ Edward H. Myles

Edward H. Myles

Chief Operating Officer & Chief Financial Officer
(Principal Financial and Accounting Officer)

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, 2024 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: February 27, 2025

/s/ Jay T. Backstrom

Jay T. Backstrom

President and Chief Executive Officer

Date: February 27, 2025

/s/ Edward H. Myles

Edward H. Myles

Chief Operating Officer & Chief Financial Officer

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.

Management Team

Jay Backstrom, MD, MPH

President & Chief Executive Officer

Junlin Ho, JD

General Counsel & Corporate Secretary

Jing Marantz, MD, PhD, MBA

Chief Medical Officer

Caryn Parlavecchio

Chief Human Resources Officer

Mo Qatanani, PhD

Chief Scientific Officer

Tracey Sacco

Chief Commercial Officer

Beth Shafer, PhD

Chief Business Officer

Lisa Wyman

Chief Technical and Quality Officer

Board of Directors

David Hallal

Chairman of the Board of Directors, Scholar Rock®
Chairman and Chief Executive Officer of ElevateBio, LLC

Srini Akkaraju, MD, PhD

Founder and Managing Partner, Samsara BioCapital

Jay Backstrom, MD, MPH

President & Chief Executive Officer, Scholar Rock®

Richard Brudnick

Chief Business Officer, Prime Medicine, Inc.

Kristina Burow

Managing Director, ARCH Venture Partners

Jeffrey S. Flier, MD

Higginson Professor of Physiology and Medicine &
Harvard University Distinguished Service Professor;
Former Dean of Harvard Medical School

Michael Gilman, PhD

Chief Executive Officer, Arrakis Therapeutics, Inc.

Katie Peng

Chief Commercial Officer, Denali Therapeutics, Inc.

Joshua Reed

Akshay Vaishnav MD, PhD

Venture Partner, Atlas Ventures

Annual Meeting of Stockholders

The Annual Meeting of Stockholders will be held by virtual meeting at **12:00 PM, EDT on May 22, 2025**, and can be accessed from the following website: <https://www.virtualshareholdermeeting.com/SRRK2025>. You may attend the meeting via the Internet by logging in with your 16-digit control number.

Independent Auditors

Ernst & Young LLP

Investor Inquiries

ir@scholarrock.com

Stock Listing

NASDAQ: SRRK

Transfer Agent

Computershare Trust Company, N.A.
P.O. Box 43006
Providence, Rhode Island 02940
(800) 736-3001

SEC Form 10-K

A copy of our Form 10-K filed with the Securities and Exchange Commission (SEC) is available free of charge on the SEC's website at www.sec.gov or from the company's investor relations department by emailing ir@scholarrock.com or sending a written request to Scholar Rock's investor relations department at:

Investor Relations

Scholar Rock, Inc.
301 Binney Street, 3rd Floor
Cambridge, MA 02142



301 Binney Street, 3rd Floor
Cambridge, MA 02142

(857) 259.3860
www.scholarrock.com
info@scholarrock.com