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

FORM 10-K

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

For the fiscal year ended December 31, 2021

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: 001-40523

ELEVATION ONCOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**84-1771427**
(State of Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
888 Seventh Ave, 12th Floor, New York, New York	10106
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: (716) 371-1125

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	**ELEV**	**The Nasdaq Stock Market**

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

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

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

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

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.0405 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. ☐

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

The aggregate market value of Common Stock held by non-affiliates of the registrant computed by reference to the price of the registrant's Common Stock as of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $210.6 million (based on the last reported sale price on the Nasdaq Global Select Market as of such date). As of February 28, 2022, there were 23,205,915. shares of the registrant's common stock, par value $.0001 per share, outstanding.

Documents Incorporated by Reference

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A relating to the 2022 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2021. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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References to Elevation

Throughout this Annual Report on Form 10-K, or Annual Report, the “Company”, “Elevation”, “Elevation Oncology”, “we”, “us”, and “our”, except where the context requires otherwise, refer to Elevation Oncology, Inc. and its consolidated subsidiary, and “our board of directors” refers to the board of directors of Elevation Oncology, Inc.

Special Note Regarding Forward-Looking Statements

This Annual Report contains forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect,” “predict,” “potential” and similar expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these words. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk factors” and elsewhere in this filing. Moreover, we operate in a competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all 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 we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements in this Annual Report include, among other things, statements about:

- our ability to develop, obtain regulatory approval and commercialize seribantumab and our future product candidates;
- the timing of our preclinical studies and clinical trials for our product candidates;
- estimates of our addressable market and market growth;
- our expectations regarding demand for, and market acceptance of, our product candidates;
- our ability to maintain and expand access to human genetics data;
- our ability to compete effectively with existing competitors and new market entrants;
- the potential effects of extensive government regulations relating to our industry;
- our ability to obtain, maintain, and protect and enforce intellectual property and proprietary rights;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights and proprietary technology of third parties;
- our ability to establish and maintain collaborations, including our existing joint ventures;
- our ability to expand our pipeline of product candidates;
- our ability to attract and retain key management and technical personnel;
- the effects of the COVID-19 pandemic on any of the above or any other aspect of our business operations; and
- our expectations regarding expenses, future revenue, capital requirements, and our needs for additional financing.

The forward-looking statements made in this filing relate only to events or information as of the date on which the statements are made in this Annual Report. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to actual results or to changes in our expectations, except as required by law. We intend the forward-looking statements contained in this Annual Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

PART I

Item 1. Business

Overview

We are a precision oncology company focused on the development of targeted therapeutics for the treatment of cancer in genomically defined patient populations. Our vision is to elevate precision medicine to the forefront of every cancer treatment journey, as we believe that each patient living with cancer deserves the opportunity to benefit from a genomically-driven treatment decision. We utilize our deep expertise in developing drugs for rare, genomically defined patient populations and strategic collaborations with our diagnostic collaborators to work towards a future where each tumor's unique genomic test result can be matched with a purpose-built precision medicine.

We are focused on identifying oncogenic drivers that are known to be predominantly mutually exclusive with other driver alterations, and pursuing innovations and efficiencies in the conduct of clinical trials that we believe may enable development of targeted therapeutics against those oncogenic drivers.

Our lead drug development candidate, seribantumab, is an Anti-HER3 monoclonal antibody and potential novel targeted therapy for solid tumors driven by neuregulin-1, or NRG1 fusions, a type of genomic alteration and oncogenic driver, and other receptor tyrosine-protein kinase erbB-, or HER3, genomically defined cancers. We have designed and initiated our registration-directed Phase 2 CRESTONE clinical trial to investigate the safety and efficacy of seribantumab in advanced solid tumors harboring an NRG1 fusion. We expect to complete enrollment of the first 20 patients in Cohort 1 of the CRESTONE study in mid-2022, and to present initial clinical data from approximately 10 patients from Cohort 1 of the CRESTONE study treated with seribantumab at 3 grams weekly at a major medical meeting in mid-2022.

We also plan to expand our drug development pipeline beyond seribantumab into additional genomically defined cancers by leveraging our value-driving partnerships with Caris Life Sciences and others, as well as by exploring further opportunities to selectively partner on additional precision oncology assets.

We are managed by a team with significant experience and track records for clinical and commercial execution in the oncology space and backed by a group of renowned scientific advisors and partners that bring diagnostic, clinical, and operational expertise to help optimize execution.

Our strategy

Our goal is to deliver safe and effective therapies for genomically defined patient populations with significant unmet clinical needs. Key elements of our strategy include:

- ***Implement an innovative operational model tailored to the efficient development and potential regulatory approval of precision therapeutics for rare, genomically defined cancers, beginning with the investigation of seribantumab for any solid tumor driven by an NRG1 fusion.*** We have designed our business model around genomically defined cancers with smaller trial size requirements and the potential for accelerated approval. Rather than follow the traditional drug discovery path, we have focused on external development to identify potential assets that we can acquire at attractive economic terms and that will enable us to move efficiently through clinical development. We acquired seribantumab in July 2019 as a Phase 2-ready asset, enabling us to move rapidly into a potentially registration-directed Phase 2 trial. We have also employed innovative models to enhance traditional patient enrollment into our clinical trials, with opportunity for enrollment not only at core sites, but also through referrals through our diagnostic partnerships, and a "just-in-time" site initiation model. This enables us to reduce overhead costs for a trial and increase the availability of eligible patients, addressing two key risks in the development of therapies for rare, genomically defined patient populations.

- ***Prioritize oncogenic drivers that are predominantly mutually exclusive oncogenic alterations to maximize the probability of clinical success.*** We focus on oncogenic driver events that are most often mutually exclusive within a tumor, meaning that co-expression with other known driver alterations is not observed. We believe that

our ability to identify and specifically target a mutually exclusive oncogenic driver alteration increases the likelihood of developing a therapy that achieves a clinical benefit for patients as a monotherapy. Our lead program focuses on NRG1 gene fusions in solid tumors, which are oncogenic drivers that are predominantly mutually exclusive with other known genomic alterations. The identification of NRG1 fusions in more than ten solid tumor types may enable a tumor-agnostic development approach.

- ***Rapidly advance our lead product candidate seribantumab, a monoclonal antibody, through late-stage clinical development for solid tumors harboring NRG1 gene fusions.*** In July 2020, we initiated the CRESTONE trial a Phase 2 clinical trial at sites across the United States, Canada, and Australia to assess the safety, tolerability, and anti-tumor activity of seribantumab in patients with tumors harboring an NRG1 fusion. We are conducting the CRESTONE trial with the intent to seek regulatory approval through the accelerated approval pathway, pending continued discussions with the U.S. Food and Drug Administration, or FDA. Given its mechanism of action and broad therapeutic window, we believe that seribantumab has the potential to effect robust and durable responses at a dosing regimen optimized for patients with solid tumors driven by an NRG1 fusion.

- ***Collaborate with diagnostic providers and next-generation sequencing, or NGS, centers of excellence to accelerate enrollment in clinical trials by identifying patients with rare, genomically defined cancers, starting with solid tumors harboring an NRG1 fusion.*** We have entered into agreements with multiple partners selected for their ability to identify NRG1 gene fusions with high sensitivity, particularly through the use of RNA-based next generation sequencing. Through these collaborations, we are able to expand identification of patients who may be eligible for enrollment in our Phase 2 CRESTONE trial beyond those patients who may be identified through traditional clinical trial site enrollment processes.

- ***Expand our pipeline of drug candidates targeted against oncogenic driver alterations through strategic collaborations and/or external development.*** We intend to continue expanding our pipeline by leveraging our partnerships with next-generation sequencing, or NGS diagnostic providers, as well as our own internal expertise and capabilities, to potentially accelerate the identification of additional actionable oncogenic targets. We then expect to in-license, acquire or discover assets with potential against those identified oncogenic driver targets. Through our collaboration with Caris Life Sciences, we continually assess oncogenic fusions and driver mutations identified through our partner's screening capabilities to identify potential targets and then elect to initiate a novel drug discovery program for those targets or evaluate existing therapeutics for potential in-licensing or product acquisition, while retaining exclusive access to all targets selected by the parties.

- ***Evaluate strategic opportunities to potentially accelerate development timelines and enhance the commercial potential of our product candidates globally***. We intend to build an integrated biopharmaceutical company focused on precision oncology with a broad portfolio of targeted therapies. We currently retain full global development and commercialization rights for seribantumab. We plan to commercialize our product candidates in key markets, either alone or with strategic partners, as well as invest in shaping the genomic testing landscape in order to maximize the worldwide commercial potential of our programs.

- ***Actively advocate for and participate in industry-wide initiatives to improve access, awareness, and clarity around precision medicines for rare, genomically defined cancers.*** We envision a future where every patient with cancer has the option of a precision therapy matched to their tumor's unique genomic driver. This begins with ensuring the wide availability of genomic testing to identify the increasing number of biomarkers that can be paired with an investigational clinical trial or a commercially available targeted therapy. We aim to increase awareness on the importance of applying the appropriate diagnostic testing method for each actionable driver alteration by collaborating with academic institutions, patient advocacy groups, medical education providers and associations, diagnostic companies, and community oncology practices to advocate for broad genomic testing of tumors, at all lines of therapy, and regardless of the stage of cancer. By comprehensively identifying all actionable genomic driver alterations present at each treatment decision timepoint, patients may dynamically benefit from the prognostic and therapeutically predictive value of diagnostic tests as both their tumor and the treatment landscape evolve. Finally, we advocate for industry-wide initiatives that remove the burden of

responsibility from the patient to educate themselves, and move towards presenting a clear, united message that prioritizes patient benefit and well-being.

Background

The rise of precision cancer therapeutics

Cancer is a heterogeneous group of diseases caused by alterations in cells that give rise to abnormal cell growth and proliferation. Many cancer therapeutics rely on the rapid growth dynamics of cancer cells to elicit a therapeutic effect; notably, most chemotherapeutics inhibit the replication of all cells in the body, but act preferentially to destroy cancer cells as they proliferate faster than non-cancer cells, resulting in significant toxicity. By contrast, targeted therapies are designed to interfere with, or target, the specific pathways within a cancer cell that contribute to the growth and survival of a tumor, while minimizing systemic adverse events.

Cancer has also historically been diagnosed, classified, and in large part, treated based on a tumor's organ site or tissue of origin, thus giving rise to therapeutics for lung cancer, breast cancer or other tissue-based designations. With advances in genomic testing, there has been widespread recognition that cancers may be defined by their unique genomic signatures, instead of tissue of origin, due to shared genomic alterations irrespective of their location in the body. This understanding has both been a result of, and driven by, an increased use of genomic sequencing to better understand the driving factors of each individual cancer. Over the last several years, the ability to conduct genomic profiling of an individual patient's tumor has become more readily accessible and affordable. Our collective understanding of the genomic makeup of tumors has facilitated the development of precision therapeutics designed to specifically inhibit the underlying causes of tumor growth and proliferation.

The precision oncology movement strives to improve patient outcomes by identifying the underlying oncogenic driver of each tumor through genomic testing and by matching it to a purpose-built targeted therapeutic. By precisely matching a therapeutic to a tumor's genomic driver of disease, the hope is to achieve a deeper and more durable response with fewer off-target side effects for every cancer — no matter how rare.

Genomic alterations fall on a spectrum of oncogenic potential

Cancer arises through a process whereby cells acquire a series of alterations that eventually precipitate unrestrained cell growth and division. The changes that accumulate in a cancer cell may encompass many distinct classes of genomic alterations, including overexpression or amplification of individual genes, specific point mutations in a single gene, and chromosomal translocations or fusions of genetic material.

These genomic alterations can be further characterized as driver or passenger alterations that fall on a spectrum of oncogenic potential. Oncogenic driver alterations confer growth and survival advantages to the cancer cells that may lead to oncogenesis and continued growth of a tumor. Passenger mutations, also known as bystander mutations, are those that arise within the cancer cell but are not the primary or underlying cause of oncogenesis and/or continued growth of a tumor.

Advances in genomic testing, including increases in the specificity and sensitivity of testing methods, have enabled improved identification of a wider range of genomic alterations. In particular, advancements in and wider availability of RNA-based NGS whole transcriptome sequencing has improved our ability to identify novel gene fusions. These "chimeric" genes arise from the re-combination of portions of two normally unrelated genes and are transcribed into corresponding fusion proteins which may retain functionalities related to either or both component proteins. If a tumor suppressor gene or oncogene is involved, the resulting fusion proteins frequently lead to unregulated cell growth and proliferation and are often the primary cause of tumor growth.

While gene fusions are generally rare, they have high oncogenic potential. Most importantly, they can appear in tumors as oncogenic drivers, predominantly mutually exclusive with any other known genomic driver alteration. Accordingly, these fusions represent important genomic alterations to identify and subsequently target with a precision therapy.

NRG1 fusions and HER3 inhibition

The ERBB family of proteins contains four members including epidermal growth factor receptor (EGFR; ERBB1; HER1), ERBB2 (HER2), ERBB3 (HER3), and ERBB4 (HER4). While EGFR, HER2, and HER4 are tyrosine kinases, HER3 is a pseudo-kinase meaning that HER3 does not have meaningful catalytic activity of its own.

When HER3 is activated by its ligand, NRG1, it undergoes an obligate pairing through homo- or heterodimerization with HER2 or other ERBB family members. The formation of these HER3-HER2 dimers and other ERBB family complexes leads to the downstream activation of PI3-Kinase and AKT, or PI3K/AKT as well as MAP-Kinase, or MAPK, key pathways that regulate cell growth and proliferation.

Alterations that disrupt signaling of ERBB and downstream signaling pathways through PI3K/AKT and MAPK are often identified in tumors.

Tumorigenesis driven by NRG1 fusions

NRG1 gene fusions are rare genomic alterations that arise when portions of the NRG1 gene are combined with portions of a second gene, known as its fusion partner. NRG1 gene fusions are transcribed by a cell into NRG1 fusion proteins. As long as the NRG1 portion of the fusion protein retains its active component, known as the EGF-like domain, the fusion protein can act like a normal NRG1 protein, and can induce signaling through the HER3 receptor. Based on current literature, it appears that nearly all NRG1 fusions contain the genomic region that encodes the EGF-like domain of the protein and therefore are able to bind to HER3 and activate downstream signaling pathways.

Production of the wild-type NRG1 protein is normally tightly regulated by a cell to prevent uncontrolled cell growth and proliferation. Cells may not be able to regulate the aberrant NRG1 fusion proteins in the same way, and their production may lead to over-activation of HER3 and downstream PI3K/AKT and MAPK pathways leading to tumor growth and proliferation (Figure 1).

Figure 1. NRG1 fusions drive tumor growth & proliferation through HER3.

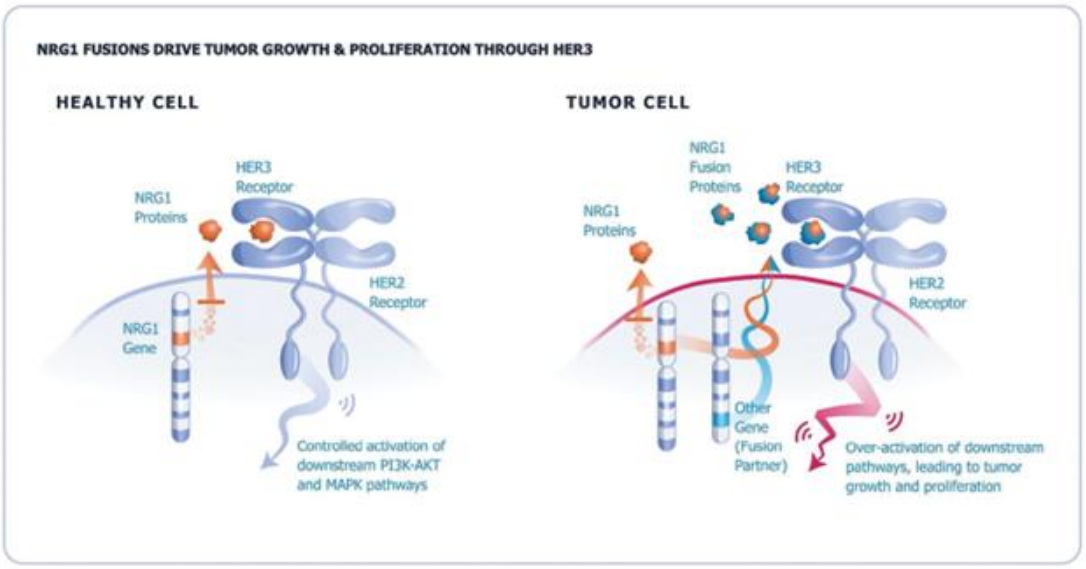

Figure 1. [**Left**] The NRG1 gene encodes the NRG1 protein, which is a ligand for HER3. Ligand-induced activation of HER3 by NRG1 enables preferential dimerization with HER2 and activation of downstream PI3K/AKT and MAPK signaling pathways. Production of the NRG1 protein is tightly regulated by the cell to avoid overactivation of downstream pathways. [**Right**] Portions of the NRG1 gene may be aberrantly combined with portions of an unrelated gene, resulting in an NRG1 gene fusion. The resulting NRG1 fusion proteins may still act as ligands for HER3 if they retain an intact EGF-like domain. Cells may not be able to regulate production of NRG1 fusion proteins, leading to tumor growth and proliferation driven by overactivation of HER3 and downstream PI3K/AKT and MAPK pathways.

Characteristics of NRG1 fusions

NRG1 fusion proteins contain components of both the NRG1 protein and the protein described by its fusion partner. At least 50% of known NRG1 fusions contain CD74, ATP1B1, SDC4, or RBPM5 as the fusion partner. It is not known at this time if there are any prognostic or functional differences between NRG1 fusions with different partners.

Importantly, when NRG1 fusions are found in a tumor, other known oncogenic drivers such as KRAS, EGFR, ALK, ROS1, and RET mutations are typically absent. Because of this, NRG1 fusions are considered oncogenic driver alterations given they are predominantly mutually exclusive when detected in patients with cancer. As a mutually exclusive oncogenic driver, we believe a targeted monotherapy approach has a strong potential to treat tumors that harbor an NRG1 fusion.

Incidence of NRG1 fusions

To our knowledge, the most comprehensive assessment of the incidence rate of NRG1 fusions was published in 2019 by Jonna et al. in *Clinical Cancer Research* with an analysis of 21,858 samples and updated at the 2020 annual meeting of the American Society of Clinical Oncology, or ASCO, based on an updated analysis of 44,570 tumor samples. Based on the observed incidence rate of approximately 0.2% and the estimated number of new cancer cases in the United States in 2020 reported in Cancer Facts and Figures 2020 by the American Cancer Society, we estimate the incidence of new patients with tumors harboring an NRG1 fusion in the United States is approximately 3,200 per year.

NRG1 fusions have been identified in more than ten unique solid tumor types to date in the published literature, and we expect that the reported number of tumor types harboring an NRG1 fusion will grow as research continues to advance. Separate reports in the published literature suggest that the prevalence of NRG1 fusions may be enriched in specific tumor subtypes; prevalence in invasive mucinous adenocarcinoma, or IMA, a subtype of NSCLC, has been reported to be up to 27-31%; prevalence in pancreatic ductal adenocarcinoma, a subtype of pancreatic cancer, has been reported to be up to 6%.

The wide range of tumor types in which an NRG1 fusion has been identified make it a strong candidate for a tumor-agnostic development strategy.

NRG1 fusions lead to a poor prognosis

There are currently no approved therapeutics specifically targeting tumors harboring an NRG1 fusion. Evidence available to date suggests that patients with tumors harboring an NRG1 fusion have a poor prognosis and limited response to currently available therapies.

A research report published in *Oncotarget* in 2016 by Shin et al. presented an analysis of disease-free survival, or DFS, and overall survival, or OS, in patients with tumors harboring an NRG1 fusion. In all patients analyzed (n=59) the presence of an NRG1 fusion resulted in inferior OS and a trend towards shorter DFS, compared to those without NRG1 fusions. To remove the confounding factor of stage of disease, a sub analysis was done on patients with stage 1 disease (n=45) where patients with tumors harboring an NRG1 fusion showed significantly inferior OS and DFS as compared to those with tumors without an NRG1 fusion.

A 2021 *Journal of Clinical Oncology* report by Drilon et al. reported an analysis from a global multicenter network of thoracic oncologists participating in an NRG1 fusion global registry trial, who identified 110 NSCLC patients with

pathologically confirmed NRG1 fusions and evaluated their response to chemotherapy, immunotherapy, chemotherapy plus immunotherapy, or off-label use of afatinib. They reported that 0-20% of patients achieved an objective response to platinum-doublet-based chemotherapy (n = 15), taxane-based chemotherapy (n = 7), immunotherapy (n = 5), or chemotherapy plus an immunotherapy (n = 9), and only 25% of patients achieved an objective response to off-label afatinib (n = 20). In this retrospective trial, it was determined that treatment with afatinib resulted in a median progression-free survival, or PFS, of 2.8 months. Limited durability is likely attributed to the fact that HER3 is a pseudo-kinase, and therefore inhibition of HER3 is not amenable to targeting by small molecule tyrosine kinase inhibitors, such as afatinib, which inhibits EGFR, HER2, and HER4. Given afatinib does not inhibit HER3, only partial inhibition of downstream signaling (PI3K/AKT and MAPK) is observed, which allows tumor cells harboring an NRG1 fusion to continue to grow and proliferate.

Evidence that targeting HER3 may be an optimal approach for treating tumors harboring an NRG1 fusions

There have been several clinical case reports published or presented on the potential of ERBB-family inhibition as a therapeutic intervention for patients with tumors harboring an NRG1 fusion. These include reports on the off-label use of afatinib as well as a few cases with monoclonal antibodies and small molecule inhibitors targeting ERBB family members. Clinical activity, including objective responses, have been reported with varying durations of response.

As reported by Drilon et al. in a 2018 report in *Cancer Discovery*, small molecule inhibition of EGFR, HER2, and HER4 with afatinib was not as effective as the use of HER3-targeted therapy. The administration of afatinib in an *in vivo* NRG1 fusion model of ovarian cancer (OV-10-0050) with a CLU-NRG1 fusion resulted in a mixed response to treatment. A potential reason for the limited effect of afatinib observed is that treatment with afatinib did not result in complete shutdown of downstream signaling through the PI3K/AKT pathway. In contrast, the specific inhibition of HER3 by the anti-HER3 monoclonal antibody (GSK2849330) induced complete, or near-complete, regressions and a near-complete suppression of downstream signaling in the same model.

Additionally described in the report, the only response observed in the Phase 1 clinical trial of GSK2849330 was in a patient with a NSCLC tumor harboring an NRG1 fusion who had been treated previously with several lines of systemic therapy (chemotherapy and immune therapy) with no response to any of these treatments. Targeted therapy with the anti-HER3 monoclonal antibody GSK2849330 resulted in a durable partial response of 19 months, which exceeded the duration of disease control achieved on all prior systemic lines of therapy in aggregate.

Seribantumab was included as part of a case series presentation at the Australasian Gastro-Intestinal Trials Group 2021 Annual Scientific Meeting. A patient with treatment-refractory metastatic pancreatic cancer had their tumor genomically profiled through the MoST program, was found to harbor an NRG1 fusion, and subsequently received treatment with seribantumab through a compassionate use program provided by Elevation Oncology. As of the data cut-off for the presentation, treatment with seribantumab resulted in durable clinical benefit for over 9 months, an approximately 90% reduction in the cancer biomarker CA19-9, and an ongoing 3 month confirmed partial response per RECIST criteria with a maximum tumor reduction of over 50%.

Our Approach

Our operational platform is designed for continued success by expanding on the promise of precision medicine and using the significant opportunities available to address multiple genomically defined cancers with first-in-class and best-in-class therapies. We are focused on developing drugs to target genomic alterations that are predominantly mutually exclusive with other known driver alterations. By targeting these unique oncogenic driver events and tailoring the best therapeutic approach, we believe we can increase the potential for therapeutic, clinical, and regulatory success in genomically defined patient populations.

Target Identification

We have established industry-wide partnerships with NGS companies to enable the identification of actionable targets. We also collaborate with academic and clinical researchers, diagnostic leaders, and community oncology practices to evaluate emerging genomic research for potential targets.

Therapeutic Candidate Selection

Following target identification, we select attractive assets in a capital-efficient manner through a targeted search for the appropriate chemical matter to address the identified target. We start by assessing existing compounds based on their mechanistic properties, observed or predicted risk-benefit profile, chemical and manufacturing properties, intellectual property, and other parameters on a case-by-case basis. We then in-license, acquire, or when there is not suitable existing chemical matter, may embark upon a drug discovery campaign with collaborators to create an appropriate candidate for future drug development. These processes allow us to select the asset that we believe may have the highest probability of technical success for the treatment of patients with genomically defined cancers.

Optimized Clinical Trial and Regulatory Execution

We aim to drive operational success by implementing process innovations that we believe may enable us to efficiently advance product candidates through clinical development in genomically defined patient populations. Given these populations are often relatively rare, we have built an innovative clinical enrollment model that recognizes the importance and impact of each individual patient. We also seek to employ expedited regulatory strategies such as Breakthrough Therapy Designation, Fast Track Designation, Priority Review, Accelerated Approval, and other collaborative mechanisms with the FDA and regulatory agencies outside the United States to optimize clinical development where applicable. We utilize our robust network of strategic partnerships to enhance patient enrollment through real-time identification and referral of genomically defined patient populations into clinical studies. Patients can be enrolled through identification at, or active referral to, core trial sites at academic medical institutions, and new trial sites can be rapidly activated through a process of “just-in-time” site initiation through a network of specialized community oncology centers. We have executed multiple strategic collaborations to support just-in-time site initiation to date. For example, through collaborations with Caris Life Sciences, Tempus, and The US Oncology Network we currently have access to approximately 400 clinical trial sites globally in support of our Phase 2 CRESTONE trial.

Our Lead Program

Seribantumab for solid tumors harboring an NRG1 fusion

Our lead program targets a genomically defined patient population whose tumors are driven by NRG1 gene fusions and predominantly mutually exclusive with other known driver alterations. Following our focused approach described above:

- We confirmed that NRG1 fusions are likely to be a clinically actionable biomarker and identified HER3 inhibition with a monoclonal antibody as a selective targeted therapeutic approach for tumors driven by an NRG1 fusion.

- The anti-HER3 monoclonal antibody seribantumab was specifically chosen as a therapeutic candidate with the potential to selectively target tumors harboring an NRG1 fusion and support an efficient development pathway as a Phase 2-ready asset.

- We designed the Phase 2 CRESTONE trial with “just-in-time” site initiation and early review of response signals, which we believe addresses inefficiencies of clinical development within rare, genomically defined patient populations, and potentially enables submission of a biologics license application, or BLA, to the FDA pursuant to an accelerated approval pathway in the United States.

We acquired seribantumab (formerly MM-121) from the previous sponsor in July 2019 following robust evaluation of HER3 inhibitors and their potential for development specifically for patients with tumors harboring an NRG1 fusion. The clinical development program of seribantumab by the previous sponsor was focused on patients with overexpression or amplification of HER3 or NRG1, with limited anti-tumor efficacy. Importantly, patients with tumors harboring an NRG1 gene fusion were not specifically selected for inclusion in these studies. We believe that patients with tumors harboring an NRG1 fusion represent the most appropriate patient population to evaluate the potential of seribantumab and that our product candidate offers significant potential for efficacy in these patients.

We selected seribantumab for development in patients with tumors harboring an NRG1 fusion, in part due to the following key characteristics.

- Seribantumab's unique mechanism of action inhibits ligand-dependent activation of HER3, and likely through the inhibition of ERBB dimerization, destabilizes the entire ERBB family of proteins.
- Previous clinical studies in more than 800 patients demonstrating that seribantumab had been generally well tolerated in clinical trials with mostly Grade 1/2 adverse events.
- Our ability to determine the predicted active dose of seribantumab from preclinical models of tumors harboring an NRG1 fusion.
- Seribantumab's favorable pharmacokinetic profile that we believe is well suited to optimized schedules and may provide a biologically effective dose in patients with tumors harboring an NRG1 fusion.
- The manufacturing process for seribantumab has been shown to be commercially scalable.
- Risks for development in genomically defined patient population have the potential to be addressed through the design of our Phase 2 CRESTONE trial of seribantumab.

Mechanism of action

Seribantumab is a fully human IgG2 monoclonal antibody that binds to HER3 and competes with the NRG1 fusion protein, preventing activation of the HER3 signaling cascade that is believed to sustain proliferation and survival of tumor cells harboring an NRG1 fusion. NRG1 fusions may act as a ligand to HER3, allowing HER3 to dimerize to HER2 and other ERBB family members and subsequently over-activating the downstream PI3K/AKT and MAPK.

Seribantumab is a fully human IgG2 monoclonal antibody that binds to a unique epitope on HER3 that prevents the ligand-induced activation of HER3, as well as disrupts the ability of HER3 to dimerize with HER2, and to a lesser extent, the other ERBB family members EGFR and HER4. By inhibiting the dimerization of HER3 with other ERBB family members, seribantumab reduces the activation of these receptors in addition to the ligand-dependent activation of HER3, and subsequent activation of PI3K/AKT and MAPK, downstream signaling pathways that are commonly implicated in tumor growth and proliferation.

Previous sponsor's Phase 1 monotherapy trial NCT00734305 (safety and pharmacokinetics)

The initial monotherapy trial conducted by the previous sponsor was a Phase 1 open label, dose escalation trial in which six cohorts of patients were enrolled followed by an expansion cohort using a maximum loading dose of 40 mg/kg followed by weekly dosing at 20 mg/kg. Overall, a total of 43 patients were exposed to seribantumab in this initial safety and pharmacology trial. The majority of adverse events observed in the monotherapy trial were transient and mild to moderate in severity. The most commonly reported adverse events were Grade 1 or 2 rash, nausea, diarrhea, and fatigue. There was one serious adverse event, or SAE, considered possibly related to seribantumab in trials conducted to date, a Grade 4 confusional state at the lowest dose level tested, 3.2 mg/kg. The event resolved after treatment discontinuation and no other dose limiting toxicities, or DLTs, were reported in this or other dose escalation cohorts in the Phase 1 monotherapy study. A maximum tolerated dose, or MTD, was not determined in this trial.

Our preclinical characterization

We sponsored a series of preclinical studies to determine the *in vitro* and *in vivo* properties of seribantumab specifically in NRG1 fusion models, some of which were published by Odintsov et al. in *Clinical Cancer Research* in 2021. Experiments were conducted in NRG1 fusion models, including patient-derived xenograft, or PDX mouse models.

Key findings from our preclinical testing of seribantumab include:

- Inhibition of HER3 resulted in reduction of tumor growth in NRG1 fusion driven tumors.
- Seribantumab reduced tumor growth to a greater extent than both clinically achievable and supra-clinical doses of afatinib in multiple NRG1 fusion models of cancer.
- Seribantumab inhibited ligand-dependent activation of HER3 and phosphorylation of all other ERBB family members.
- Seribantumab inhibited HER3 dimerization with HER2 due to the unique epitope on HER3 to which seribantumab binds.
- The active dose of seribantumab was determined and confirmed across multiple NRG1 fusion model.

Figure 2. Seribantumab inhibits signaling through HER3 and blocks HER3-HER2 dimerization.

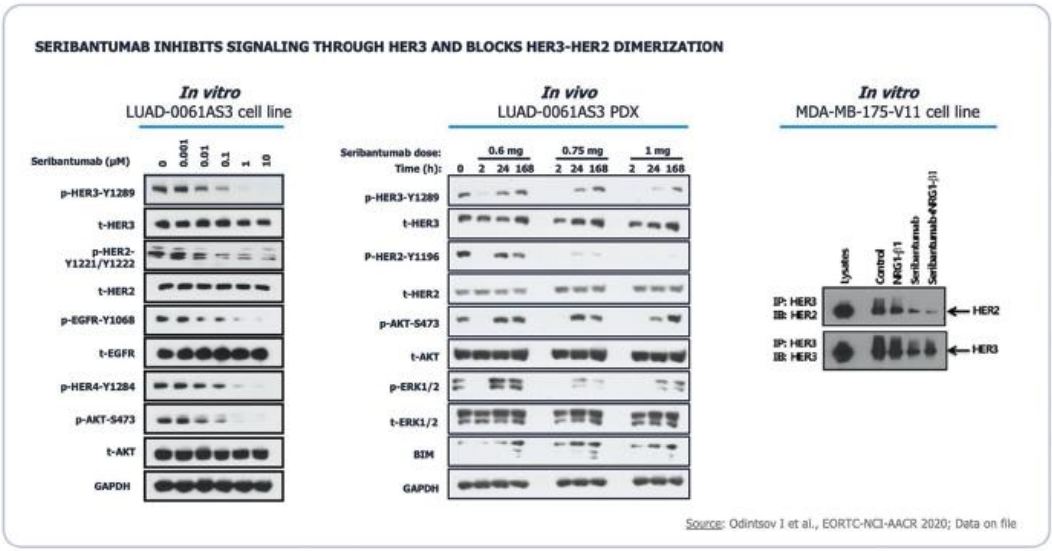

Figure 2. [**Left**] Treatment of the LUAD0061AS3 cell line (which has an SLC3A2-NRG1 fusion) with seribantumab showed dose-dependent inhibition of HER3, HER2, EGFR, HER4, and AKT phosphorylation *in vitro*. [**Middle**] Treatment of a LUAD0061AS3 PDX model confirmed reduction of HER3 and HER2 phosphorylation as well as reduction of phosphorylation of downstream AKT and ERK following a single flat dose of seribantumab (0.6 mg, 0.75 mg or 1 mg) *in vivo*. Tumors were removed at 2-, 24-, or 168-hours post-drug administration, to determine impact on signaling activity over time. All doses of seribantumab resulted in reduced phosphorylation of HER2, HER3, AKT, and ERK1/2 by the 2h time point, with higher doses being more effective at the longer time points. However, at the 24h and 168h time points, reactivation of HER3, AKT and ERK1/2 protein phosphorylation was observed, despite consistent

inhibition of HER2. Figures reproduced with permission from Clinical Cancer Research. [**Right**] MDA-MB-175-VII is a breast cancer model with a DOC4-NRG1 fusion. Immunoprecipitation (IP) of HER3 was followed by immunoblot (IB, Western blot) analysis for HER2 or HER3. In this NRG1 fusion containing cell line, HER3-HER2 dimers were detected under serum-depleted conditions. Treatment with NRG1-ß1 ligand did not increase HER3-HER2 association beyond basal levels, suggesting near-maximum association. Reduced levels of HER2 in the HER3 precipitate extracted following treatment with seribantumab suggests that seribantumab is able to block HER3-HER2 dimerization.

Figure 3. Preclinical proof of concept (*in vivo*): Seribantumab drives tumor regression in a lung SLC3A2-NRG1 fusion PDX model (LUAD-0061AS3).

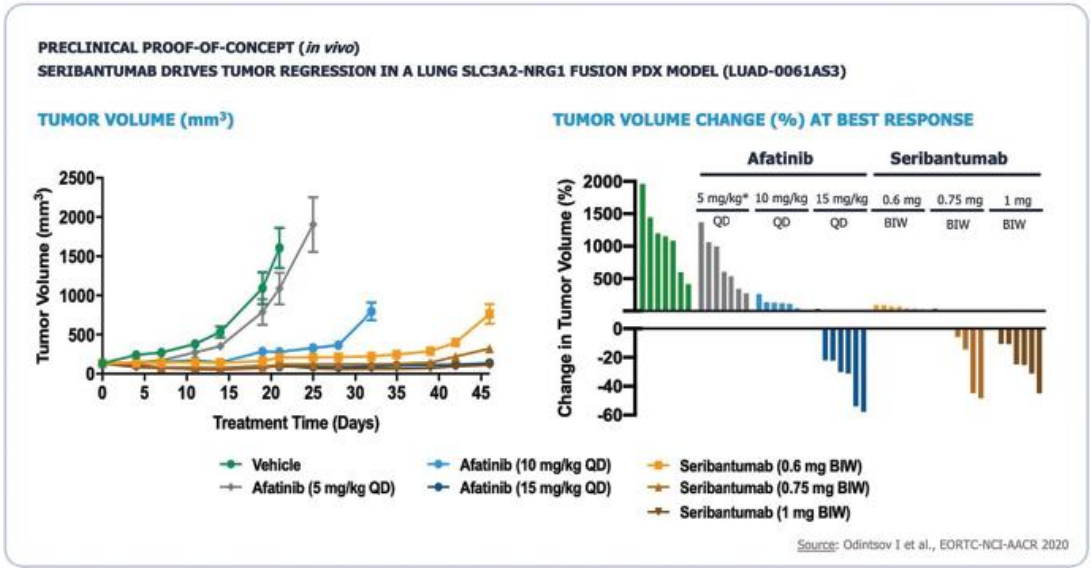

Figure 3: The LUAD-0061AS3 PDX model was developed from a lung cancer specimen with an SLCA3A2/NRG1 fusion and was used to test repeat dosing of seribantumab *in vivo*. Notably, this specimen was derived from a patient who had progressed after prior standard therapy and progression on afatinib therapy. In this trial, PDX tumors (approximately 3 mm^3) were implanted subcutaneously into the flanks of immunodeficient mice. Treatment was initiated when the tumors reached a volume of 150-200 mm^3. Each treatment group consisted of 7 mice while 5 mice were used in the vehicle control group. Treatment started on day 14 of the experiment and consisted of vehicle (PBS), seribantumab (0.6, 0.75 or 1 mg per dose BIW, or afatinib (5, 10, or 15 mg/kg QD). A dose-related decline in tumor volume was observed across all doses of seribantumab, with the best response observed with the 1 mg/kg dose where maximal tumor regression was approximately 60%. Afatinib was not associated with tumor regression at 5 mg/kg; however tumor regression of approximately 30% was observed at a dose of 15 mg/kg, which is approximately 3-fold higher than the clinically achievable dose of 40 mg/day in humans.

Figure 4. Preclinical proof of concept (*in vivo*):

Seribantumab drives near-complete tumor regression in an ovarian CLU-NRG1 fusion PDX model (OV-10-0050).

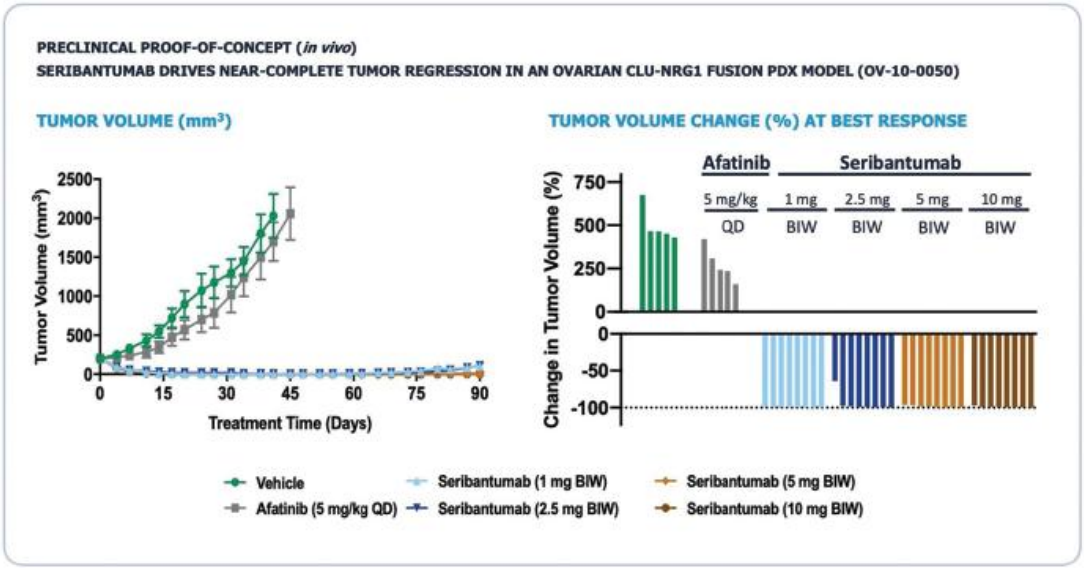

Figure 4: The OV-10-0050 PDX model was developed from an ovarian cancer specimen with a CLU-NRG1 fusion. Seribantumab at doses of 2.5 mg, 5 mg, and 10 mg BIW were tested. Near complete and complete tumor regressions were observed across the entire dose range, with complete tumor regressions observed in nearly all animals at the highest dose level of 10 mg BIW. Afatinib dosed at 5 mg/kg QD did not induce tumor regressions.

Based on the collective results from these studies, we believe that the active dose of seribantumab necessary to reduce HER3 and downstream ERBB signaling, reduce the growth of tumors, and extend the duration of response ranges from approximately 1 mg BIW and up to at least 10 mg BIW in these preclinical cancer models driven by an NRG1 fusion, which is approximately equivalent to a 260 mg - 2.6 g fixed dose in humans and well within the 3 gram weekly clinical dose of seribantumab. The inhibitory capability of seribantumab was evident in tumor types with different tissues of origin (lung and ovarian) and different NRG1 fusion partners (SLCA32-NRG1 and CLU-NRG1, respectively).

Optimized Clinical Trial and Regulatory Execution: Phase 2 Tumor-Agnostic CRESTONE trial (NCT04383210)

In July 2020, we initiated our Phase 2 CRESTONE trial following a Type C meeting with FDA as the first clinical trial of seribantumab in patients with solid tumors driven by an NRG1 fusion.

The CRESTONE trial is as an open-label, international, multi-center, tumor-agnostic Phase 2 trial in adult patients with recurrent, locally advanced or metastatic solid tumors that harbor an NRG1 gene fusion and have progressed after at least one prior line of standard therapy. Patients will be enrolled into one of three cohorts depending on prior treatments received and the presence or absence of an NRG1 fusion with intact EGF-like domain that is mutually exclusive with any other actionable molecular alteration. The trial is designed as a potentially registrational trial, contingent on continued discussions with the FDA.

A cohort design has been introduced to proactively control for innate biological variability in NRG1 fusions, such as impact of the expression of an intact EGF-like domain, as well as potential variability in response due to prior treatment with other inhibitors of the ERBB family. Cohort 1 is designated as the pivotal cohort and therefore has the most

stringent eligibility criteria. Cohorts 2 and 3 are exploratory in nature, and not intended to contribute to the population supporting a potential registration application.

All patient tumors will be tested for an NRG1 fusion based on local CLIA-certified or similarly accredited lab testing of tumor tissue prior to initiating further screening procedures. All patients must have received at least one prior line of standard therapy.

- Cohort 1 (Pivotal): At least 55 patients with a centrally confirmed NRG1 fusion who have not been previously treated with an EGFR-, HER2-, or HER3-directed therapy. Patients eligible for Cohort 1 must have a tumor with an NRG1 fusion with an intact EGF-like domain and no other known and actionable oncogenic driver alterations.

- Cohort 2 (Exploratory): Up to ten patients with tumors harboring an NRG1 fusion with an intact EGF-like domain and no other known and actionable oncogenic driver alterations, and who are relapsed/refractory to prior EGFR-, HER2-, or HER3-directed therapy.

- Cohort 3 (Exploratory): Up to ten patients who have (i) tumors harboring an NRG1 fusion without an intact EGF-like domain, (ii) tumors with other NRG1 alterations, (iii) tumors with additional known alterations without standard treatment options, or (iv) insufficient tissue biopsies available for central confirmation of NRG1 fusion status.

The primary endpoint of the CRESTONE trial is to determine the ORR by independent radiologic review according to RECIST 1.1. Tumor assessments will be measured and recorded by the local radiologist beginning at week 6. Independent central review of scans will be conducted for patients enrolled in Cohort 1.

Key secondary endpoints include DOR, PFS, OS, Clinical Benefit Rate (CBR; CR, PR, SD > 24 weeks), and the safety profile of seribantumab in patients with a tumor harboring an NRG1 fusion. Patients are expected to be treated until investigator-assessed progressive disease or unacceptable toxicity.

After all screening procedures and determination of eligibility for trial treatment (including a local NRG1 fusion positive testing result) have been completed, eligible patients will be assigned to the appropriate cohort based upon prior treatment history and local NRG1 fusion testing results. We expect to complete enrollment of the first 20 patients in Cohort 1 of the CRESTONE study in mid-2022, and to present initial clinical data from approximately 10 patients from Cohort 1 of the CRESTONE study treated with seribantumab at 3 grams weekly at a major medical meeting in mid-2022. We believe that the design and conduct of CRESTONE, subject to discussions with the FDA, may support submission of a BLA for accelerated approval in advanced solid tumors harboring an NRG1 fusion.

Key design components of CRESTONE

Several important design considerations have been built into the CRESTONE protocol that we believe may optimize for efficient conduct and a clean signal in the primary efficacy analysis population.

- A tumor-agnostic trial design maximizes opportunity for patient eligibility in this rare, genomically defined population.

- To avoid introduction of delays in patient screening leading to delayed initiation of treatment in this aggressive disease, patient eligibility is based on readily accessible, local CLIA-certified testing including PCR, FISH, DNA- or RNA-based NGS testing.

- To control for variability introduced by screening through local CLIA-certified testing, all patients in Cohort 1 will also have a central confirmatory test by RNA-based NGS to confirm the presence of an NRG1 fusion to help rule out any false-positive test results that may come from their prior local CLIA-certified testing. Only

patients with a centrally confirmed NRG1 fusion are included in the primary efficacy analysis population for statistical analysis.

- Due to the currently limited understanding of clinical impact of prior exposure to anti-ERBB therapy, patients that have received prior anti-ERBB therapy are excluded from Cohort 1. These patients may be enrolled into Cohort 2.

- The current literature suggests that an NRG1 fusion must retain a functional EGF-like binding domain to enable ligand-dependent HER3 signaling. Therefore, patients with an NRG1 fusion that lacks an EGF-like domain are excluded from Cohort 1. These patients may instead be enrolled in Cohort 3.

- Patients with co-expression of other known oncogenic drivers are excluded from Cohort 1. We believe that seribantumab as a monotherapy has the greatest potential for positive clinical outcomes in tumors uniquely driven by an NRG1 fusion. Patients with co-expression of other known oncogenic drivers, where there is no suitable alternative therapy to target these oncogenic drivers, may instead be enrolled in Cohort 3.

- Because NRG1 fusions are often found in more aggressive tumor types, it is important to achieve steady state of seribantumab as quickly as possible for disease control. The design of CRESTONE includes a proactive safety run-in and dose optimization phase to ensure that all subsequent patients comprising the primary efficacy analysis population are receiving an optimal dose specific to the NRG1 fusion population.

Patient identification and clinical conduct in CRESTONE

We proactively addressed key challenges in identifying and enrolling patients into trials for rare genomically defined tumors. We are employing multiple innovative models designed to ensure Good Clinical Practice and enhance enrollment of our Phase 2 CRESTONE trial through real-time nationwide identification of patients with tumors harboring an NRG1 fusion from our academic core sites and within our partner networks, in a capital-efficient manner. Through these mechanisms, we are rapidly alerted when any patient with an NRG1 fusion is identified across major diagnostic networks and have access to approximately 400 potential clinical trial sites in total.

Currently, patients may be enrolled onto CRESTONE via three mechanisms:

- *Enrollment at core sites:* These clinical trial sites are located at major academic and community medical centers and are strategically selected due to their deep clinical trial experience and an existing ability to locally test for NRG1 fusions. These sites are activated on a permanent basis for the duration of the trial.

- *Referral to core sites from diagnostic partner networks:* We have partnered with diagnostic providers such as Ashion Analytics (now Exact Sciences), NeoGenomics, and Strata Oncology and anticipate the potential to engage in additional partnerships in the future. These partnerships allow us access to diagnostic data generated using comprehensive DNA- and RNA-based NGS assays for the presence of an NRG1 fusion. When a patient with a tumor that has an NRG1 fusion is identified in their networks, we are alerted and put in touch with the treating physician to determine if the patient is eligible for CRESTONE with the treating physician being notified of the most proximal CRESTONE site.

- *"On-demand" site initiation:* Our partnerships with diagnostic providers such as Caris Life Sciences and Tempus, and health networks like The US Oncology Network (through their Selected Trials for Accelerate Rollout program), give us access to pre-qualified sites that can be quickly activated in approximately 14 days or fewer following the identification of a patient with a tumor harboring an NRG1 fusion that meets trial entry criteria and qualifies for CRESTONE. These sites are in addition to the core sites participating in CRESTONE.

We believe that recent advances in genomic testing, and subsequent increased adoption of RNA-based NGS, will result in improved identification of patients with tumors harboring an NRG1 fusion. In addition to academic and community-based medical centers that are routinely conducting testing, there are multiple commercial diagnostic companies that

include NRG1 fusions on their CLIA-certified testing panels. Some examples of these companies are: Ashion Analytics (now Exact Sciences), Caris, Illumina, Invitae (ArcherDx), NeoGenomics, Strata Oncology, Tempus and ThermoFisher, among others. In addition, Foundation Medicine can detect gene fusions potentially indicative of an NRG1 fusion through the identification of common NRG1 fusion partners, such as CD74. We anticipate partnering with a diagnostic provider to develop a companion diagnostic for seribantumab use in patients with tumors harboring an NRG1 fusion. This may be done in parallel to the CRESTONE trial or as a post-marketing commitment following a potential accelerated approval contingent upon continued discussion with the FDA.

We believe that the number of genomic tests that are conducted across tumor types, and the number of companies that include NRG1 fusions on their test panels, will continue to increase over time.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational product candidates, as well as our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

We are currently party to a manufacturing agreement with Samsung Biologics Co., Ltd., or Samsung, for the manufacturing of seribantumab drug substance and the performance of associated quality related services. Options for redundant or replacement supply are under active evaluation. Seribantumab is currently being manufactured at a scale appropriate for clinical trials and has previously been manufactured at a scale suitable for commercialization. To the extent we approach commercialization for seribantumab or any other product candidates, we expect that we would identify and qualify additional manufacturers to provide the drug substance and fill finish services as a part of such commercialization plans.

We generally expect to rely on third parties for the manufacturing of any companion diagnostics we may develop.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our team, and our development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

We compete directly with companies that focus on oncology and companies dedicating their resources to cancer therapies. With the proliferation of new drugs and therapies into oncology, we expect to face increasingly intense competition as new technologies become available and new therapeutic candidates are clinically developed or approved therapies are explored for new indications. Any candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly

through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

The key competitive factors affecting the success of all of our therapeutic antibody candidates, if approved, are likely to be their efficacy, safety, dosing convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, and are more convenient or less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we can, which could result in our competitors establishing a strong market position before we are able to enter the market or could otherwise make our development more complicated. We believe the key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and patient convenience. Even if our antibody candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then.

There are a number of biological and biotechnology companies that currently are pursuing the development of precision oncology therapies for patients with undrugged, genetically-defined cancers with high unmet need. In particular, we expect that our current lead product candidate, seribantumab, will compete against other ERBB or HER3 inhibitors that are in development for targeting tumors with an NRG1 fusion, including those of Merus N.V. (zenocutuzumab — MCLA-128), Hummingbird Bioscience Ltd. (HMBD-001 — 10D1F), GamaMabs Pharma (9F7-F11), and AVEO Oncology (AV-203). We may face further competition from companies pursuing the development of product candidates that are ERBB or HER3 inhibitors not currently in defined clinical plans for targeting tumors with an NRG1 fusion, including ISU ABXIS, Daiichi Sankyo, Celldex, GlaxoSmithKline, Boehringer Ingelheim, or others. Development efforts and clinical results of these other future product candidates may be unsuccessful, which could result in a negative perception of HER3 inhibitors, for instance, and negatively impact the regulatory approval process of our lead product candidate, which could have a material and adverse effect on our business.

Asset purchase, licensing and collaboration agreements

Previous sponsor

In May 2019, we entered into an asset purchase agreement with the previous sponsor, pursuant to which we acquired the previous sponsor's anti-HER3 antibody programs, or the Acquired Product Candidates, including seribantumab. Upon closing of the asset purchase agreement in July 2019, we paid the previous sponsor an upfront cash payment of $3.5 million. In addition to the foregoing payment, we may become obligated to pay the previous sponsor up to $54.5 million in additional potential development, regulatory approval and commercial-based milestone payments, consisting of:

- $3.0 million for achievement of the primary endpoint in the first registrational clinical trial of any Acquired Product Candidate;
- up to $16.5 million in total payments for the achievement of various regulatory approval and reimbursement-based milestones in the United States, Europe and Japan; and
- up to $35.0 million in total payments for achieving various cumulative worldwide net sales targets between $100.0 million and $300.0 million for the Acquired Product Candidates.

Dyax

Pursuant to the asset purchase agreement with the previous sponsor, and in connection with the closing of the asset purchase agreement, we (i) assumed all of the previous sponsor's obligations and rights under the amended and restated collaboration agreement, or the Dyax collaboration agreement, between the previous sponsor and Dyax Corp., or Dyax,

which was entered into in January 2007, including an exclusive, worldwide product license to clinically develop or commercialize seribantumab and (ii) agreed to be bound to the terms of a sublicense agreement between the previous sponsor and Dyax entered into in June 2008. Under the Dyax collaboration agreement, Dyax used its proprietary phage display technology to identify antibodies that bind to targets of interest to us as therapeutics or diagnostics. Seribantumab was identified through the Dyax collaboration agreement. In January 2016, Dyax was acquired by Shire plc, which was subsequently acquired by Takeda Pharmaceutical Company Limited in January 2019.

We may be required to make additional maximum aggregate development and regulatory milestone payments of up to approximately $9.3 million for seribantumab. In addition, Dyax is entitled to tiered mid single digit royalties based on net sales of seribantumab. Our obligation to pay royalties to Dyax continues on a country-by-country basis until the later of a specified number of years after the first commercial sale of seribantumab in such country and the expiration of the patent rights covering the product in such country. We are obligated to use commercially reasonable efforts to develop and commercialize the antibodies for which we obtain a commercial license.

This agreement will remain in effect, unless terminated earlier, for so long as we or any of our affiliates or sublicensees continue to develop or commercialize products that remain royalty-bearing under the agreement. Either party may terminate the agreement in the event of an uncured material breach by the other party. We also may terminate the agreement in its entirety or on a product-by-product basis at any time upon 90 days' prior written notice.

Ligand Pharmaceuticals

Pursuant to the asset purchase agreement with the previous sponsor, and in connection with the closing of the asset purchase agreement, we purchased from the previous sponsor all of the right, title and interest in and to the commercial license agreement between the previous sponsor and Selexis SA, or Selexis, for non-exclusive rights to technology for use in the manufacture of certain biologic products. Under this agreement, we are required to make aggregate milestone payments of up to €0.9 million, per licensed product, and pay royalties of less than one percent on net sales of product, which royalty payments expire in 2026. The obligation to pay royalties with respect to each product sold in a country continues until the expiration of the patent rights covering the product in such country. Either party may terminate the agreement in the event of an uncured material breach by the other party. We also have the right to terminate the agreement at any time upon 60 days' prior written notice. In November of 2021, the Selexis agreement was assigned to Ligand Pharmaceuticals Incorporated.

Caris Agreement

In June 2021, we entered into a collaboration agreement with Caris, or the Caris Agreement. Under the terms of the Caris Agreement, Caris will identify targets for the collaboration and provide those targets to Elevation at regular intervals for review and approval. Once a target is selected by the collaboration's joint steering committee, the collaboration will retain access to the selected targets.

The financial terms surrounding development and commercialization of each product candidate identified for the collaboration and included in the Caris Agreement vary based on the level of participation elected by each party in the development and commercialization efforts following identification of a target. There are no upfront or milestone payments or royalties due to either party under the collaboration. With respect to proceeds from any potential commercial transaction related to a product resulting from the collaboration, Caris will be entitled to a tiered initial percentage ranging from the mid-single digits to low teens based on the product candidate's potential peak sales revenue with the remaining proceeds allocated based on each party's pro rata share of expenses incurred in development of the product. In the case of an out-licensing transaction of an asset instead of a sale, Caris and we will split all consideration received in the transaction in a similar manner. The Caris Agreement provides flexibility for Caris and us to jointly develop and commercialize, or for either us or Caris to incur development and commercialization expenses. The ultimate percentage of proceeds payable to us and Caris will depend on the level of development and commercialization participation elected by each party.

We will own the intellectual property rights to the therapeutics developed under the collaboration, and Caris will own the intellectual property rights to the diagnostics developed under the collaboration.

Either party may terminate the Caris Agreement for uncured material breach by the other party or in the case of the other party's insolvency. The term of the Caris Agreement is three years, automatically renewing for one-year terms. Either party may terminate the agreement at the end of a term by written notice to the other, subject to the continuation of exclusivity with respect to any target selected by the joint steering committee, so long as commercially reasonable efforts are used to discover, identify, develop and/or commercialize a therapeutic related to such target.

Intellectual property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the compositions of matter of our product candidate, its methods of use, and other inventions that are important to our business.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions, and know-how related to our business, to defend and enforce our patents, to preserve the confidentiality of our trade secrets, and to operate without infringing valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how and continuing technological innovation to develop, strengthen, and maintain our proprietary position in the field of precision oncology.

Our wholly owned patent portfolio includes a patent family with claims directed to antibodies and related compositions covering seribantumab, as well as methods of treating cancer using such antibodies and compositions. The family contains three U.S. patents directed to seribantumab which expire in February 2028 and a fourth U.S. patent which expires in October 2029 (including 614 days of Patent Term Adjustment), subject to any disclaimers or extensions. The family also contains a pending U.S. application, which if issued, would expire in February 2028, subject to any disclaimers or extensions.

In addition, the above-discussed patent family includes granted patents in China, Europe, Hong Kong, Israel, and Japan with claims directed to compositions of matter covering seribantumab and related methods of therapy. These patents expire in February 2028, subject to any disclaimers or extensions.

Our patent portfolio further includes an additional early-stage, unpublished patent family specifically covering the use of seribantumab to treat patients harboring an NRG1 fusion according to our CRESTONE clinical trial dosing regimen. Any patents issuing from this family would expire in March 2042, subject to any disclaimers or extensions.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In the countries in which we file, the patent term is 20 years from the earliest non-provisional filing date, subject to any disclaimers or extensions. The term of a patent in the United States can be adjusted due to any failure of the United States Patent and Trademark Office following certain statutory and regulation deadlines for issuing a patent.

In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for a portion of the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the original expiration of the patent. The protection provided by a patent varies from country to country, and is dependent on the type of patent granted, the scope of the patent claims, and the legal remedies available in a given country. Additionally, we expect seribantumab to be subject to biological exclusivity in the United States for twelve years from BLA approval under the Biologics Price Competition and Innovation Act of 2009. See "Government Regulation and Product Approval — Biosimilars."

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 during the course of the individual'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.

Governmental Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, biological products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act, with the exception that the section of the FDC Act that governs the approval of drugs via new drug applications, or NDAs, does not apply to the approval of biologics. In contrast, biologics are approved for marketing under provisions of the Public Health Service Act, or PHSA, via a BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Biological product development for a new product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including Good Laboratory Practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as tests of reproductive toxicity and carcinogenicity in animals, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with Good Clinical Practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA regulations or presents an unacceptable risk to the clinical trial patients. Imposition of a clinical hold may be full or partial. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or

IRB, for approval. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. 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 or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Clinical trials to support BLAs for marketing approval are typically conducted in three sequential phases. In Phase 1, the initial introduction of the drug or biologic into patients, the product is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure, and to obtain early evidence of a treatment effect if possible. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the biologic for a particular indication, determine optimal dose and regimen, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical effects and confirm efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the biologic and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the biologic. In rare instances, a single Phase 3 trial may be sufficient when either (1) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) the single trial is supported by other confirmatory evidence. Approval on the basis of a single trial may be subject to a requirement for additional post-approval studies.

These phases may overlap or be combined. For example, a Phase 1/2 clinical trial may contain both a dose-escalation stage and a dose-expansion stage, the latter of which may confirm tolerability at the recommended dose for expansion in future clinical trials (as in traditional Phase 1 clinical trials) and provide insight into the anti-tumor effects of the investigational therapy in selected subpopulation(s). Typically, during the development of oncology therapies, all subjects enrolled in Phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies.

In addition, the manufacturer of an investigational biologic in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug or biologic.

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA approval of the BLA is required before marketing and distribution of the product may begin in the United States. The BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting a BLA is substantial. The submission of most BLAs is additionally subject to a substantial application user fee. Under an approved BLA, the applicant is also subject to an annual program fee. These fees typically increase annually. A BLA for a drug that has been designated as an orphan drug is not subject to an application fee, unless the BLA includes an indication for other than a rare disease or condition. The FDA has 60 days from its receipt of a BLA to determine whether the application will be filed based on the FDA's determination that it is adequately organized and sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals to complete the review of BLAs. Most applications are classified as Standard Review products that are reviewed within ten months of the date the FDA files the BLA; applications classified as Priority Review are reviewed within six months of the date the FDA files the BLA. A BLA can be classified for Priority Review when the FDA determines the biologic has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority reviews may be extended by the FDA for three or more additional months to consider certain late-submitted information, or information intended to clarify information already provided in the BLA submission.

The FDA may also refer applications for novel biologic products, as well as biologic products that present difficult questions of safety or efficacy, to be reviewed by an advisory committee — typically a panel that includes clinicians, statisticians and other experts — for review, evaluation, and a recommendation as to whether the BLA should be approved. The FDA is not bound by the recommendation of an advisory committee, but generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic product is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practice, or cGMP is satisfactory and the BLA contains data that provide substantial evidence that the drug is safe and effective, or the biologic is safe, pure, potent, and effective, in the respective claimed indication.

After the FDA evaluates the BLA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the BLA submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the biologic with specific prescribing information for specific indications. As a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the biologic outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product's safe use, or ETASU. An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved BLA, including changes in indications, product labeling, manufacturing processes or facilities, require submission and FDA approval of a new BLA, or supplement to an approved BLA, before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing original BLAs.

Fast Track Designation and Priority Review

FDA is required to facilitate the development, and expedite the review, of drugs or biologic products that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment 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. Any product submitted to 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.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

Breakthrough Therapy Designation

FDA is also required to expedite the development and review of applications for approval of products that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new product candidate may request that FDA designate the product

candidate for a specific indication as a breakthrough therapy concurrent with, or after, the submission of the IND for the product candidate. FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner.

Accelerated Approval

Accelerated approval may be granted for a product that is intended to treat a serious or life-threatening condition and that generally provides a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large studies to demonstrate a clinical or survival benefit. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in most cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Orphan Drugs

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

Orphan drug designation must be requested before submitting a BLA. After FDA grants orphan drug designation, the identity of the drug and its potential orphan use are disclosed publicly by FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The first BLA applicant to receive FDA approval for a particular active moiety to treat a rare disease for which it has such designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Other benefits of orphan drug designation include tax credits for certain research and an exemption from the BLA application fee.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs and biologic products, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made

public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, BLAs, or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any biological product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer.

The Best Pharmaceuticals for Children Act, or BPCA, provides a six-month extension of any non-patent exclusivity for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new biologic in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend biologics licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases within the United States.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the lot manufacturing history and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before allowing the manufacturer to release the lots for distribution. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of a BLA, biologics manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Post-Approval Requirements

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging, and labeling procedures must

continue to conform to cGMPs after approval. Biologics manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a biologic product's manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Biosimilars

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical trials, animal trials, and a clinical trial or trials, unless the Secretary of Health and Human Services waives a required element. A biosimilar product may be deemed interchangeable with a previously approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. To date, a number of biosimilar products and two interchangeable products have been approved under the BPCIA. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose some hurdles to biosimilar product implementation, which is still being evaluated by the FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure, or BLA approval, of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the biosimilar abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) eighteen months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

FDA Approval and Regulation of Companion Diagnostics

If safe and effective use of a product depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, before or at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, if FDA determines that a companion diagnostic device is essential to the safe and effective use of a new therapeutic product or indication, FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication.

Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. The review of *in vitro* companion diagnostics in conjunction with the review of our products will, therefore, likely involve coordination of review by CDER and the FDA's Office of In Vitro Diagnostics and Radiological Health. We anticipate partnering with a diagnostic provider to develop a companion diagnostic for seribantumab use in patients with tumors harboring an NRG1 fusion. Review and approval of a companion diagnostic is typically done in parallel with development of the therapeutic product. However, it is possible that FDA may permit approval of the companion diagnostic for seribantumab as a post-marketing commitment following a potential regulatory approval.

Under the FDC Act, *in vitro* diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDC Act and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. The vast majority of companion diagnostics require PMA approval.

The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, a PMA application typically requires data regarding analytical and clinical validation studies. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, additional testing and/or restrictions on labeling, promotion, sale and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained, or problems are identified following initial marketing.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also register their establishments and list their devices with the FDA. A medical device manufacturer's manufacturing processes and the processes of the specification developer and repackager/relabeler (if different from the manufacturer) and initial importer (if manufactured outside of the United States), are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry. These laws include anti-kickback, false claims, transparency and health information privacy laws and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, or the ACA, amended the intent element of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal civil False Claims Act.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates and their subcontractors that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, 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 attorney’s fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not pre-empted by HIPAA.

Further, pursuant to the ACA, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule that requires certain manufacturers of prescription drugs to collect and annually report information on certain payments or transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) physician assistants, certain types of advance practice nurses, and teaching hospitals, as well as ownership and investment interests held by

physicians and their immediate family members. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

Analogous state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers, or that apply regardless of payor. In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Further, certain states require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain drug pricing information, including information pertaining to and justifying price increases. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Certain states and local jurisdictions also require the registration of pharmaceutical sales representatives. Additionally, we may also be subject to state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that business arrangements with third parties comply with applicable state, federal, and foreign healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

U.S. Healthcare Reform

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The Department of Health and Human Services, or HHS, plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. Many similar proposals, including the plans to give Medicare Part D authority to negotiate drug prices, require drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation, and cap out-of-pocket costs, have already been included in policy statements and legislation currently being considered by Congress. It is unclear to what extent these and other statutory, regulatory, and administrative initiatives will be enacted and implemented.

We expect that additional state and federal healthcare reform measures will be adopted in the future. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Coverage and Reimbursement

Patients in the United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their prescription drugs. Accordingly, market acceptance of our drug products is dependent on the extent to which third-party coverage and reimbursement is available from government health administration authorities (including in connection with government healthcare programs, such as Medicare and Medicaid in the United States), private healthcare insurers and other healthcare funding organizations. Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. Coverage decisions may not favor new drug products when more established or lower-cost therapeutic alternatives are already available. Patients are unlikely to use our products unless reimbursement is adequate to cover all or a significant portion of the cost of our drug products.

Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time-consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our drug products. Additionally, we may develop, either by ourselves or with collaborators, companion diagnostic tests for our product candidates for certain indications. We, or our collaborators, if any, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved.

The market for our product candidates will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. Competition to be included in such formularies often leads to downward pricing pressures. In particular, third-party payors may refuse to include a particular reference listed drug in their formularies or otherwise restrict patient access to a reference listed drug when a less costly generic equivalent or other alternative is available.

The U.S. government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our drugs products from coverage and limit payments for pharmaceuticals.

In addition, we expect that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities to continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more drug products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees and human capital resources

As of February 28, 2022, we had 35 full-time employees. Of these employees, five held Ph.D. or Pharm.D degrees, and 26 were engaged in research, development and technical operations. From time to time, we also retain independent contractors and consultants to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purpose of our incentive share plan is to attract, retain and motivate selected employees, consultants and directors through the granting of incentive share-based compensation awards and cash-based performance bonus awards.

Facilities

We are a remote-first company, meaning that substantially all of our employees work remotely. As a result of this strategy, we do not maintain a corporate headquarters or lease any corporate facilities. We believe that our facilities are adequate to meet our needs for the immediate future, and that, should we need additional physical office space, suitable additional space will be available in the future on commercially reasonable terms.

Legal proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

Corporate information

Our principal executive offices are located at 888 Seventh Ave, 12th Floor, New York, New York 10106 and our telephone number is (716) 371 1125. Our website address is www. elevationoncology.com. Information contained on or accessible through our website is not a part of this Annual Report. The following filings are available through the Securities and Exchange Commission, or the SEC, which maintains an Internet site at www.sec.gov, and through our website as soon as reasonably practicable after we file them with the SEC: Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, as well as any amendments to such reports and all other filings pursuant to Section 13(a) or 15(d) of the Securities Act of 1933, as amended, or the Securities Act.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider and read carefully all of the risks described below, together with the other information contained in this Annual Report, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report, before deciding whether to invest in our common stock. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. Unless otherwise indicated, references to our business being harmed in these risk factors will include harm to our business, reputation, financial condition, results of operations, net revenue and future prospects. In such event, the trading price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report.

Risk Factor Summary

The following summarizes the most material risks that make an investment in our securities risky or speculative. If any of the following risks occur or persist, our business, financial condition and results of operations could be materially harmed and the price of our common stock could significantly decline.

- We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability. We have incurred significant operating losses since our inception in 2019 and have not generated any revenue. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.

- We are highly dependent on the success of our lead product candidate, seribantumab. We have not completed clinical development or obtained regulatory approval for any product candidate. We may never obtain approval for seribantumab or any other product candidate.

- The COVID-19 pandemic could adversely impact our business, including the conduct of our clinical trials.

- If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

- Adverse side effects or other safety risks associated with seribantumab or our other future product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the commercial profile of an approved product or result in significant negative consequences following marketing approval, if any.

- We may in the future seek to engage in strategic transactions to acquire or in-license new products, product candidates or technologies. If we are unable to realize the benefits from such transactions, it may adversely affect our ability to develop and commercialize product candidates, negatively impact our cash position, increase our expenses and present significant distractions to our management.

- The development and commercialization of biological products are subject to extensive regulation, and we may not obtain regulatory approvals for seribantumab or any other future product candidates, on a timely basis or at all.

- If we are unable to successfully develop, validate, obtain regulatory approval of and commercialize companion diagnostic tests for seribantumab or any future product candidates that require or would benefit from such tests,

or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

- Manufacturing biological products is complex and subject to product loss for a variety of reasons. We rely on third-party suppliers, including single source suppliers, to manufacture clinical supplies of our lead product candidate and we intend to rely on third parties to produce commercial supplies of any approved product.

- The incidence and prevalence for target patient populations of seribantumab and our future product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, then our revenue potential and ability to achieve profitability will be adversely affected.

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

- We expect to significantly expand our development and regulatory capabilities as we grow our company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

- If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our seribantumab and our future product candidates may be adversely affected.

Risks related to our financial position and need for additional capital

We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability. We have incurred significant operating losses since our inception in 2019 and have not generated any revenue. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.

Investment in drug development is a highly speculative undertaking and involves a substantial degree of risk. We commenced operations in 2019 and are a clinical-stage biologics company with a limited operating history. We have not yet commercialized any product, nor do we expect to generate revenue from sales of any products for several years, if at all. Consequently, there have been limited operations upon which you can evaluate our business, and predictions about our future success or viability may not be as cancer therapies. For the years ended December 31, 2021 and 2020, we had a net loss of $32.0 million and $17.3 million, respectively. As of December 31, 2021, we had an accumulated deficit of $55.2 million. We expect to continue to incur significant research and development and other expenses related to our ongoing operations, which we anticipate will result in net losses for at least the next several years.

Since our inception, we have focused substantially all of our efforts and financial resources on the acquisition and clinical development of our lead product candidate, seribantumab. To date, we have funded our operations with proceeds from sales of shares of our convertible preferred stock and our initial public offering. From our inception through December 31, 2021, we received an aggregate of $97.2 million in net proceeds from sale of our convertible preferred stock. We received an aggregate of $97.1 million in net proceeds from our initial public offering. As of December 31, 2021, our cash and cash equivalents were $146.3 million.

We expect to incur increasing levels of operating losses for the foreseeable future, particularly as we advance seribantumab and potential future product candidates through clinical development. Our prior losses, combined with expected future losses, have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect our research and development expenses to significantly increase in connection with our additional planned clinical trials for seribantumab, including our ongoing Phase 2 clinical trial, CRESTONE, and the planned exploratory cohorts, and the development of other future product candidates we may choose to pursue. In addition, if we obtain marketing approval for seribantumab or another future product candidate, we will incur significant sales, marketing and outsourced manufacturing expenses in connection with the commercialization of seribantumab or such

other future product candidate. After our initial public offering, we incurred and will continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue and we do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and begin to sell, seribantumab or another future product candidate. Our ability to generate revenue and become profitable will depend on a number of factors, including, but not limited to, our ability to:

- successfully meet our clinical endpoints in our Phase 2 CRESTONE clinical trial;
- initiate and successfully complete all safety, pharmacokinetic and other registrational-enabling studies required to obtain U.S. and foreign marketing approval for seribantumab as a treatment for patients with solid tumors driven by an NRG1 gene fusion;
- initiate and complete successful later-stage clinical trials that meet their clinical endpoints;
- submit a BLA for seribantumab to the FDA that is filed by the FDA;
- obtain marketing approval for seribantumab and our other potential future product candidates;
- establish licenses, collaborations or strategic partnerships that may increase the value of our programs;
- successfully manufacture or contract with others to manufacture seribantumab and our other future product candidates;
- commercialize seribantumab, if approved, by building a sales force or entering into collaborations with third parties;
- obtain, maintain, protect and defend our intellectual property portfolio;
- achieve market acceptance of seribantumab and our other potential future product candidates with the medical community and with third-party payors; and
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel.

We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

In cases where we are successful in obtaining regulatory approval to market our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is significantly lower than we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if they are approved.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses we will incur and when, or if, we will be able to achieve profitability. If we decide to or are required by the FDA or regulatory authorities in other jurisdictions to perform studies or clinical trials in addition to those we currently anticipate, or if there are any delays in establishing appropriate manufacturing

arrangements for, in initiating or completing our current and planned clinical trials for, or in the development of, our product candidates, our expenses could increase materially and our potential profitability could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Accordingly, you should not rely upon the results of any quarterly or annual periods as predictions or indications of future operating performance. We expect our financial condition and operating results to fluctuate from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We require substantial additional funding to pursue our business objectives. If we are unable to raise additional capital when needed or on terms acceptable to us, we could be forced to delay, reduce or terminate our research or drug development programs, any future commercialization efforts or other operations.

Identifying and developing 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 regulatory approval and begin selling any approved product. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the clinical development of seribantumab and seek to develop or acquire additional product candidates. We expect increased expenses as we continue our research and development activities, initiate additional clinical trials and seek marketing approval for seribantumab and our future product candidates. In addition, if we obtain marketing approval for seribantumab, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, following the closing of our initial public offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on favorable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise additional capital when needed or on favorable terms, we could be forced to delay, reduce or eliminate our research and development programs, our commercialization plans or other operations.

We believe that our existing cash and cash equivalents as of December 31, 2021 will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changes beyond our control may occur that would cause us to use our available capital before that time, including changes in and progress of our drug development activities and changes in government regulations. Our future capital requirements will depend on many factors, including:

- the progress, timing and results of preclinical studies and clinical trials for seribantumab or any future product candidates;
- disruptions or delays in enrollment of our clinical trials;
- the extent to which we develop, in-license or acquire other product candidates or technologies;
- the number and development requirements of other future product candidates that we may pursue, and other indications for seribantumab that we may pursue;
- the costs, timing and outcome of obtaining regulatory approvals of seribantumab or future product candidates and any companion diagnostics that we may pursue;
- the scope and costs of making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of seribantumab or future product candidates;

- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of seribantumab or future product candidates;
- the costs associated with commercializing any approved product candidates, including establishing sales, marketing and distribution capabilities;
- the costs associated with completing any post-marketing studies or trials required by the FDA or other regulatory authorities;
- the revenue, if any, received from commercial sales of seribantumab, if approved, or any other future product candidates that receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims that we may become subject to, including any litigation costs and the outcome of such litigation;
- the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims; and
- to the extent we pursue strategic collaborations, including collaborations to commercialize seribantumab or to develop any future product candidates, our ability to establish and maintain collaborations on favorable terms, if at all, as well as the timing and amount of any milestone or royalty payments that we are required to make or are eligible to receive under any such collaborations.

We require additional capital to complete our planned clinical development programs for our current product candidates to obtain regulatory approval. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors over which we may have no or limited control. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of seribantumab or future product candidates or we may be unable to take advantage of future business opportunities. Furthermore, any additional capital-raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize seribantumab and future product candidates.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution 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 grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks related to the design and development of our product candidates

We are highly dependent on the success of our lead product candidate, seribantumab. We have not completed clinical development or obtained regulatory approval for any product candidate. We may never obtain approval for seribantumab or any other product candidate.

Our future success is highly dependent on our ability to obtain regulatory approval for, and then successfully commercialize or identify a strategic partner to commercialize, our lead product candidate, seribantumab. Seribantumab is currently being evaluated in a Phase 2 clinical trial, which we refer to as CRESTONE. We currently have no products that are approved for sale in any jurisdiction. Seribantumab or any of our other future product candidates may not achieve success in their clinical trials or obtain regulatory approval. If we do not obtain regulatory approval for seribantumab and successfully commercialize seribantumab in one or more indications or if we experience significant delays in doing so, we may never generate any revenue or become profitable.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of seribantumab or other future product candidates. The success of seribantumab or any other future product candidate will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials, including our CRESTONE trial;
- timely and successful enrollment of patients in, and completion of, clinical trials with favorable results;
- demonstration of safety, efficacy and acceptable risk-benefit profiles of seribantumab and our future product candidates to the satisfaction of the FDA and other regulatory agencies;
- our ability, or that of our collaborators, to develop and obtain clearance or approval of companion diagnostics, on a timely basis, or at all;
- receipt and related terms of marketing approvals from applicable regulatory authorities for seribantumab and our future product candidates, including the completion of any required post-marketing studies or trials;
- raising additional funds necessary to complete the clinical development of and commercialization of seribantumab;
- successfully identifying and developing, acquiring or in-licensing additional product candidates to expand our pipeline;
- acceptance of an IND by the FDA or other similar clinical trial applications from other regulatory authorities for clinical trials for future product candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for seribantumab and our future product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if approved, whether alone or in collaboration with third parties;
- acceptance of our products, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies available on the market or in development;

- obtaining and maintaining third-party payor coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of any products following regulatory approval.

Many of these factors are beyond our control, and it is possible that none of our product candidates, including seribantumab, will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we experience significant delays or are otherwise unable to successfully commercialize our product candidates, it would materially harm our business.

Drug development is a lengthy and expensive process, and clinical testing is uncertain as to the outcome.

We currently have one product candidate in Phase 2 clinical development, and the risk of failure is high. We are unable to predict when or if seribantumab will prove effective and safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome.

A failure of one or more clinical trials can occur at any stage of testing. The outcomes of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials or of clinical trials of the same product candidates in other indications, and interim or preliminary results of a clinical trial do not necessarily predict final results. For example, Merrimack Pharmaceuticals, Inc., or the previous sponsor, terminated its Phase 2 clinical trial of seribantumab in combination with docetaxel in patients with heregulin positive non-small cell lung cancer based on an interim analysis that demonstrated that the addition of seribantumab to docetaxel did not improve progression-free survival over docetaxel alone in this patient population. The previous sponsor also terminated its Phase 2 clinical trial of seribantumab in combination with fulvestrant in patients with heregulin positive, hormone receptor positive, ERBB2 (HER2) negative, metastatic breast cancer based on the interim analysis of the results of the non-small lung cancer trial. Although our CRESTONE trial of seribantumab is in a tumor-agnostic NRG1 fusion indication and therefore differs from the previous trials conducted by the previous sponsor, we may observe similar outcomes that could limit our ability to receive regulatory approval for seribantumab. While we believe that oncogenic driver events are a primary cause for the oncogenesis and progression of certain tumors, the signaling pathways in cancer are complex and treatment with a monotherapy may not produce a durable clinical benefit and combinations with other anti-cancer agents may need to be explored. There are no approved therapies for patients with tumors harboring an NRG1 fusion and our approach of inhibiting HER3 may not result in a durable clinical outcome. In addition, while some results in patients, such as observations of stable disease, may suggest encouraging clinical activity with respect to seribantumab, we expect that stable disease would not be considered to be a sufficient response for regulatory approval purposes. Furthermore, we may observe adverse safety events in the CRESTONE trial or later trials that were not observed in prior trials, which would alter the anticipated risk-benefit profile of seribantumab and reduce the likelihood that seribantumab receives regulatory approval.

The COVID-19 pandemic could adversely impact our business, including the conduct of our clinical trials.

The ongoing COVID-19 pandemic, both in the United States and in other countries in which we have planned or have active clinical trial sites and where our third-party manufacturers operate, could cause significant disruptions that could severely impact our business, including:

- delays or difficulties in screening, enrolling and maintaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

- inability or unwillingness of subjects to travel to the clinical trial sites;
- delays, difficulties or incompleteness in data collection and analysis and other related activities;
- decreased implementation of protocol required clinical trial activities and quality of source data verification at clinical trial sites;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials and our other research and development activities, including because of sickness of employees or their families or mitigation measures such as lock-downs and social distancing;
- delays due to production shortages resulting from any events affecting raw material supply or manufacturing capabilities domestically and abroad;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global and domestic shipping that may affect the transport of clinical trial materials, such as investigational drug products used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, delays or require us to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of regulatory authorities such as FDA or European Medicines Agency, or the European Medicines Agency, or EMA, to accept data from clinical trials in affected geographies; and
- adverse impacts on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed.

Such disruptions could impede, delay, limit or prevent completion of our ongoing clinical trials and preclinical studies or commencement of new clinical trials and ultimately lead to the delay or denial of regulatory approval of seribantumab, which would seriously harm our operations and financial condition and increase our costs and expenses. Furthermore, if either we or any third party in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the COVID-19 pandemic, our supply chain may be disrupted, limiting our ability to manufacture product candidates for our clinical trials. We are in close contact with our clinical research organizations, or CROs, our contract manufacturing organizations, or CMOs, and clinical sites as we seek to mitigate the impact of COVID-19 on our CRESTONE trial and current timelines. Measures we have taken in response to COVID-19 include, where feasible, conducting remote clinical trial site activations and data monitoring, and limiting on-site patient visits by adjusting patient assessments and protocol. However, despite these efforts, we have experienced limited delays in trial site initiations, patient participation and patient enrollment in some of our clinical trials and we may continue to experience some delays in our clinical trials and preclinical studies and delays in data collection and analysis.

These negative impacts could be exacerbated as the COVID-19 pandemic and the response to it continues to evolve. The COVID-19 pandemic could also affect the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to planned or completed clinical trials and ultimately of reviews and approvals of

seribantumab. The extent to which the pandemic impacts our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the success of mass vaccination efforts globally, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken by governmental authorities to contain and address the challenges posed by COVID-19.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete the development and/or commercialization of seribantumab or our other future product candidates.

Any delays in the commencement or completion of our ongoing, planned or future clinical trials could significantly increase our product development costs. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize seribantumab or our future product candidates, including:

- regulators, institutional review boards, or IRBs, or ethics committees, or ECs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA may disagree as to the design or implementation of our clinical trials or with our recommended Phase 2 doses for seribantumab, or with respect to any of our future product candidates;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective CROs and prospective trial sites;
- clinical trials for seribantumab or our future product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay or halt clinical trials or abandon product development programs;
- lack of adequate funding to continue clinical trials;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or may be lower than we anticipate due to challenges in recruiting and enrolling suitable patients who meet the trial criteria, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate;
- competition for clinical trial participants from investigational and approved therapies may make it more difficult to enroll patients in our clinical trials;
- we may experience difficulties in maintaining contact with patients after treatment, resulting in incomplete data;
- we or third-party collaborators may fail to obtain regulatory approval of companion diagnostic tests, if required, on a timely basis, or at all;
- our third-party contractors may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- we may have to suspend or terminate clinical trials for various reasons, including a finding by us or by a Data Monitoring Committee for a trial that the participants are being exposed to unacceptable health risks;
- seribantumab or our future product candidates may have undesirable or unexpected side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ECs to suspend or terminate the trials;
- the cost of clinical trials may be greater than we anticipate;

- changes to clinical trial protocols;
- the supply or quality of seribantumab or our future product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate and result in delays or suspension of our clinical trials; and
- the impact of the ongoing COVID-19 pandemic, which may slow potential enrollment, reduce the number of eligible patients for clinical trials, or reduce the number of patients who remain in our trials.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial or obtain timely marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured or will be completed on schedule, or at all. For example, the FDA may place a partial or full clinical hold on the CRESTONE trial or any of our future clinical trials for a variety of reasons, including safety concerns and noncompliance with regulatory requirements. If we are not able to complete successful clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize seribantumab or our future product candidates.

Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which would limit our future revenues and harm our commercial prospects.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

We may not be able to initiate or continue our ongoing or planned clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. In addition, some of our competitors currently have ongoing clinical trials for product candidates that would treat the same patients as our lead clinical product candidate, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. This is acutely relevant for our development of seribantumab for the treatment of patients with solid tumors driven by an NRG1 gene fusion, which are rare genomic alterations. Enrolling patients for our clinical trials requires promptly identifying cancer patients with NRG1 fusions and placing these patients in one of our qualified sites in a timely manner. We rely on several diagnostic partners to conduct initial testing to identify patients with NRG1 fusions that are eligible for the CRESTONE trial. If one or more of these partners encounters delays or is otherwise unable to conduct these tests and identify potential patients, enrollment in our clinical trials may be substantially delayed. In addition, these partners work with several other companies, including our competitors, and may divert resources to collaborations with these other companies, which may detrimentally affect enrollment in our clinical trials. Patient enrollment is also affected by other factors, including:

- the severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- the incidence and prevalence of our target indications;
- clinicians' and patients' awareness of genomic testing mechanisms to screen patients for NRG1 gene fusions and perceptions as to the potential advantages and risks of our product candidates in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- competing studies or trials with similar eligibility criteria;
- invasive procedures required to enroll patients and to obtain evidence of the product candidates' performance during clinical trials;

- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- efforts to facilitate timely enrollment in clinical trials;
- whether we are subject to a partial or full clinical hold on any of our clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll and maintain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials, including due to the COVID-19 pandemic, may result in increased development costs, which would cause the value of our company to decline, limit our ability to obtain additional financing and delay or limit our ability to obtain regulatory approval for our product candidates.

Adverse side effects or other safety risks associated with seribantumab or our other future product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the commercial profile of an approved product or result in significant negative consequences following marketing approval, if any.

As is the case with biologics generally, we have observed side effects and adverse events associated with seribantumab. Although seribantumab has been evaluated in over 800 patients in clinical trials to date, unexpected side effects may still arise in our ongoing or any future clinical trial. These side effects have included rashes, diarrhea, nausea, fatigue and hypomagnesemia. Additionally, reported treatment emergent serious adverse events, or SAEs, included one patient at the lowest dose cohort (3.2mg/kg), who experienced Grade 4 confusional state determined to be possibly related to seribantumab, and which was considered to be the only dose limiting toxicity, or DLT.

Results of our ongoing and planned clinical trials, which will include testing of seribantumab at doses and on schedules that have not been previously tested clinically, could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects could result in the delay, suspension or termination of clinical trials by us or regulatory authorities for a number of reasons. Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered with a significantly larger number of patients exposed to the drug.

Additionally, due to the high mortality rates of the cancers for which we are initially pursuing development and the pretreated nature of many patients in our ongoing clinical trial of seribantumab, a material percentage of patients in these clinical trials may die during a trial. If we elect to, or are required to, delay, suspend or terminate any clinical trial, whether due to a patient death or otherwise, the commercial prospects of seribantumab or our future product candidates will be harmed and our ability to generate product revenues will be delayed or eliminated. SAEs observed in clinical trials could hinder or prevent market acceptance of our product candidates, which would harm our commercial prospects our financial condition and our reputation.

Moreover, if seribantumab or any of our future product candidates is associated with undesirable or unexpected side effects in clinical trials, we may elect to abandon or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, even if it is approved. We may also be required to modify our trial plans based on findings in our clinical trials. Side effects could also affect patient recruitment or the ability of enrolled patients to complete a trial. Many drugs that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions, require additional testing to confirm these determinations, require more restrictive labeling or deny regulatory approval of the product candidate.

It is possible that, as we test our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our product candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

In addition, if our lead product candidate receives marketing approval, and we or others later identify undesirable side effects caused by treatment with such drug, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of the drug;
- we may be required to recall a product or change the way the drug is administered to patients;
- regulatory authorities may require additional warnings in the labeling, such as a contraindication or a boxed warning, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement an REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- we may be subject to regulatory investigations and government enforcement actions;
- the drug could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Preliminary, interim and topline data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and is subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials, such as the planned interim data analysis for our open-label CRESTONE trial. These updates will be based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more

comprehensive review of the data related to the particular study or trial. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Therefore, positive interim results in any ongoing clinical trial may not be predictive of such results in the completed study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data has been received and fully evaluated. Topline data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data is available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Adverse changes between preliminary or interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock. See the description of risks under the heading "Risks Related to our Common Stock" for more disclosure related to the risk of volatility in our stock price.

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

Additionally, our CRESTONE trial and potentially other future clinical trials we conduct may be open-label trials in which both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved product or placebo. Open-label clinical trials typically test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

If the preliminary or topline data that we report differs from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, seribantumab, or any other future product candidates may be harmed.

We may in the future seek to engage in strategic transactions to acquire or in-license new products, product candidates or technologies. If we are unable to realize the benefits from such transactions, it may adversely affect our ability to develop and commercialize product candidates, negatively impact our cash position, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases, joint ventures and in-licensing of new products, product candidates or technologies that we believe will complement or augment our existing business. For example, in 2019, we acquired our lead product candidate, seribantumab, pursuant to an asset acquisition agreement with the previous sponsor. If we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

Following any such strategic transaction, we may not achieve any expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near-term and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including, but not limited to, exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the transaction or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and could have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and could have a negative impact on the competitiveness of any product candidate that reaches market.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other future product candidates or for other indications that later prove to have greater commercial potential.

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

We may in the future conduct clinical trials for seribantumab or other product candidates outside the United States, and the FDA or comparable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more clinical trials outside the United States. Further, we may open sites for our CRESTONE trial that are located outside the United States. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from clinical trials conducted outside the United States is intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of these data alone unless the data is applicable to the U.S. population and U.S. medical practice and the trials were performed by clinical investigators of recognized competence and pursuant to GCP, regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many other regulatory authorities have similar approval requirements. In addition, such trials would be subject to the applicable local laws of the respective jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any comparable regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA or any comparable regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects.

Risks related to government regulation

The development and commercialization of biological products are subject to extensive regulation, and we may not obtain regulatory approvals for seribantumab or any other future product candidates, on a timely basis or at all.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety, and other post-marketing information and reports, and other possible activities relating to seribantumab, currently our only product candidate in clinical trials, as well as any other product candidates that we may develop in the future, are subject to extensive regulation. Marketing approval of biologics in the United States requires the submission of a BLA to the FDA, and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the BLA for that product. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls. Our product candidates must also be approved by comparable regulatory authorities in other jurisdictions prior to commercialization in those jurisdictions.

FDA approval of a BLA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized. Accordingly, there can be no assurance that any of our product candidates will receive regulatory approval in the United States, or other jurisdictions. Most applications for standard review biologic products are reviewed within 10 to 12 months; most applications for priority review biologics are reviewed in six to eight months. Priority review can be applied to biologics that the FDA determines may offer significant improvement in safety or effectiveness compared to marketed products or where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification.

The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. For example, if successful, we believe that the CRESTONE trial may be sufficient to support FDA approval of a BLA for seribantumab, but the FDA may disagree with the sufficiency of our data and require additional clinical trials. In addition, development programs that span many tumor types are relatively novel, and, to date, the FDA has approved only a handful of therapies to treat multiple tumor types based on a common biomarker. We cannot be sure that the FDA will accept our BLA for seribantumab or our other product candidates. Further, depending upon the results of the CRESTONE trial, we may choose to seek Subpart H accelerated approval for seribantumab, which would require completion of a confirmatory trial to validate its clinical benefit. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage. The results of preclinical and early clinical trials of seribantumab or any other future product candidate may not be predictive of the results of our later-stage clinical trials.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the biologics industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials is susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval.

The FDA could delay, limit or deny approval of a product candidate for many reasons, including because the FDA:

- may not deem our product candidate to be safe and effective;
- determines that the product candidate does not have an acceptable benefit-risk profile;
- determines in the case of a BLA seeking accelerated approval that the BLA does not provide evidence that the product candidate represents a meaningful advantage over available therapies for each tumor type;
- determines that the objective response rate, or ORR, and duration of response are not clinically meaningful;
- determines that a tissue agnostic indication is not appropriate, for example, because a consistent anti-tumor effect is not observed across multiple tumor types or the response is too heavily weighted on a specific tumor type;
- may not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk;
- may determine that the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may not accept clinical data from trials, which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- may disagree regarding the formulation, labeling and/or specifications;
- may not approve the manufacturing processes associated with our product candidate or may determine that a manufacturing facility does not have an acceptable compliance status;
- may change approval policies or adopt new regulations; or
- may not file a submission due to, among other reasons, the content or formatting of the submission.

We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for seribantumab.

If we experience delays in obtaining approval or if we fail to obtain approval of seribantumab, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired.

The accelerated approval pathway for seribantumab may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that it will receive marketing approval.

Under the FDA's accelerated approval program, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. We may seek accelerated approval for seribantumab on the basis of ORR with an acceptable duration of response, a surrogate endpoint that we believe is reasonably likely to predict clinical benefit. Whether the ORR we observe in CRESTONE will be adequate to support an accelerated approval for a tissue

agnostic indication for seribantumab will depend on a number of factors, including the response rate, the durability of the responses, the observed toxicity profile, prior therapies received, and the consistency of the ORR across tumor types, with efficacy not heavily weighted toward a specific tumor type. This analysis may be complicated by whether there is an available therapy against which to compare seribantumab for certain tumor types based on the patients we enroll.

For drugs or biologics granted accelerated approval, post-marketing confirmatory trials are required to describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated and/or fully enrolled prior to approval. If any of our competitors were to receive full approval on the basis of a confirmatory trial for an indication for which we are seeking accelerated approval before we receive accelerated approval, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need and accelerated approval of our product candidate would be more difficult or may not occur. Many cancer therapies rely on accelerated approval, and the treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials. Moreover, the FDA may withdraw approval of our product candidate approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the candidate;
- other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial of our product candidate with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant product candidate.

Our failure to obtain marketing approval in jurisdictions outside the United States would prevent seribantumab from being marketed in those jurisdictions, and any approval we are granted for it in the United States would not assure approval in other jurisdictions.

In order to market and sell our products in any jurisdiction outside the United States, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to submit for marketing approvals and may not receive necessary approvals to commercialize our products in any market, which would impair our financial prospects.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as “orphan drugs.” Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or if the disease or condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing the drug for the type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers. Additionally, 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, except in certain circumstances, such as a showing of clinical superiority (i.e., another product is safer, more effective or makes a major contribution to patient care) over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity.

The FDA has granted orphan drug designation to seribantumab in the United States for patients with heregulin- positive non-small-cell lung cancer. We may apply for an additional orphan drug designation in the United States or other geographies for seribantumab or our future product candidates. However, obtaining an orphan drug designation can be difficult, and we may not be successful in doing so. Even if we obtain orphan drug designation for a product candidate in specific indications, we may not be the first to obtain regulatory approval of the product candidate for the orphan-designated indication, due to the uncertainties associated with developing biological products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for orphan designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation does not ensure that we will receive marketing exclusivity in a particular market, and we cannot assure you that any future application for orphan drug designation in any other geography or with respect to any other future product candidate will be granted. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

A Breakthrough Therapy Designation by the FDA for any of our current or future product candidates may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the product candidate will receive marketing approval.

We may seek a Breakthrough Therapy Designation for seribantumab or our future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that a product candidate 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 drug may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if the product candidate qualifies as a breakthrough therapy, the FDA may later decide that the product candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened.

If we decide to pursue a Fast Track Designation by the FDA, it may not lead to a faster development or regulatory review or approval process.

We may seek Fast Track Designation for seribantumab or our future product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures.

The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

If we are unable to successfully develop, validate, obtain regulatory approval of and commercialize companion diagnostic tests for seribantumab or any future product candidates that require or would benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

A companion diagnostic is a medical device, often an *in vitro* device, which provides information that is essential for the safe and effective use of a corresponding therapeutic drug or biologic product. A companion diagnostic can be used to identify patients who are most likely to benefit from the therapeutic product. We plan to engage a third-party provider to develop companion diagnostic tests to identify NRG1 fusions.

A companion diagnostic is generally developed in conjunction with the clinical program for an associated therapeutic product. To date, the FDA has generally required premarket approval of companion diagnostics for cancer therapies. Generally, when a companion diagnostic is essential to the safe and effective use of a drug product, the FDA requires that the companion diagnostic be approved before or concurrent with approval of the therapeutic product and before a product can be commercialized. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect. However, it is possible that FDA may permit approval of the companion diagnostic for seribantumab as a post-marketing commitment following a potential regulatory approval.

Development of a companion diagnostic could include additional meetings with regulatory authorities, such as a pre-submission meeting and the requirement to submit an investigational device exemption application. In the case of a companion diagnostic that is designated as "significant risk device," approval of an investigational device exemption by the FDA and IRB is required before such diagnostic is used in conjunction with the clinical trials for a corresponding product candidate.

To be successful in developing, validating, obtaining approval of and commercializing a companion diagnostic, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. We have no prior experience with medical device or diagnostic test development. If we choose to develop and seek FDA approval for companion diagnostic tests on our own, we will require additional personnel. We may rely on third parties for the design, development, testing, validation and manufacture of companion diagnostic tests for our therapeutic product candidates that require such tests, the application for and receipt of any required regulatory approvals, and the commercial supply of these companion diagnostics. If these parties are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. For any product candidate for which a companion diagnostic is necessary to select patients who may benefit from use of the product candidate, any failure to successfully develop a companion diagnostic may cause or contribute to delayed enrollment of our clinical trials, and may prevent us from initiating a pivotal trial. In addition, the commercial success of any product candidate that requires a companion diagnostic will be tied to and dependent upon the receipt of required regulatory approvals and the continued ability of such third parties to make the companion diagnostic commercially available to us on reasonable terms in the relevant geographies. Any failure to do so could materially harm our business, results of operations and financial condition.

Even if we obtain marketing approval for a product candidate, the terms of approvals, ongoing regulation of our products or other post-approval restrictions may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Any product candidates for which we receive accelerated approval from the FDA are required to undergo one or more confirmatory clinical trials. If such a product candidate fails to meet its safety and efficacy endpoints in such

confirmatory clinical trials, the regulatory authority may withdraw its conditional approval. There is no assurance that any such product will successfully advance through its confirmatory clinical trial(s). Therefore, even if a product candidate receives accelerated approval from the FDA, such approval may be withdrawn at a later date.

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, which may include the requirement to implement a REMS or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product.

We must also comply with requirements concerning advertising and promotion for our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs or biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to current good manufacturing practices, or cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our CMOs will be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, even if we obtain marketing approval for a product candidate, we and our CMOs will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. As a result, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing approval will be subject to ongoing enforcement of post-marketing requirements by regulatory agencies, and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug and biologic products, including requirements pertaining to their marketing and promotion in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant liability. Violations of such requirements may lead to investigations alleging violations of the FDC Act, and other statutes, including the False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;

- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

Our current and future relationships with customers and third-party payors may be subject to applicable anti-kickback, fraud and abuse, transparency, health privacy, and other healthcare laws and regulations, which could expose us to significant penalties, including criminal, civil, and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as, market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations that may be applicable to our business include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the False Claims Act, which can be enforced by civil whistleblower or qui tam actions on behalf of the government, and criminal false claims laws and the civil

monetary penalties law, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government 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 federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, regardless of the payor (e.g. public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information;

- the federal Physician Payments Sunshine Act's transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the ACA, requires certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advance practice nurses and teaching hospitals, as well as ownership and investment interests held by physicians, and their immediate family members. The reported information is made available on a public website; and

- analogous state laws and regulations such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require biologics companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, including price increases. State and local laws require the registration of pharmaceutical sales representatives. State and non-U.S. laws that also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law 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 governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of 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 significant criminal, civil and administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may face difficulties from healthcare legislative reform measures.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or together, the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow-on biologic products, (ii) prescribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics, (v) established a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts (now 70%) off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D, (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vii) expanded the entities eligible for discounts under the Public Health program (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research and (ix) established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, legislative and judicial efforts to modify, repeal or otherwise invalidate all or certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Act included, among other things, a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and closed on August 15, 2021. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and healthcare measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. U.S. federal government agencies also currently face potentially significant spending reductions, which may further impact healthcare expenditures, uncluding reductions of Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. The Medicare reductions phase back in starting with a 1% reduction in effect from April 1, 2022 to June 30, 2022 before increasing to the full 2% reduction. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers,

including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Moreover, payment methodologies, including payment for companion diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. In addition, CMS has begun bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting and, beginning in 2018, CMS will pay for clinical laboratory services based on a weighted average of reported prices that private payors, Medicare Advantage plans, and Medicaid Managed Care plans pay for laboratory services. Further, on March 16, 2018, CMS finalized its National Coverage Determination, or NCD, for certain diagnostic laboratory tests using next generation sequencing that are approved by the FDA as a companion *in vitro* diagnostic and used in a cancer with an FDA-approved companion diagnostic indication. Under the NCD, diagnostic tests that gain FDA approval or clearance as an *in vitro* companion diagnostic will automatically receive full coverage and be available for patients with recurrent, metastatic relapsed, refractory or stages III and IV cancer. Additionally, the NCD extended coverage to repeat testing when the patient has a new primary diagnosis of cancer.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in July 2021, President Biden issued an executive order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates, and directed various executive branch agencies to take actions to lower drug prices and promote generic competition. Several pending legislative efforts, including President Biden's larger Build Back Better legislative agenda and draft bill text, incorporate these drug pricing reforms in addition to inflationary rebates on Part B and Part D drugs that would be payable on commercial and governmental program utilization, policies aimed at redesigning the Medicare Part D benefit and adopting drug price transparency measures. Drug manufacturers who are unwilling to negotiate with Medicare would be subject to additional excise taxes. Additionally, the plan would impose tax penalties on drug manufacturers that increase the prices of drug products faster than the rate of inflation. If elements of the recently announced prescription drug pricing plan become law, our pricing strategy and commercial prospects may be adversely affected.

Additionally, on September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. This plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. Many similar proposals, including the plans to give Medicare Part D authority to negotiate drug prices, require drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation, and cap out-of-pocket costs, have already been included in policy statements and legislation currently being considered by Congress. It is unclear to what extent these new proposals or any future legislation or regulations by the Biden Administration will have on our business.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to

access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law. We may choose to seek an expanded access program for our product candidates, or to utilize comparable rules in other countries that allow the use of a drug, on a named patient basis or under a compassionate use program.

We expect that additional state and federal healthcare reform measures will be adopted in the future. Such reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the EU, the pricing of prescription biological products is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our lead product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade, such as arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for biological products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries. In addition, the recent withdrawal of the United Kingdom from its membership in the EU, often referred to as “Brexit”, could lead to legal and regulatory uncertainty in the United Kingdom and may lead to the United Kingdom and EU adopting divergent laws and regulations, including those related to the pricing of prescription biological products, as the United Kingdom determines which EU laws to replicate or replace. If the United Kingdom were to significantly alter its regulations affecting the pricing of prescription biological products, we could face significant new costs. As a result, Brexit could impair our ability to transact business in the EU and the United Kingdom.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates and products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, 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, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of such third party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, 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 biological products 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 United States, 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 United States, 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 product candidates and products outside of the United States, 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 harm our business.

We and our third-party contractors are subject to numerous foreign, federal, state and local 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 operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also 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. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources, including any available insurance.

In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U.S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations.

Although we maintain liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We are subject to certain U.S. and certain other anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

U.S. and other anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, CMOs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or

government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks related to our reliance on third parties

We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform all of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.

We do not have the ability to independently conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are dependent on third parties to conduct our ongoing CRESTONE trial and our ongoing and planned preclinical studies and clinical trials of our future product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these CROs and other third parties are not our employees, and we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP, requirements, which are regulations and guidelines enforced by the FDA for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure, or the failure of third parties on whom we rely, to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other biological product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for seribantumab or any other future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

Manufacturing biological products is complex and subject to product loss for a variety of reasons. We rely on third-party suppliers, including single source suppliers, to manufacture clinical supplies of our lead product candidate and we intend to rely on third parties to produce commercial supplies of any approved product. This reliance on third parties increases the risk that we will not have sufficient quantities of our lead product candidate or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of seribantumab and our future product candidates for clinical testing, product development purposes, to support regulatory application submissions, as well as for commercial manufacture if a product candidate obtains marketing approval. In addition, we expect to contract with analytical laboratories for release and stability testing of our product candidates. We acquire our clinical supply of seribantumab from our contract manufacturer on an ongoing basis after the completion of stability testing, and have periodically encountered delays in receiving such clinical supply. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. In addition, the ongoing COVID-19 pandemic may result in disruptions to the operations or an extended shutdown of certain businesses, which could include certain of our contract manufacturers.

We may be unable to establish any agreements with third-party manufacturers or do so on favorable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory, compliance and quality assurance;
- reliance on the third party for product development, analytical testing, and data generation to support regulatory applications;
- lack of qualified backup suppliers for those components or materials that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter or other enforcement action by FDA or other regulatory authority;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our drugs under specified storage conditions and in a timely manner.

We have only limited clinical trial supply arrangements in place for seribantumab, and these arrangements do not extend to commercial supply. We acquire many key materials on a purchase order basis. As a result, we do not have long-term committed arrangements with respect to seribantumab or any future product candidate. We will need to establish one or more agreements with third parties in order to develop and scale up our drug manufacturing process, conduct drug testing and generate data to support one or more regulatory submissions. If we obtain marketing approval for seribantumab or any future product candidate, we will need to establish an agreement for commercial manufacture with a third party.

In addition, we currently use two suppliers for certain key components of our manufacturing process. Even if we are able to replace any raw materials or other materials with an alternative, such alternatives may cost more, result in lower yields or not be as suitable for our purposes. In addition, some of the materials that we use to manufacture our product candidates are complex materials, which may be more difficult to substitute. Therefore, any disruptions arising from our current supplier could result in delays and additional regulatory submissions.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If the FDA determines that our CMOs are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve a BLA until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third-party manufacturers and suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our CMOs are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our CMOs, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

Further, if we make manufacturing or formulation changes to our product candidates or add or change CMOs in the future, the FDA or other regulatory authorities will require a demonstration of the comparability of the new product to the prior product, including potentially through a clinical bridging study.

In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of regulatory actions that may be brought against these third parties in the future, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

Our product candidates and any products that we may develop may compete with other future product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

As we prepare for potential commercialization, we will need to take steps to increase the scale of production of our lead product candidate. Although seribantumab was previously manufactured at commercial scale, we have not yet scaled up the manufacturing process for commercialization since acquiring seribantumab. Third party manufacturers may be unable to successfully increase the manufacturing capacity for seribantumab in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up or commercial activities. For example, if microbial, viral or other contaminations are discovered in the clinical trial supply of seribantumab or in the manufacturing facilities in which it is made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substances. If our current CMOs for preclinical and clinical testing cannot perform as agreed, we may be required to replace such CMOs. Although we believe that there are several potential alternative manufacturers who could manufacture seribantumab, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or we may not be able to reach agreement with any alternative manufacturer. Further, our third-party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments or public health epidemics such as the COVID-19 pandemic. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and

we may be unable to replace them on a timely basis or at all. Further, to meet the demand for COVID-19 vaccine production, manufacturers are required to prioritize rated orders issued by the Federal Emergency Management Agency pursuant to the U.S. Defense Production Act of 1950, or the DPA. The potential for manufacturing facilities and materials to be commandeered under the DPA, or equivalent foreign legislation, could make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials.

Our current and anticipated future dependence upon others for the manufacture of our lead product candidate or products may adversely affect our future profit margins and our ability to commercialize any products that obtain marketing approval on a timely and competitive basis.

We may enter into collaborations with third parties for the development and commercialization of seribantumab and any future product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of seribantumab and our future product candidates.

We may seek third-party collaborators for the development and commercialization of seribantumab or our future product candidates on a select basis. We have not entered into any collaborations to date. Our likely collaborators for any future collaboration arrangements include large and mid-size biologics companies, regional and national biologics companies and biotechnology companies. We will face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a future collaboration will depend, among other things, upon our assessment of the future 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 do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our future collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations with future collaborators involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates 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 or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;

- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and

- if a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we establish one or more collaborations, all of the risks relating to product development, regulatory approval and commercialization described herein would also apply to the activities of any such future collaborators.

Risks related to commercialization of our product candidates

The incidence and prevalence for target patient populations of seribantumab and our future product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, then our revenue potential and ability to achieve profitability will be adversely affected.

The total addressable market opportunity for seribantumab and any other future product candidates we may develop will ultimately depend upon, among other things, the diagnosis criteria included in the final labeling for each such product candidate if it is approved for sale for these indications, acceptance by the medical community, patient access, drug and any related companion diagnostic pricing and their reimbursement. Additionally, for enrollment in the CRESTONE trial, we are utilizing novel RNA-based testing methodologies to identify NRG1 gene fusions due to the methodology's higher sensitivity compared to DNA-based testing methodologies for identifying oncogenic fusions. We may continue to prioritize novel RNA-based testing methodologies to identify NRG1 gene fusions for seribantumab. The total addressable market opportunity for seribantumab and any other future product candidates we may develop will depend upon commercially available RNA-based next generation sequencing testing.

We may initially seek regulatory approval of seribantumab or our future product candidates as therapies for relapsed or refractory patients. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Even if our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If seribantumab or our future product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments, such as existing targeted therapies, chemotherapy, and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;

- the acceptance of our product candidates as front-line treatments for various indications;

- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the size of the target patient population;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the strength of marketing and distribution support;
- publicity for our product candidates and competing products and treatments;
- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability of third-party payor coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups; and
- any restrictions on the use of our products together with other medications.

We currently have no marketing and sales organization and have no experience as a company in commercializing products and we may have to invest significant resources to develop these capabilities. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate revenue.

We have never commercialized a product candidate and we currently have no sales or marketing infrastructure and have no experience in the sale, marketing or distribution of biological products. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidate and undertaking preclinical studies and clinical trials of our product candidate. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaboration or other arrangements with third parties.

There are risks involved with establishing our own sales and marketing capabilities. 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. These efforts are expected to 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 products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our inability to raise financing necessary to build our commercialization infrastructure;

- the inability of sales personnel to obtain access to physicians or educate an adequate number of physicians as to the benefits of our products;
- unfavorable third-party payor coverage and reimbursement in any geography;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Furthermore, developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidate. We may not be able to build an effective sales and marketing organization in the United States, the EU or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidate, we may have difficulties generating revenue from them.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues and our profitability, if any, are likely to 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 market and sell our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of these third parties 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 any product candidate for which we receive marketing approval.

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

The development and commercialization of biological products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biologics companies, specialty biologics companies and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide.

There are a number of biological and biotechnology companies that currently are pursuing the development of precision oncology therapies for patients with undrugged, genetically-defined cancers with high unmet need. In particular, we expect that seribantumab will compete against other ERBB or HER3 inhibitors that target tumors with an NRG1 gene fusion. Several such candidates are currently in clinical development, including those of Merus N.V. (zenocutuzumab — MCLA-128), Rain Therapeutics, Inc. (tarloxotinib), Hummingbird Bioscience Ltd. (HMBD-001 — 10D1F), GamaMabs Pharma (9F7-F11) and AVEO Pharmaceuticals, Inc. (AV-203). We may face further competition from companies pursuing the development of product candidates that are ERBB or HER3 inhibitors not currently in defined clinical plans for targeting tumors with an NRG1 fusion, including ISU ABXIS Co., Ltd, Daiichi Sankyo Company, Ltd, Celldex Therapeutics, Inc., GlaxoSmithKline PLC, Boehringer Ingelheim International GmbH, or others. Development efforts with respect to, and clinical trial results of, these potentially competitive product candidates may be unsuccessful, which could result in a negative perception of HER3 inhibitors in general, for instance, which could in turn negatively impact the regulatory approval process for seribantumab.

Many of the companies against which we are competing or against which we may compete in the future, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and sales

and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the oncology market for cost-effective and reimbursable cancer treatments. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While seribantumab or our future product candidates, if approved, may compete with these existing drugs and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. As a result, obtaining market acceptance of, and gaining significant share of the market for, our product candidates may pose challenges. In addition, many companies are developing new oncology therapeutics, and we cannot predict what the standard of care will be as product candidates progress through clinical development.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with a more favorable labeling than seribantumab or our future product candidates. Our competitors also may obtain FDA, foreign regulatory authority, or other marketing or regulatory approval for their products more rapidly than any approval we may obtain for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, thereby limiting our potential for commercial success.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government healthcare programs, private health insurers and other organizations. Third-party payors decide which medications they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, which decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often, but not always, follow CMS’s decisions regarding coverage and reimbursement.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining coverage and adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited

levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Additionally, we may develop, either by ourselves or with collaborators, companion diagnostic tests for our lead product candidate for certain indications. We, or our collaborators, if any, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, if approved. While we have not yet developed any companion diagnostic test for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons that are applicable to our product candidates.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from third- party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercialize any products that we may develop. If we cannot successfully defend ourselves against any claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- diversion of management and scientific resources from our business operations;
- substantial monetary awards to trial participants or patients;

- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Our current product liability insurance coverage for the United States and certain other jurisdictions may not be adequate to cover all liabilities that we may incur. We likely will need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of seribantumab or our future product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. A successful product liability claim or series of claims brought against us could decrease our cash and adversely affect our business and financial condition.

Risks related to employee matters and our operations

We expect to significantly expand our development and regulatory capabilities as we grow our company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2021, we had 23 full-time employees. We expect significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, late-stage regulatory affairs, finance, accounting, business operations, public company compliance, communications and other corporate development functions, and, if seribantumab or any of our future product candidates receives marketing approval, sales, marketing and distribution. If we acquire additional product candidates or enter into future collaborations, we may have to further expand our employee base beyond our current projections, which may include further preclinical research and development or later-stage regulatory operations. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth and with developing sales, marketing and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Further, rapid expansion of our workforce while remaining a virtual company and working through the COVID-19 pandemic may have a detrimental impact on employee morale and cohesion.

Further, we currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third-party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacturing of seribantumab or any future product candidates. We cannot assure you that the services of such third-party contract organizations, 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 or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of seribantumab or any future product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

If we are not able to effectively manage growth and expand our organization, we may not be able to successfully implement the tasks necessary to further develop and commercialize seribantumab or our future product candidates and, accordingly, we may not achieve our research, development and commercialization goals.

Our future success depends on our ability to retain key employees and to attract, retain and motivate qualified personnel and manage our human capital.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on

the development and management expertise of Shawn Leland, our founder and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical teams. We currently do not maintain key person insurance on these individuals. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and manufacturing strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Recruiting and retaining qualified finance and accounting personnel will also be critical to our success. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among pharmaceutical companies. Many of the other pharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our lead product candidate and to grow our business and operations as currently contemplated.

Our employees, clinical trial investigators, CROs, CMOs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, CMOs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct or (v) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are a virtual company and our business depends on the efficient and uninterrupted operation of our information technology systems and those of our third-party CROs, CMOs, or other vendors, contractors or consultants, may fail or suffer security breaches, cyber-attacks, loss or leakage of data and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are a virtual company and our business success depends on the security and efficient and uninterrupted operation of our information technology systems and we may be unable to adequately protect our information technology systems from cyber-attacks, which could result in the disclosure of confidential information, damage our reputation, and subject us to significant financial and legal exposure. We are increasingly dependent upon information technology systems,

infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and sensitive personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party CROs, CMOs, vendors, and other contractors and consultants who have access to our confidential information. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud-based systems during the remote work environment resulting from the COVID-19 pandemic, could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs, CMOs, vendors and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, accidents by our employees or third party service providers, natural disasters, terrorism, war, global pandemics, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, third-party CROs, CMOs, vendors, contractors, consultants, business partners and/or other third parties, or from cyber-attacks or supply chain attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure, or that of our third-party CROs, CMOs, vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. The COVID-19 pandemic is generally increasing the attack surface available for exploitation, as more companies and individuals work online and remotely, and as such, the risk of a cybersecurity incident occurring, and our investment in risk mitigations against such an incident, are increasing. For example, there has been an increase in phishing and spam email attacks as well as social engineering attempts from “hackers” hoping to use the recent COVID-19 pandemic to their advantage. We may not be able to anticipate all types of security threats, nor implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. Any breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties, including under HIPAA, and other relevant state and federal privacy laws in the United States. If the information technology systems of our third-party CROs, CMOs, vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

While we have not experienced any such system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third-party CROs, CMOs, vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party CROs, CMOs, vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our lead product candidate could be delayed. In addition, the loss of clinical trial data for seribantumab or any other future product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or those of our third-party CROs, CMOs, vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and sensitive personal information), which could result in financial, legal, business and reputational harm to us.

A security breach may cause us to breach customer contracts. Our agreements with certain customers may require us to use industry-standard or reasonable measures to safeguard sensitive personal information or confidential information. A security breach could lead to claims by our customers, their end users, or other relevant stakeholders that we have failed to comply with such legal or contractual obligations. As a result, we could be subject to legal action or our customers could end their relationships with us. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages.

In addition, litigation resulting from security breaches may adversely affect our business. Unauthorized access to our platform, systems, networks, or physical facilities could result in litigation with our customers, our customers' end users, or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices or modify our solutions and/or platform capabilities in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur and the confidentiality, integrity or availability of our data or the data of our partners, our customers or our customers' end users was disrupted, we could incur significant liability, or our platform, systems or networks may be perceived as less desirable, which could negatively affect our business and damage our reputation.

We may not have adequate insurance coverage with respect to security breaches or disruptions. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

We are subject to stringent and changing laws, regulations, rules, policies, standards, and contractual obligations related to privacy and data security. Our actual or perceived failure to comply with such obligations 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 and any potential collaborators may be subject to federal, state and other data protection laws and regulations (i.e., laws and regulations that address privacy and data security). The regulatory framework for privacy, data security and data transfers worldwide is rapidly evolving and there has been an increasing focus on privacy and data protection issues with the potential to affect our business and as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. Failure to comply with any of these laws and regulations could result in enforcement actions against us, including fines, public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business.

In the United States, 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 collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to penalties if we 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.

In addition, the state of California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the CCPA) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with a private right of action for data breaches. The CCPA went into effect on January 1, 2020 and may

impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Additionally, although not effective until January 1, 2023, the California Privacy Rights Act, or the CPRA, which expands upon the CCPA, was recently passed in California. The CCPA gives (and the CPRA will give) California residents expanded privacy rights, including the right to request correction, access, and deletion of their personal information, the right to opt out of certain personal information sharing, and the right to receive detailed information about how their personal information is processed. The CCPA and CPRA provide for unlimited civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA and CPRA may increase our compliance costs and potential liability, particularly in the event of a data breach. Additionally, the CCPA has prompted a number of proposals in the U.S. for new federal and state-level privacy legislation that, if passed, could increase our potential liability, increase our compliance costs, and adversely affect our business.

Additionally, laws, regulations, rules and standards in many foreign jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information, which may impose significant compliance obligations on us. For example, in the EU, the processing of personal data, is governed by the provisions of the General Data Protection Regulation, or the GDPR.

In May 2018, the GDPR took effect in the European Economic Area, or the EEA. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of natural persons. Among other things, the GDPR imposes strict obligations on the ability to process health-related and other personal data of data subjects in the EEA, including in relation to use, collection, analysis and transfer (including cross-border transfers) of such personal data. The GDPR includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators. The GDPR also includes certain requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, as well as requirements for establishing a lawful basis on which personal data can be processed. In addition, the GDPR increases the scrutiny of cross-border transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws, and imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue). Further, recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of information from the EEA to the United States. For example, on June 16, 2020, the Court of Justice of the European Union, or the CJEU, declared the EU-U.S. Privacy Shield framework, or the Privacy Shield, to be invalid. As a result, Privacy Shield is no longer a valid mechanism for transferring personal data from the EEA to the United States. Moreover, it is uncertain whether the standard contractual clauses will also be invalidated by the European courts or legislature, which seems possible given the rationale behind the CJEU’s concerns about U.S. law and practice on government surveillance. 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.

We also may make public statements about our use and disclosure of personal information through our privacy policy and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. Despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our policies, certifications, and documentation. The publication of our privacy policy and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any failure, real or perceived, by us to comply with our posted privacy policies or with any legal or regulatory requirements, standards, certifications or orders or other privacy or consumer protection-related laws and regulations applicable to us could cause our customers to reduce their use of our solutions and services and could materially and adversely affect our business, results of operations, financial condition, cash flows and prospects.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, transfer, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and foreign data protection 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 about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to 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 or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, public health epidemic, including the COVID-19 pandemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party CMOs, 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. Extreme weather conditions or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party CMOs, 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.

Operating as a virtual company, our employees conduct business outside of any leased or owned facilities. These locations may be subject to additional security and other risk factors due to the limited control of our employees. 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 these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Cuts and Jobs Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act, or any other newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act, the CARES Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, unused U.S. federal net operating losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely but the deductibility of such federal net operating losses may be limited to 80% of current year

taxable income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act. In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, if we undergo, or have undergone, an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional ownership changes in the future. As a result, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Risks related to intellectual property

If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize seribantumab and our future product candidates may be adversely affected.

Our success depends in large part on our ability to protect our proprietary technologies that we believe are important to our business, including pursuing, obtaining and maintaining patent protection in the United States and other countries intended to cover the compositions of matter of seribantumab and our future product candidates, their methods of use, related technologies and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. If we do not adequately pursue, obtain, maintain, protect or enforce our intellectual property, third parties, including our competitors, may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

The patent application and approval process is expensive, time-consuming and complex. We may not be able to file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. We also cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdictions. It is also possible that we will fail to identify patentable aspects of our product candidates before it is too late to obtain patent protection. Moreover, depending on the terms of any future license agreements to which we may become a party, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering technology licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Furthermore, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. The standards applied by the United States Patent and Trademark Office, or the USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Thus, we cannot offer any assurances about which, if any, patents will be issued, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and product candidates. While we have filed patent applications covering aspects of our current lead product candidate, we currently have only one U.S. application specifically covering the use of seribantumab to treat patients with tumors harboring an NRG1 fusion according to our CRESTONE clinical dosing regimen. Any patents issuing from this currently unpublished application would expire in 2042, subject to any disclaimers or extensions.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until at least one patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file or invent (prior to March 16, 2013) any patent application related to our current or future product candidates. In addition, we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, CMOs, hospitals, independent treatment centers, consultants, independent contractors, suppliers, advisors and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, if third parties have filed patent applications related to our current or future product candidates or technology, we may not be able to obtain our own patent rights to those product candidates or technology.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, revocation, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, our patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of other countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Moreover, the coverage claimed in a patent application can be significantly reduced before the

patent is issued and its scope can be reinterpreted after issuance. Consequently, we do not know whether our lead product candidate will be protectable or remain protected by valid and enforceable patents. Our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic versions or "follow-on" versions of any approved products by submitting abbreviated new drug applications, or ANDAs, or new drug applications under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, respectively, to the FDA during which they may claim that patents owned by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Furthermore, future patents may be subject to a reservation of rights by one or more third parties. For example, to the extent the research resulting in future patent rights or technologies is funded in the future in part by the U.S. government, the government could have certain rights in any resulting patents and technology, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf for non-commercial purposes. If the U.S. government then decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may also permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government may also exercise its march-in rights if it determines that action is necessary because we failed to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of aforementioned proprietary rights could harm our competitive position, business, financial condition, results of operations, and prospects.

Changes to patent laws in the United States and other 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 biotechnology and pharmaceutical industries involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. For example, the Leahy-Smith Act allows third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. In addition, the Leahy-Smith Act has transformed the U.S. patent system from a "first-to-invent" system to a "first-to-file" system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The first-to-file provisions, however, only became effective on March 16, 2013. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our potential collaboration partners' patent applications and the enforcement or defense of our or our future collaboration partners' issued patents, all of which could harm our business, results of operations, financial condition and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights, trade secrets or other intellectual property. To counter infringement, misappropriation or other violations, we may be required to file infringement, misappropriation or other violation claims, which can be expensive and time consuming and divert the time and attention of our management and business and scientific personnel. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their patents or their other intellectual property, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate legal proceedings against us seeking a declaration that certain of our intellectual property is non-infringed, invalid or unenforceable. The outcome of any such proceeding is generally unpredictable.

In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we could lose at least a part, and perhaps all, of the patent protection covering such a product candidate. Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our product candidates in one or more foreign countries. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail

in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Furthermore, third parties may also raise invalidity or unenforceability claims before administrative bodies in the United States or foreign authorities, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or written description. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution of the patent. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel and the patent examiner were unaware during prosecution. Moreover, it is possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our lead product candidate. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects.

We may not be able to effectively protect or enforce our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents with respect to our product candidates in all countries throughout the world would be prohibitively expensive, and the laws of other countries may not protect our rights to the same extent as the laws of the United States. The requirements for patentability may differ in certain countries, particularly in developing countries. In addition, any future intellectual property license agreements may not always include worldwide rights. Consequently, competitors and other third parties 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 may obtain patent protection, but where patent enforcement is not as strong as that in the United States and where our ability to enforce our patents to stop infringing activities may be inadequate. These products may compete with our products in such territories and in jurisdictions where we do not have any patent rights or where any future patent claims or other intellectual property or proprietary rights may not be effective or sufficient to prevent them from competing with us, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, our ability to protect and enforce our intellectual property and proprietary rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property and proprietary rights in certain jurisdictions. The legal systems of some countries, including, for example, India, China and other developing countries, do not view favorably the enforcement of patents and other intellectual property or proprietary rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property or proprietary rights. For example, many countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business, could put our patents, trademarks or other intellectual property and proprietary rights at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not

issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property and proprietary rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property and proprietary rights in such countries may be inadequate.

If we are sued for infringing, misappropriating or otherwise violating intellectual property or proprietary rights of third parties, such litigation or disputes could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

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, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. If any third-party patents, patent applications or other proprietary rights are found to cover our product candidates or any related companion diagnostics or their compositions, methods of use or manufacturing, we may be required to pay damages, which could be substantial, and we would not be free to manufacture or market our product candidates or to do so without obtaining a license, which may not be available on commercially reasonable terms, or at all.

We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property or proprietary rights with respect to our product candidates and technologies we use in our business. Our competitors or other third parties may assert infringement claims against us, alleging that our product candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. If a patent holder believes our product candidate infringes its patent rights, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect.

There is a substantial amount of intellectual property litigation in the biotechnology and biological product industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property or proprietary rights with respect to our product candidates, including interference proceedings before the USPTO. Third parties may assert infringement, misappropriation or other claims against us based on existing or future intellectual property or proprietary rights. The outcome of intellectual property litigation and other disputes is subject to uncertainties that cannot be adequately quantified in advance. The biological product and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of using or manufacturing products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods of use, manufacturing or other applicable activities either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be successful in doing so. However, proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, or enforceability. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and business and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate or otherwise violate a third party’s intellectual property or proprietary rights and we are unsuccessful in demonstrating that such intellectual property or proprietary rights are invalid or unenforceable, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in

order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non- exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees or consultants or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Some of our employees and consultants are currently or have been previously employed at universities or at other biotechnology or biologics companies, including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such other current or previous employment. 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 these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property or personnel or sustain damages. Such intellectual property could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. In addition, such agreements may not be self-executing such that the intellectual property subject to such agreements may not be assigned to us without additional assignments being executed, and we may fail to obtain such assignments. In addition, such agreements may be breached. In addition, we have multiple sponsored research agreements relating to our lead product candidate with various academic institutions. Some of these academic institutions may not have intellectual property assignments or similar agreements with their employees and consultants, which may result in claims by or against us related to ownership of any intellectual property. Accordingly, we may be forced to bring claims against third parties, or defend claims that they may bring against us to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Rights to improvements to our product candidates may be held by third parties, which could require us to obtain a license to such rights. Such a license may not be available on commercially reasonable terms, if at all.

We have entered into agreements with third parties to conduct clinical testing of our product candidates, which provide that improvements to our product candidates may be owned solely by a party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby giving our competitors and other third parties access to the

same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such improvements, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or any future licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or any future licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or any future licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or any future licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

The term of our patents may be inadequate to protect our competitive position on our products.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, our wholly owned patent portfolio includes a patent family with claims directed to antibodies and related compositions covering seribantumab, as well as methods of treating cancer using such antibodies and compositions. The family contains three U.S. patents directed to seribantumab which expire in February 2028 and a fourth U.S. patent which expires in October 2029 (including 614 days of Patent Term Adjustment), subject to any disclaimers or extensions. The family also contains a pending U.S. application, which if issued, would expire in February 2028, subject to any disclaimers or extensions. In addition, the above-discussed patent family includes granted patents in China, Europe, Hong Kong, Israel, and Japan with claims directed to compositions of matter covering seribantumab and related methods of therapy. These patents expire in February 2028, subject to any disclaimers or extensions. Depending upon the timing, duration and other factors relating to any FDA marketing approval we receive for our lead product candidate, 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, or the Hatch-Waxman Amendments. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the normal expiration of the patent, limited to the approved indication (or any additional indications approved during the period of extension), as compensation for patent term lost to the regulatory review process during which the sponsor was unable to commercially market its new product. 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 applicable to an approved drug is eligible for the extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available for our patents, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. 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. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent offices, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. In the future, we may rely on licensing partners to pay these fees due to U.S. and non-U.S. patent agencies and to comply with these other requirements with respect to any future licensed patents and patent applications. While an inadvertent lapse can 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 a patent or patent rights in the relevant jurisdiction. Non-compliance 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. In such an event, our competitors and other third parties might be able to enter the market with similar or identical products of technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We rely on proprietary know-how and trade secret protection and confidentiality agreements to protect proprietary know-how or trade secrets that are not patentable or that we elect not to patent. We seek to protect our trade secrets and proprietary know-how in part by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, consultants, independent contractors, advisors, CMOs, CROs, hospitals, independent treatment centers, suppliers, collaborators and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary know-how. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our business, financial condition, results of operations and prospects our business and competitive position could be materially harmed.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products similar to any product candidates we may develop or utilize similarly related technologies that are not covered by the claims of the patents that we may license or may own in the future;
- we, or any future license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or any future license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating any of our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks related to our common stock

The market price of our common stock is likely to be highly volatile, which could result in substantial losses for purchasers of our common stock.

The market price of our common stock is likely to continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, investors may not be able to sell their common stock at or above the price initially paid for the stock. The market price for our common stock may be influenced by many factors, including the other risks described in this section of this Annual Report and the following:

- enrollment or results of clinical trials of seribantumab or our future product candidates, or those of our competitors or our future collaborators, or changes in the development status of our product candidates;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to seribantumab or any future product candidate;

- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including but not limited to those with development and commercialization partners;
- market conditions in the biologics and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for seribantumab or any future product candidates;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- share price and fluctuations of trading volume of our common stock;
- sales of our common stock by us, insiders or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;

- natural disasters and other calamities; and
- general economic, industry and market conditions, or other events or factors, many of which are beyond our control, such as the COVID-19 pandemic.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

In the past, securities class action litigation has often been brought against public companies following declines in the market price of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. In connection with our initial public offering, each of our officers, directors and substantially all of our pre-initial public offering, or IPO stockholders entered into lock-up agreements with the underwriters that restricted their ability to sell or transfer their shares. These lock-up agreements expired on December 22, 2021. However, shares of our common stock held by our officers, directors and their affiliated entities will be subject to volume limitations under Rule 144 under the Securities Act. In addition, shares of our common stock that are subject to outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act. The holders of a significant portion of our outstanding common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock, even if our business is doing well.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

Based on the beneficial ownership of our common stock as of December 31, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially hold the majority of our outstanding voting stock. As a result, these stockholders, if acting together, have significant control over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit

our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an "emerging growth company," we are only required to provide two years of audited financial statements.

We could be an "emerging growth company" until December 31, 2026, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates equals or exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an "emerging growth company" as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an "emerging growth company" immediately. Even after we no longer qualify as an "emerging growth company," we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, if our revenues remain less than $100.0 million, and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. 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 share price may be more volatile.

Under the JOBS Act, "emerging growth companies" can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

Anti-takeover provisions in our restated certificate of incorporation and bylaws and under Delaware law could prevent or delay an acquisition of us, which may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management and, therefore, decrease the trading price of our common stock.

Our restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;

- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our amended and restated certificate of incorporation and amended and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law, or DGCL, may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

Any provision of our restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

The exclusive forum provision in our organizational documents may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims.

Our restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware is 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 DGCL, our restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision.

This choice of forum provision may result in increased costs for investors to bring a claim. Further, this 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 any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our amended and restated bylaws provide that the federal district courts of the United States of America, to the fullest extent permitted by law, shall be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no

assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court.

Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholder's ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business.

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

As a public company, we will incur significant legal, accounting, compliance and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our products once commercialized. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies.

This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are not currently required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an "emerging growth company," we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. In addition, for as long as we are a smaller reporting company with less than $100 million in annual revenue, we would be exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act. To achieve compliance with Section 404 within the prescribed period, we will be 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, potentially 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. This process will be time- consuming, costly and complicated. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on the Nasdaq Global Select Market.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

General risk factors

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If no or few securities or industry analysts commence or maintain coverage of us, the trading price for our common stock could be impacted negatively. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. However, any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system will be met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make required related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a risk management program or processes or procedures for identifying and addressing risks to our business in other areas.

Failure to establish and maintain an effective system of internal controls could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud in which case, our stockholders could lose confidence in our financial reporting and the market price of our common stock could decline.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Global Select Market. Under 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 beginning with our second annual report on Form 10-K. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. However, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an EGC. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be 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, including through hiring additional financial and accounting personnel, potentially 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. During our evaluation of our internal control, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective.

In addition, our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

Furthermore, in connection with the future attestation process by our independent registered public accounting firm, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, our stockholders could lose confidence in our reporting and the market price of our common stock could decline. In addition, we could be subject to sanctions or investigations by the Nasdaq Global Select Market, the SEC or other regulatory authorities.

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 pharmaceutical and biologics 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Not applicable.

Item 3. Legal Proceedings

At each reporting date, we evaluate whether or not a potential loss amount or a potential range of losses is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. We expense as incurred the costs related to such legal proceedings. We are not a part to any material legal matters or claims and did not have contingency reserves established for any litigation liabilities as of December 31, 2021.

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 trades under the symbol "ELEV" on The Nasdaq Stock Market and has been publicly traded since June 25, 2021. Prior to this time, there was no public market for our common stock.

Holders of Our Common Stock

As of February 28, 2022, there were approximately 17 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

Dividends

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds from Public Offering of Common Stock

On June 29, 2021, we closed our initial public offering of common stock under a registration statement on Form S-1 (333-256787) that was declared effective by the Securities and Exchange Commission (the "SEC") on June 25, 2021.

We received net proceeds of $91.1 million, after deducting underwriting discounts, commissions, and other expenses of $8.9 million. On July 19, 2021, in connection with our IPO, the underwriters exercised the right to purchase 403,407 shares of our common stock at a price of $16.00 per share for net proceeds of $6.0 million, after deduction underwriting discounts of $0.5 million.

There has been no material change in the planned use of proceeds from our IPO as described in the registration statement on Form S-1.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a precision oncology company focused on the development of targeted therapeutics for the treatment of cancer in genomically defined patient populations. Our vision is to elevate precision medicine to the forefront of every cancer treatment journey, as we believe that each patient living with cancer deserves the opportunity to benefit from a genomically-driven treatment decision. We utilize our deep expertise in developing drugs for rare, genomically defined patient populations and strategic collaborations with our diagnostic collaborators to work towards a future where each tumor's unique genomic test result can be matched with a purpose-built precision medicine.

We are focused on identifying oncogenic drivers that are known to be predominantly mutually exclusive with other driver alterations, and pursuing innovations and efficiencies in the conduct of clinical trials that we believe may enable development of targeted therapeutics against those oncogenic drivers.

Our lead program is focused on NRG1 fusions, which are rare genomic alterations that have recently been identified as oncogenic driver alterations and that we believe have the potential to be therapeutically actionable through targeted HER3 inhibition. We have designed and initiated our potentially registration-enabling Phase 2 CRESTONE trial to investigate the safety and efficacy of seribantumab, an anti-HER3 monoclonal antibody, in advanced solid tumors harboring an NRG1 fusion. We are conducting this trial in a tumor-agnostic fashion, such that any patient with a solid tumor that harbors an NRG1 fusion, regardless of the tissue of origin, may be eligible. We believe that the design and conduct of the CRESTONE trial has the possibility to produce results that may provide support for us to seek accelerated approval of seribantumab for patients with advanced solid tumors harboring an NRG1 fusion, subject to discussions with the FDA. Any accelerated marketing approval is subject to continued discussions with the FDA, and agreement on post-approval confirmatory trials to confirm an anticipated clinical benefit. If the CRESTONE trial meets its primary endpoint, and subject to continued discussions with the FDA, we anticipate submitting a BLA under an accelerated approval pathway for the treatment of patients with solid tumors harboring an NRG1 fusion. Even if the CRESTONE trial meets its primary endpoint, there can be no assurance that the FDA or other regulators will find such data sufficient to support a BLA submission or that additional trials will not be required. Further updates on the CRESTONE trial may be provided following additional information including, but not limited to, interactions with the FDA or other regulators, with whom we plan to discuss the interim clinical data and any resulting development pathways and opportunities. We expect to complete enrollment of the first 20 patients in Cohort 1 of the CRESTONE study in mid-2022, and to present initial clinical data from approximately 10 patients from Cohort 1 of the CRESTONE study treated with seribantumab at 3 grams weekly at a major medical meeting in mid-2022.

We were incorporated in April 2019. We have devoted substantially all of our resources to developing our lead product candidate, initiating the CRESTONE clinical trial, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. To date, we have financed our operations through private placements of convertible preferred stock and our IPO. On June 29, 2021, we closed our IPO and issued 6,250,000 shares of our common stock at a price of $16.00 per share, for net proceeds of $91.1 million, after deducting underwriting discounts, commissions, and other expenses of $8.9 million. In connection with the IPO, all shares of Series A and Series B convertible preferred stock outstanding automatically converted into 15,736,053 shares of common stock. On July 19, 2021, in connection with our IPO, the underwriters exercised the right to purchase 403,407 shares of our common stock at a price of $16.00 for net proceeds of $6.0 million. Prior to our IPO, we had received net proceeds of approximately $97.2 million from sales of our convertible preferred stock.

Since our inception, we have incurred significant operating losses on an aggregate basis. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were $32.0 million and $17.3 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $55.2 million. These losses have resulted primarily from costs incurred in connection with research and development activities, acquisition, patent investment, and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

Our future capital requirements will depend on many factors, including:

- the progress, timing and results of preclinical studies and clinical trials for our current or any future product candidates;
- disruptions or delays in enrollment of our clinical trials due to the COVID-19 pandemic;
- the extent to which we develop, in-license or acquire other pipeline product candidates or technologies;
- the number and development requirements of other future product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of obtaining regulatory approvals of our current or future product candidates and any companion diagnostics we may pursue;
- the scope and costs of making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our current or future product candidates;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or future product candidates;
- the costs associated with commercializing any approved product candidates, including establishing sales, marketing and distribution capabilities;
- the costs associated with completing any post-marketing studies or trials required by the Food and Drug Administration, or FDA, or other regulatory authorities;
- the revenue, if any, received from commercial sales of seribantumab, if approved, or any other future product candidates that receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims that we may become subject to, including any litigation costs and the outcome of such litigation;
- the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims; and
- to the extent we pursue strategic collaborations, including collaborations to commercialize seribantumab or to develop any future product candidates, our ability to establish and maintain collaborations on favorable terms, if at all, as well as the timing and amount of any milestone or royalty payments we are required to make or are eligible to receive under such collaborations, if any.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for seribantumab or our other future product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal

commercialization capability to support product sales, marketing and distribution. Further, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company.

As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on favorable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital or debt when needed or on favorable terms, we could be forced to delay, reduce or eliminate our research and development programs, our commercialization plans or other operations.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of December 31, 2021, we had cash and cash equivalents of $146.3 million. We believe that our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources.”

Impact of COVID-19

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. economy and in financial markets. The extent of the impact of COVID-19 on our operational and financial performance will continue to depend on certain developments, including the duration and spread of the outbreak, new variants, the vaccination and booster rate, impact on our clinical studies, employee or industry events, and effect on our suppliers and manufacturers, all of which are uncertain and cannot be predicted.

While we are currently continuing the clinical trials we have underway, COVID-19 precautions may directly or indirectly impact the timeline for some of our clinical trials. To date, we have been able to continue to enroll our patients in our Phase 2 CRESTONE clinical trial and currently do not anticipate any interruptions of clinical enrollment. However, we are continuing to assess the potential impact of the COVID-19 pandemic on our current and future business and operations, including our expenses and clinical trials, as well as on our industry and the healthcare system.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including expenses, clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

Components of our Results of Operations

Operating Expenses

Research and Development Expenses

Our operating expenses since our inception have consisted solely of research and development costs and general and administrative costs. Research and development expenses consist primarily of costs incurred for our research activities, including the development of our product candidates, which include:

- employee-related expenses, including salaries, related benefits, and stock-based compensation expense for employees engaged in research and development activities;
- external research and development expenses incurred in connection with the preclinical and clinical development of seribantumab, including expenses incurred under agreements with contract research organizations, and consultants;
- costs incurred with contract manufacturing organizations that manufacture drug products for use in our preclinical studies and clinical trials of seribantumab;
- fees paid to consultants for services directly related to our product development and regulatory efforts; and
- costs related to compliance with regulatory requirements related to conducting our clinical activity.

Research and development costs consist of salaries and benefits, including associated stock-based compensation, and fees paid to other entities that conduct certain research and development activities on our behalf. Research and development costs are expensed as incurred. We estimate preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and contract research organizations, and clinical manufacturing organizations that conduct and manage preclinical studies and clinical trials on our behalf based on actual time and expenses incurred by them. Further, we accrue expenses related to clinical trials based on the level of patient activity according to the related agreement. We monitor patient enrollment levels and related activity to the extent reasonably possible and adjust estimates accordingly.

To date, all of our research and development expenses have been incurred to advance our lead product candidate, seribantumab. We expect that significant additional spending will be required to progress seribantumab through the remainder of its clinical development, as well as advance any future product candidate through clinical development. These expenses will primarily consist of expenses for the administration of clinical studies as well as manufacturing costs for clinical material supply. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates.

The successful development and commercialization of seribantumab or our other future product candidates is highly uncertain. The success of seribantumab, or any other future product candidate will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials, including our CRESTONE trial;
- acceptance of a BLA by the FDA, or other similar clinical trial applications from foreign regulatory authorities for seribantumab and our future clinical trials for our future product candidates;
- timely and successful enrollment of patients in, and completion of, clinical trials with favorable results;
- demonstration of safety, efficacy and acceptable risk-benefit profiles of our product candidates, including our lead product candidate, seribantumab, to the satisfaction of the FDA and foreign regulatory agencies;

- our ability, or that of our collaborators, to develop and obtain clearance or approval of companion diagnostics, on a timely basis, or at all;
- receipt and related terms of marketing approvals from applicable regulatory authorities, including the completion of any required post-marketing studies or trials;
- raising additional funds necessary to complete clinical development of and commercialize our lead product candidate;
- successfully identifying future acquisition, collaboration or in-license candidates to expand our product candidate pipeline;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates, including our lead product candidate, seribantumab;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- developing and implementing marketing and reimbursement strategies;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining third-party payor coverage and adequate reimbursement;
- protecting and enforcing our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

Many of these factors are beyond our control, and it is possible that none of our product candidates, including our lead product candidate, seribantumab, will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. For example, our business could be substantially harmed if results of our ongoing CRESTONE clinical trial of seribantumab vary adversely from our expectations.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; and insurance costs.

We anticipate that our general and administrative expenses will increase in the future as we support our continued research activities and development of our product candidates. We also anticipate that our general and administrative expenses will increase as a result of increased payroll, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company. In addition, if we obtain regulatory approval for seribantumab, or any of our future product candidates, we expect to incur

significant expenses related to building a sales and marketing team to support product sales, and marketing and distribution activities, to the extent that such activities are not supported by one or more third-party collaborators.

Results of operations

Comparison of the years ended December 31, 2021 and 2020:

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

	Year Ended December 31,		
	2021	2020	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 23,595	$ 15,476	$ 8,119
General and administrative	8,451	1,800	6,651
Total operating expenses	32,046	17,276	14,770
Loss from operations	(32,046)	(17,276)	(14,770)
Other income (expenses), net	7	11	(4)
Net loss	$ (32,039)	$ (17,265)	$ (14,774)

Research and Development Expenses

	Year Ended December 31,		
	2021	2020	Changes
	(in thousands)		
Seribantumab	$ 17,576	$ 12,387	$ 5,189
Unallocated and other research and development expenses	2,675	1,844	831
Unallocated personnel costs (including stock-based compensation)	3,344	1,245	2,099
Total research and development expenses	$ 23,595	$ 15,476	$ 8,119

Research and development expenses were $23.6 million for the year ended December 31, 2021, compared to $15.5 million for the year ended December 31, 2020. The increase of $8.1 million was primarily due to a $3.5 million increase in clinical trial expenses associated with the CRESTONE clinical trial, a $2.0 million increase in costs related to manufacturing clinical supply of seribantumab for use in the CRESTONE clinical trial, a $2.1 million increase in employee related costs, including stock-based compensation, and $0.5 million increase in other expenses.

General and Administrative Expenses

General and administrative expenses were $8.5 million for the year ended December 31, 2021, compared to $1.8 million for the year ended December 31, 2020. The increase of $6.7 million was primarily due to an increase of $3.0 million personnel costs, including stock-based compensation, $1.5 million in director and officer and other insurance, $1.3 million of professional fees, and $0.9 million of other expenses.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue from product sales or any other sources and have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of any product candidates for several years, if ever.

On June 29, 2021, we closed our IPO and issued 6,250,000 shares of our common stock for net proceeds of approximately $91.1 million. On July 19, 2021, in conjunction with our IPO, the underwriters exercised the right to purchase 403,407 shares of our common stock at a price of $16.00 per share for net proceeds of $6.0 million. Prior to our IPO, we had received net proceeds of approximately $97.2 million from the sale of our convertible preferred stock. As of December 31, 2021, we had cash and cash equivalents of $146.3 million.

Cash Flows

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

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Statement of cash flows data:		
Cash used in operating activities	$ (30,167)	$ (12,298)
Cash used in investing activities	—	(71)
Cash provided by financing activities	97,051	90,029
Net increase in cash and cash equivalents	$ 66,884	$ 77,660

Operating Activities

During the year ended December 31, 2021, cash used in operating activities was $30.2 million, which consisted primarily of our net loss of $32.0 million, partially offset by $1.6 million of stock-based compensation expense and $0.2 million of cash used in changes in our operating assets and liabilities. Changes in our operating assets and liabilities consisted primarily of a decrease of $2.0 million in accrued expenses, due to the timing of payments related to research and development costs, partially offset by an increase of $1.7 million in prepaid expenses and other current assets, due to increased insurance due to operating as of public company.

During the year ended December 31, 2020, cash used in operating activities was $12.3 million, which consisted primarily of our net loss of $17.3 million, partially offset by $4.9 million of cash provided by changes in our operating assets and liabilities. Changes in our operating assets and liabilities of $4.9 million during the year ended December 31, 2020, consisted of an increase of $6.2 million in accounts payable and accrued expenses, partially offset by an increase of $1.3 million of prepaid expenses and other assets. The increase in accounts payable and accrued expenses was largely due to the timing of payments related to research and development costs.

Investing Activities

During the year ended December 31, 2021, there was no cash used in or provided by investing activities.

During the year ended December 31, 2020 cash used in investing activities was $0.1 million, and consisted of purchases of property and equipment.

Financing Activities

During the year ended December 31, 2021, cash provided by financing activities was $97.1 million, which consisted of net proceeds from the issuance of common stock upon the completion of our IPO.

During the year ended December 31, 2020 cash provided by financing activities was $90.0 million, which consisted primarily of net proceeds of $90.0 million from the sale and issuance of our Series A and Series B convertible preferred stock.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for seribantumab, and seek to develop, in-license or acquire additional product candidates. In addition, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development activities;

- successful enrollment in and completion of clinical trials, including CRESTONE;
- the timing and outcome of regulatory review of our product candidates;
- the cost to develop companion diagnostics as needed for each of our product candidates;
- our ability to establish agreements with third-party manufacturers for clinical supply for our clinical trials and, if any of our product candidates are approved, commercial manufacturing;
- addition and retention of key research and development personnel;
- our efforts to enhance operational, financial and information management systems, and hire additional personnel, including personnel to support development of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we obtain marketing approval;
- the legal patent costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims; and
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder.

We believe our cash and cash equivalents of $146.3 million as of December 31, 2021 will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Our future capital requirements will depend on many factors, including:

- the progress, timing and results of preclinical studies and clinical trials for our current or any future product candidates;
- disruptions or delays in enrollment of our clinical trials due to the COVID-19 pandemic;
- the extent to which we develop, in-license or acquire other pipeline product candidates or technologies;
- the number and development requirements of other future product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of obtaining regulatory approvals of our current or future product candidates and any companion diagnostics we may pursue;
- the scope and costs of making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our current or future product candidates;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or future product candidates;
- the costs associated with commercializing any approved product candidates, including establishing sales, marketing and distribution capabilities;

- the costs associated with completing any post-marketing studies or trials required by the Food and Drug Administration, or FDA, or other regulatory authorities;

- the revenue, if any, received from commercial sales of seribantumab, if approved, or any other future product candidates that receive marketing approval;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims that we may become subject to, including any litigation costs and the outcome of such litigation;

- the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims; and

- to the extent we pursue strategic collaborations, including collaborations to commercialize seribantumab or to develop any future product candidates, our ability to establish and maintain collaborations on favorable terms, if at all, as well as the timing and amount of any milestone or royalty payments we are required to make or are eligible to receive under such collaborations, if any.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for seribantumab or our other future product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on favorable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital or debt when needed or on favorable terms, we could be forced to delay, reduce or eliminate our research and development programs, our commercialization plans or other operations.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts do not contain any minimum purchase commitments and provide for termination upon notice. Payments due upon cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation.

In May 2019, we entered into an asset purchase agreement with the previous sponsor, pursuant to which we acquired all rights and interest to patents, know-how, and inventory for assets related to seribantumab. If we are successful in developing and commercializing seribantumab, we may be obligated to pay the previous sponsor up to $54.5 million in development, regulatory and sales milestone payments pursuant to the terms of the asset purchase agreement. Additionally, in conjunction with the asset purchase agreement with the previous sponsor, we assumed the rights and obligations under certain collaboration and license agreements which may require the payment of milestones and/or royalties on future sales of seribantumab. We are currently unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. See “Business — Asset purchase, licensing and collaboration agreements” for additional information about these license agreements, including with respect to potential payments thereunder.

Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing at the end of this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Costs and Accruals

Research and development costs consist of salaries and benefits, including associated stock-based compensation, and fees paid to other entities that conduct certain research and development activities on our behalf. Research and development costs are expensed as incurred. We estimate preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and contract research organizations, and clinical manufacturing organizations that conduct and manage preclinical studies and clinical trials on our behalf based on actual time and expenses incurred by them. Further, we accrue expenses related to clinical trials based on the level of patient activity according to the related agreement. We monitor patient enrollment levels and related activity to the extent reasonably possible and adjusts estimates accordingly.

We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the services have 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 actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation Expense

We measure stock-based compensation expense at the accounting measurement date based on the fair value of the award and recognize the expense on a straight-line basis over the requisite service period of the award, which is typically the vesting period. Compensation expense is measured using the fair value of the award at the grant date and is adjusted to reflect actual forfeitures as they occur.

We estimate the fair value of stock options using the Black-Scholes option pricing model that takes into account the fair value of our common stock, the exercise price, the expected term of the option, the expected volatility of our common stock, expected dividends on our common stock, and the risk-free interest rate over the expected life of the option.

Expected term — We use the simplified method described in the Securities and Exchange Commission Staff Accounting Bulletin Topic 14.D.2 to calculate the expected term as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees.

Expected volatility — We estimate expected volatility based on the historical volatility of publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price.

Risk-free interest rate — The risk-free rate assumption is based on the U.S. Treasury yield curves whose terms are consistent with the expected term of the stock options.

Expected dividend — We have not issued any dividends and do not expect to issue dividends over the life of the options. As a result, we have estimated the dividend yield to be zero.

We classify stock-based compensation expense in our statement of operations in the same manner in which the award recipient's payroll costs or service payments are classified.

Determination of the Fair Value of Common Stock

Prior to the Company's IPO in June 2021, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant. In order to determine the fair value of our common stock, our board of directors considered, among other things, the prices at which we sold convertible preferred stock and valuations of our common stock prepared by an unrelated third-party valuation firm, with input from management, in accordance with the guidance provided by the *American Institute of Certified Public Accountants Practice Guide, Valuation of Privately Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market for our common stock at the time, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including (1) our stage of development and our business strategy; (2) the progress of our research and development programs; (3) the illiquid nature of our common stock; (4) the prices at which we sold convertible preferred stock and the superior rights and preferences of the convertible preferred stock relative to our common stock at the time of each grant; (5) external market conditions affecting the biotechnology industry, and trends within the biotechnology industry; (6) our financial position, including cash on hand, and our historical and forecasted performance and operating results; (7) the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or a sale of our company in light of prevailing market conditions; and (8) the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

As a public trading market for our common stock has been established, the fair value of our common stock is determined based on the quoted market price of our common stock. We classify stock-based compensation expense in our statement of operations in the same manner in which the award recipient's payroll costs or service payments are classified.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

All of our cash and money market funds are held with a single financial institution. Due to its size, we believe this financial institution represents a minimal credit risk. Our money market funds are invested in high grade U.S. Treasuries with maturities of 90 days or less. As a result, we believe our money market fund represents a minimal credit risk.

Item 8. Consolidated Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Elevation Oncology, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Elevation Oncology, Inc. and Subsidiary (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit) and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020 and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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 from 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 consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company's auditor since 2020

Tysons, Virginia
March 2, 2022

ELEVATION ONCOLOGY, INC.
Consolidated Balance Sheets
(in thousands, except share and per-share information)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 146,284	$ 79,400
Prepaid expenses and other current assets	3,140	1,386
Total current assets	149,424	80,786
Property and equipment, net	38	56
Other assets, net	32	65
Total assets	$ 149,494	$ 80,907
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 5,648	$ 5,679
Accrued expenses	3,141	1,106
Total current liabilities	8,789	6,785
Non-current liabilities:		
Restricted stock repurchase liability	8	15
Total liabilities	8,797	6,800
Commitments and contingencies		
Series A convertible preferred stock, $0.0001 par value; 0 and 32,450,000 authorized, issued and outstanding as of December 31, 2021 and 2020, respectively; aggregate liquidation preference of $0 and $32,450 as of December 31, 2021 and 2020, respectively	—	32,373
Series B convertible preferred stock, $0.0001 par value; 0 and 34,043,889 authorized, issued and outstanding as of December 31, 2021 and 2020, respectively; aggregate liquidation preference of $0 and $65,000 as of December 31, 2021 and 2020, respectively	—	64,815
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2021; no shares issued or outstanding as of December 31, 2021 and 2020, respectively	—	—
Common stock, $0.0001 par value; 500,000,000 and 86,000,000 shares authorized as of December 31, 2021 and 2020, respectively; 23,225,637 and 836,177 issued as of December 31, 2021 and 2020, respectively; 23,205,915 and 800,679 outstanding as of December 31, 2021 and 2020, respectively	2	—
Additional paid-in capital	195,881	66
Accumulated deficit	(55,186)	(23,147)
Total stockholders' equity (deficit)	140,697	(23,081)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 149,494	$ 80,907

See accompanying notes to the consolidated financial statements.

ELEVATION ONCOLOGY, INC.
Consolidated Statements of Operations
(in thousands, except share and per-share information)

	Year Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	$ 23,595	$ 15,476
General and administrative	8,451	1,800
Total operating expenses	32,046	17,276
Loss from operations	(32,046)	(17,276)
Other income (expenses), net	7	11
Net loss	$ (32,039)	$ (17,265)
Net loss per share, basic and diluted	$ (2.64)	$ (21.80)
Weighted average common shares outstanding, basic and diluted	12,132,610	791,821

See accompanying notes to the consolidated financial statements.

ELEVATION ONCOLOGY, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands, except share information)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity (Defici
Balance at December 31, 2019	7,266,750	$ 7,190	—	$ —	788,847	$ —	$ 9	$ (5,882)	$ (5,873
Issuance of Series A convertible preferred stock, net of issuance costs of $0	25,183,250	25,183	—	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $185	—	—	34,043,889	64,815	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	52	—	52
Vesting of restricted common stock	—	—	—	—	11,832	—	5	—	5
Net loss	—	—	—	—	—	—	—	(17,265)	(17,265
Balance at December 31, 2020	32,450,000	$ 32,373	34,043,889	$ 64,815	800,679	$ —	$ 66	$ (23,147)	$ (23,081
Vesting of restricted common stock	—	—	—	—	15,776	—	7	—	7
Stock-based compensation	—	—	—	—	—	—	1,571	—	1,571
Issuance of initial public offering common stock, net	(32,450,000)	(32,373)	(34,043,889)	(64,815)	22,389,460	2	194,237	—	194,239
Net loss	—	—	—	—	—	—	—	(32,039)	(32,039
Balance at December 31, 2021	—	$ —	—	$ —	23,205,915	$ 2	$ 195,881	$ (55,186)	$ 140,697

See accompanying notes to the consolidated financial statements.

ELEVATION ONCOLOGY, INC.
Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2021	2020
Operating activities		
Net loss	$ (32,039)	$ (17,265)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	1,571	52
Depreciation expense	18	15
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,722)	(1,212)
Other assets, net	—	(65)
Accounts payable	(30)	5,219
Accrued expenses	2,035	958
Net cash used in operating activities	(30,167)	(12,298)
Investing activities		
Purchases of property and equipment	—	(71)
Net cash used in investing activities	—	(71)
Financing activities		
Proceeds from the issuance of restricted common stock	—	20
Proceeds from issuance of common stock upon initial public offering, net of issuance costs	97,062	—
Proceeds from the issuance of convertible preferred stock	—	90,183
Cash paid for issuance costs of convertible preferred stock	(11)	(174)
Net cash provided by financing activities	97,051	90,029
Increase in cash and cash equivalents	66,884	77,660
Cash and cash equivalents, beginning of year	79,400	1,740
Cash and cash equivalents, end of year	$ 146,284	$ 79,400
Supplemental disclosure of non-cash financing activities		
Issuance costs in accrued expenses	$ —	$ 11
Conversion of convertible preferred stock upon IPO	$ 97,188	$ —

See accompanying notes to the consolidated financial statements.

ELEVATION ONCOLOGY, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS

Elevation Oncology, Inc. (the "Company" or "Elevation"), which was formerly known as 14ner, Inc., was incorporated under the laws of the State of Delaware on April 29, 2019 ("Inception"). The Company is a clinical-stage biopharmaceutical company focused on the development of precision medicines for patients with genomically defined cancers. The Company acquired its lead product candidate, seribantumab, pursuant to an asset purchase agreement executed with Merrimack Pharmaceuticals, Inc. (the "previous sponsor") during the period ended December 31, 2019 (see Note 9). Seribantumab has been shown preclinically to inhibit tumor growth driven by NRG1 fusions and is currently being tested in the Company's Phase 2 CRESTONE clinical trial for patients with tumors of any origin that have an NRG1 fusion. The Company is actively evaluating opportunities for pipeline expansion including prioritizing additional targeted therapy approaches in tumor types defined by genomic driver alterations.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities.

There can be no assurance that the Company's research and development of its product candidates will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies.

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. economy and in financial markets. The extent of the impact of COVID-19 on the Company's operational and financial performance will continue to depend on certain developments, including the duration and spread of the outbreak, new variants, the vaccination and booster rate, impact on the Company's clinical studies, employee or industry events, and effect on our suppliers and manufacturers, all of which are uncertain and cannot be predicted. COVID-19 has not had a significant impact on the operations or financial results of the Company to date.

Liquidity

In July 2019 and November 2020, the Company received gross proceeds of $97.2 million from the issuance and sale of its Series A and Series B convertible preferred stock (see Note 6).

On June 17, 2021, the Company effected a 1.0 for 4.225582 reverse stock split of its issued and outstanding shares of common stock and proportional adjustment to the existing conversion ratios for each series of the Company's convertible preferred stock (see Note 6). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

On June 29, 2021, the Company closed its initial public offering ("IPO") and issued 6,250,000 shares of its common stock at a price of $16.00 per share for net proceeds of $91.1 million, after deducting underwriting discounts and commissions and expenses of $8.9 million. In connection with the IPO, all shares of Series A and Series B convertible preferred stock converted into 15,736,053 shares of common stock. On July 19, 2021, in connection with the Company's IPO, the underwriters exercised the right to purchase 403,407 shares of the Company's common stock at a price of $16.00 per share for net proceeds of $6.0 million, after deduction underwriting discounts of $0.5 million.

The Company has historical losses from operations and anticipates that it will continue to incur losses for the foreseeable future as it continues the research and development of its product candidates. The Company incurred net losses of $32.0 million and $17.3 million for the years ended December 31, 2021 and 2020, respectively, and had an accumulated deficit of $55.2 million as of December 31, 2021. Through December 31, 2021, the Company has funded its operations with proceeds from the sale of convertible preferred stock and common stock. The Company expects that its cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance date of the consolidated financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Elevation Oncology Securities Corporation, which was established on November 19, 2021. All significant intercompany balances and transaction have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in accordance with GAAP requires the use of estimates and assumptions, based on judgments considered reasonable, which affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company bases its estimates and assumptions on known trends and events and various other factors that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accruals for research and development expenses, the valuation of common stock and the assumptions used in the valuation of share-based compensation awards. Changes in estimates are recorded in the period in which they become known. Due to the risks and uncertainties involved in the Company's business and evolving market conditions and, given the subjective element of the estimates and assumptions made, actual results may differ from estimated results.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available and regularly reviewed 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, which is the development of precision medicines for patients with genomically defined cancers. All material long-lived assets of the Company reside in the United States.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. As of December 31, 2021 and 2020, cash equivalents consisted of money-market funds. The Company places its cash with a high-credit-quality financial institution domiciled in the United States.

Concentrations of Credit Risk and Significant Suppliers

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. The Company's money market funds are invested in highly rated funds. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents and does not believe that it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including preclinical and clinical testing. These programs could be adversely affected by a significant interruption in the supply of such drug substance and drug products. During the year ended December 31, 2021, the Company had two vendors that accounted for approximately 61% of its research and development expense. As of December 31, 2021, the Company had one vendor that accounted for approximately 74% of the total accounts payable. During the year ended December 31, 2020, the Company had one vendor that accounted for approximately 46% of its research and development expense. The same vendor also accounted for approximately 95% of the total accounts payable as of December 31, 2020.

Property and Equipment

Property and equipment consist of computer software that is recorded at cost and depreciated on a straight-line basis over the estimated useful lives of the assets. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized.

The Company reviews its long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying value of assets may not be recoverable. Recoverability is measured by comparison of the asset's book value to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets. No impairment losses have been recorded through December 31, 2021.

Cloud Computing Arrangements

The Company defers implementation costs incurred in cloud computing hosting arrangements in accordance with Accounting Standards Update ("ASU") 2018-15 and amortizes these costs over the noncancelable term of the cloud computing arrangement, plus any optional renewal periods (1) that are reasonably certain to be exercised by the Company or (2) for which exercises of the renewal option is controlled by the cloud service provider. Costs incurred during the application development stage are capitalized within either prepaid expenses and other current assets, or in other assets, net on the Company's balance sheet. Amortization of implementation costs are on a straight-line basis over the related hosting arrangement term and is reflected in research and development expenses in the consolidated statements of operations.

Classification and Accretion of Convertible Preferred Stock

The Company's convertible preferred stock is classified outside of stockholders' deficit on the balance sheet because the holders of such shares have liquidation rights in the event of a deemed liquidation that, in certain situations, are not solely within the control of the Company and would require the redemption of the then-outstanding convertible preferred stock. The convertible preferred stock is not redeemable, except in the event of a deemed liquidation (see Note 6). Because the occurrence of a deemed liquidation event is not currently probable, the carrying values of the convertible

preferred stock are not being accreted to their redemption values. Subsequent adjustments to the carrying values of the convertible preferred stock would be made only when a deemed liquidation event becomes probable. Upon the closing the Company's IPO in June 2021, all outstanding convertible preferred stock automatically converted into shares of common stock.

Fair Value Measurements

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

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

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above (see Note 3).

Patent Costs

The legal and professional costs incurred by the Company to maintain its patent rights have been expensed as part of general and administrative expenses since inception. As of December 31, 2021 and 2020, the Company has determined that these expenses have not met the criteria to be capitalized. Intellectual property-related expenses for the year ended December 31, 2021 and 2020 were $0.2 million and $0.1 million, respectively.

Research and Development Costs

Research and development costs consist of salaries and benefits, including associated stock-based compensation, and fees paid to other entities that conduct certain research and development activities on the Company's behalf. Research and development costs are expensed as incurred. The Company estimates preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and contract research organizations and clinical manufacturing organizations that conduct and manage preclinical studies and clinical trials on the Company's behalf based on actual time and expenses incurred by them. Further, the Company accrues expenses related to clinical trials based on the level of patient activity according to the related agreement. The Company monitors patient enrollment levels and related activity to the extent reasonably possible and adjusts estimates accordingly.

The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the services have been performed or when the goods have been received rather than when the payment is made.

Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to the Company's prior estimates of accrued research and development expenses.

Stock-Based Compensation

The Company measures stock-based compensation cost at the accounting measurement date based on the fair value of the award and recognizes the expense on a straight-line basis over the requisite service period of the award, which is typically the vesting period. Compensation expense is measured using the fair value of the award at the grant date and is adjusted to reflect actual forfeitures as they occur.

The Company estimates the fair value of stock options using the Black-Scholes option pricing model that takes into account the exercise price, the fair value of the Company's common stock, the expected term of the option, the expected volatility of the Company's common stock, expected dividends on the Company's common stock, and the risk-free interest rate over the expected life of the option.

Fair value of common stock—Prior to IPO in June 2021, the Company valued its common stock by taking into consideration its most recently available valuation of common shares performed by management and the board of directors, as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant. Upon IPO, the fair value of the Company's common stock is determined based on the quoted market price of its common stock.

Expected term—The Company uses the simplified method described in the Securities and Exchange Commission Staff Accounting Bulletin Topic 14.D.2 to calculate the expected term as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees.

Expected volatility—The Company estimates expected volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its traded stock price.

Risk-free interest rate—The risk-free rate assumption is based on the U.S. Treasury yield curves whose terms are consistent with the expected term of the stock options.

Expected dividend—The Company has not issued any dividends and does not expect to issue dividends over the life of the options. As a result, the Company has estimated the dividend yield to be zero.

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

Net Loss per Common Share

The Company's net loss is equivalent to net loss attributable to common stockholders for all periods presented. Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period and the effect of dilutive securities.

The Company applies the two-class method to calculate its basic and diluted net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. The Company's participating securities contractually entitle the holders of such shares to participate in dividends; but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated

financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. The Company accounts for uncertainty in income taxes recognized. If the tax position is deemed more likely than not to be sustained, it would then be assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. To date the Company has no uncertain tax positions and there have been no interest and penalties.

Recently issued accounting pronouncements

In December 2019, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. Among other items, the amendments in ASU 2019-12 simplify the accounting treatment of tax law changes and year-to-date losses in interim periods. An entity generally recognizes the effects of a change in tax law in the period of enactment; however, there is an exception for tax laws with delayed effective dates. Under current guidance, an entity may not adjust its annual effective tax rate for a tax law change until the period in which the law is effective. This exception was removed under ASU 2019-12, thereby providing that all effects of a tax law change are recognized in the period of enactment, including adjustment of the estimated annual effective tax rate. Regarding year-to-date losses in interim periods, an entity is required to estimate its annual effective tax rate for the full fiscal year at the end of each interim period and use that rate to calculate its income taxes on a year-to-date basis. However, current guidance provides an exception that when a loss in an interim period exceeds the anticipated loss for the year, the income tax benefit is limited to the amount that would be recognized if the year-to-date loss were the anticipated loss for the full year. ASU 2019-12 removes this exception and provides that in this situation, an entity would compute its income tax benefit at each interim period based on its estimated annual effective tax rate. ASU 2019-12 is effective for fiscal years beginning after December 15, 2021, with early adoption permitted. The Company has not elected to early adopt ASU 2019-12 and is currently evaluating the impact the adoption of the standard will have on its financial statements and related disclosures.

3. FAIR VALUE MEASUREMENTS OF FINANCIAL ASSETS

The Company's financial assets subject to fair value measurements on a recurring basis and the level of inputs used for such measurements were as follows:

	As of December 31, 2021			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Money market funds included in cash and cash equivalents	$ 106,000	$ —	$ —	$ 106,000

	As of December 31, 2020			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Money market funds included in cash and cash equivalents	$ 76,013	$ —	$ —	$ 76,013

During the years ended December 31, 2021and 2020, the Company had no transfers between Level 1, Level 2 or Level 3 financial assets.

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net, consisted of the following (in thousands):

	Estimated Useful Life	December 31, 2021	December 31, 2020
		(in thousands)	
Computer software	4 years	$ 71	$ 71
Less: Accumulated depreciation		(33)	(15)
Property and equipment, net		$ 38	$ 56

The Company recorded less than $0.1 million of depreciation expense during the years ended December 31, 2021 and 2020.

5. ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	December 31, 2021	December 31, 2020
	(in thousands)	
Accrued preclinical and clinical trial costs	$ 1,260	$ 505
Accrued compensation	1,059	429
Accrued consulting	77	127
Accrued professional services	499	28
Accrued other	246	17
Total accrued expenses	$ 3,141	$ 1,106

6. CONVERTIBLE PREFERRED STOCK

The Company had issued Series A and Series B convertible preferred stock (collectively, the “Convertible Preferred Stock”). As of December 31, 2020, the Company’s certificate of incorporation, as amended and restated, authorized the Company to issue 66,493,889 shares of $0.0001 par value convertible preferred stock, of which 32,450,000 were designated as Series A convertible preferred stock (“Series A”) and 34,043,889 were designated as Series B convertible preferred stock (“Series B”). As of December 31, 2020, all of the Company’s Convertible Preferred Stock was classified outside of stockholders’ deficit because the shares contained deemed liquidation rights that were a contingent redemption feature not solely within the control of the Company.

Series A

On July 12, 2019, the Company sold 5,450,000 shares of Series A at a price of $1.00 per share (“Series A Original Issue Price”) pursuant to the Series A stock purchase agreement (the “Series A Purchase Agreement”), for gross proceeds of $5.5 million. On August 7, 2019, investors purchased an additional 1,816,750 shares of Series A at the Series A Original Issue Price, for gross proceeds of $1.8 million.

Upon achievement of the Milestone Closing (as defined in the Series A Purchase Agreement) and approval by the Company’s board of directors, the Company issued an additional 25,183,250 shares of Series A at the Series A Original Issue Price on January 9, 2020 for gross proceeds of $25.2 million.

Series B

On November 10, 2020, the Company sold 34,043,889 shares of Series B at a price of $1.9093 per share (“Series B Original Issue Price”), pursuant to the Series B stock purchase agreement for gross proceeds of $65.0 million.

Conversion

Upon the closing the Company's IPO in June 2021, all outstanding convertible preferred stock automatically converted into shares of common stock. There are 10,000,000 authorized preferred shares of December 31, 2021.

7. COMMON STOCK

As of December 31, 2021, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 500,000,000 shares of $0.0001 par value common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors.

Initial Public Offering

On June 29, 2021, the Company closed its IPO and issued 6,250,000 shares of its common stock at a price of $16.00 per share for net proceeds of $91.1 million, after deducting underwriting discounts and commissions and expenses of $8.9 million. In connection with the IPO, all shares of Series A and Series B convertible preferred stock converted into 15,736,053 shares of common stock. On July 19, 2021, in connection with the Company's IPO, the underwriters exercised the right to purchase 403,407 shares of the Company's common stock at a price of $16.00 per share for net proceeds of $6.0 million, after deduction underwriting discounts of $0.5 million.

The Company has reserved a total of 27,565,320 shares of common stock as of December 31, 2021 for common stock outstanding, the exercise of outstanding stock options and the number of shares remaining available for future grant under the Company's 2021 Stock Incentive Plan. The Company had reserved a total of 19,831,875 shares of common stock as of December 31, 2020 for common stock outstanding, the conversion of the outstanding shares of Convertible Preferred Stock, the exercise of outstanding stock options and the number of shares remaining available for future grant under the Company's 2019 Stock Incentive Plan.

8. STOCK-BASED COMPENSATION

Stock-based compensation expense as reflected in the Company's consolidated statements of operations was as follows (in thousand):

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Research and development	$ 244	$ 24
General and administrative	1,327	28
Stock-based compensation expense included in operating expenses	$ 1,571	$ 52

2021 Equity Incentive Plan

The Company has two equity incentive plans: the 2019 Equity Incentive Plan ("2019 Plan"), and the 2021 Equity Incentive Plan ("2021 Plan"). New awards can only be granted under the 2021 Plan, under which it is able to issue equity to employees, board members, consultants, and advisors. The 2021 Plan became effective on June 24, 2021, the date the prospectus related to the Company's IPO was deemed effective by the SEC. The 2021 Plan authorizes the award of stock options, restricted stock awards ("RSAs"), stock appreciation rights ("SARs"), restricted stock units ("RSUs"), cash awards, performance awards and stock bonus awards. The Company has initially reserved 1,483,445 shares of its common stock, plus any reserved shares not issued or subject to outstanding grants under the 2019 Plan on the effective date of the 2021 Plan, for issuance pursuant to awards granted under the 2021 Plan. Of this amount, 1,720,291 shares were available for future grants as of December 31, 2021. The number of shares reserved for issuance under the 2021 Plan will increase automatically on January 1 of each of 2022 through 2031 by the number of shares equal to the lesser of 5% of the aggregate number of outstanding shares of the Company's common stock as of the immediately preceding December 31, or a number as may be determined by our board of directors. As such, 1,160,296 shares were added to the Plan in January 2021.

2019 Stock Incentive Plan

The total number of shares of common stock available for issuance under the 2019 Plan was 1,972,114 shares when the 2019 Plan was adopted. In December 2019 and November 2020, the Company increased the number of shares of common stock reserved for issuance under the 2019 Plan by 144,950 shares and 1,189,911 shares, respectively. Shares underlying any awards that were forfeited, canceled, or reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated or shares that were withheld upon exercise of an option or settlement of an award to cover the exercise price or tax withholding were to be added back to the shares available for issuance under the 2019 Plan. For the year ended December 31, 2021, 1,016,337 options were granted under the 2019 Plan. The 2019 Plan was terminated in connection with the Company's IPO. The Company will not grant any additional awards under the 2019 Plan thereafter.

2021 Employee Stock Purchase Plan

The Company has adopted the Employee Stock Purchase Plan ("ESPP") which became effective June 24, 2021, the date the prospectus related to the Company's IPO was deemed effective by the SEC, to enable eligible employees to purchase shares of its common stock with accumulated payroll deductions at a discount beginning on a date to be determined by the board of directors or compensation committee. The ESPP is intended to qualify under Section 423 of the Code. The Company has initially reserved 228,222 shares of its common stock for sale under the ESPP. The aggregate number of shares reserved for sale under the ESPP will increase automatically on January 1st of each of 2022 through 2031 by the number of shares equal to the lesser of 1% of the total outstanding shares of the Company's common stock as of the immediately preceding December 31 (rounded to the nearest whole share) or a number of shares as may be determined by the board of directors in any particular year. As such, 232,059 shares were added to the Plan in January 2021.

The aggregate number of shares issued over the term of the ESPP, subject to stock-splits, recapitalizations or similar events, may not exceed 4,564,440 shares of the Company's common stock.

Stock Options

A summary of stock option activity for employee and nonemployee awards under the 2019 and 2021 Plans is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	1,761,062	$ 0.95	9.54	$ 723
Granted	1,309,400	$ 7.80		
Cancelled	(48,663)	3.98		
Outstanding at December 31, 2021	3,021,799	$ 3.71	8.94	$ 10,903
Vested at December 31, 2021	680,951	$ 1.23	8.39	$ 3,437
Vested and expected to vest at December 31, 2021	3,021,799	$ 3.71	8.94	$ 10,903

The weighted average grant-date fair value of stock options granted during the year ended December 31, 2021 and 2020 was $4.60 and $0.73 per share, respectively. The fair value of each stock option was estimated using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,	
	2021	2020
Risk-free interest rate	0.95 - 1.35 %	0.2−0.75 %
Volatility	75-77 %	74%−79 %
Dividend yield	— %	— %
Expected term (years)	6	3−6

The fair value of options that vested during the years ended December 31, 2021 and 2020 was $0.6 million and $0 million, respectively. The Company recorded stock-based compensation expense associated with stock option awards of $1.1 million and $0.1 million during the 12 months ended December 31, 2021 and 2020, respectively. As of December 31, 2021, there was $6.4 million of total unrecognized compensation cost related to unvested stock-based awards, which the Company expects to recognize over a remaining weighted-average period of 3.2 years.

Restricted Common Stock

The terms of the 2019 Plan permitted certain option holders to exercise options before their options were vested, subject to certain limitations. Upon early exercise, the awards become subject to a restricted stock agreement and are subject to the same vesting provisions in the original stock option awards. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment, at the lesser of the price paid by the purchaser or the fair value of the shares at the time of repurchase. Such shares are not deemed to be issued for accounting purposes until they vest and are therefore excluded from shares outstanding until the repurchase right lapses and the shares are no longer subject to the repurchase feature. The liability is reclassified into common stock and additional paid-in capital as the shares vest and the repurchase right lapses. Accordingly, the Company has recorded the unvested portion of the exercise proceeds of less than $0.01 million as a liability from the early exercise in the accompanying consolidated balance sheets as of December 31, 2021 and 2020, respectively. The Company recorded stock-based compensation expense associated with restricted common stock of less than $0.1 million during the 12 months ended December 31, 2021 and 2020.

Restricted Stock Units

The Company issues RSUs to employees that generally vest over a four-year period with 25% of awards vesting after one year and then quarterly thereafter. Any unvested shares will be forfeited upon termination of services. The fair value of an RSU is equal to the fair market value price of the Company's common stock on the date of grant. RSU expense is amortized straight-line over the vesting period.

The following table summarizes activity related to restricted stock units:

	Number of shares	Weighted average grant date fair value
Unvested at December 31, 2020	—	$ —
Granted	200,996	16.00
Unvested at December 31, 2021	200,996	16.00

The Company recorded stock-based compensation expense of $0.4 million for the 12 months ended December 31, 2021, related to RSUs. As of December 31, 2021, the total unrecognized expense related to all RSUs was $2.8 million, which the Company expects to recognize over a weighted-average period of 3.4 years.

9. ASSET PURCHASE AND LICENSE AGREEMENTS

In May 2019, the Company entered into an asset purchase agreement with the previous sponsor, pursuant to which it acquired all rights and interest to patents, know-how, and inventory for assets related to seribantumab, a fully humanized immunoglobulin G2 monoclonal antibody against HER3.

Pursuant to the asset purchase agreement, the Company made an upfront, non-refundable payment of $3.5 million at closing. If the Company succeeds in developing and commercializing seribantumab, the Company may be obligated to pay the previous sponsor up to $54.5 million in development, regulatory and sales milestone payments.

Under the terms of the asset purchase agreement, the Company assumed the rights and obligations of the following collaboration and license agreements previously held by the previous sponsor:

- *Dyax*—The Company assumed all rights and obligations provided for under the amended and restated collaboration agreement executed between Dyax Corp. ("Dyax") and the previous sponsor (the "Dyax Agreement"). Pursuant to the Dyax Agreement, Dyax utilized its proprietary phage technology to identify antibodies that would bind to targets of interest to the previous sponsor. Additionally, Dyax granted to the previous sponsor a world-wide, non-exclusive, royalty free right to use and make any and all of the antibodies identified by Dyax for certain research purposes. Seribantumab was identified as a result of the research activities performed under the Dyax Agreement.

Pursuant to the terms of the Dyax Agreement, the Company may be obligated to pay Dyax milestone payments of up to approximately $9.3 million if certain development and regulatory milestones are achieved. In addition, Dyax is entitled to mid-single digit royalties based on net sales of seribantumab. The Company's obligation to pay royalties to Dyax continues on a product-by-product and country-by-country basis until the later of a specified number of years after the first commercial sale in such country and the expiration of the patent rights covering seribantumab in such country.

The Dyax Agreement will remain in effect, unless earlier terminated, for so long as the Company continues to develop or commercialize seribantumab. Either party may terminate the agreement in the event of an uncured material breach by the other party. The Company also has the right to terminate the agreement in its entirety or on a product-by-product basis at any time upon 90 days' prior written notice.

- *Ligand Pharmaceuticals*—The Company assumed all rights and obligations provided for under the amended commercial license agreement executed between Selexis SA ("Selexis") and the previous sponsor (the "Selexis Agreement"). Pursuant to the Selexis Agreement, the Company received non-exclusive rights to technology for use in the manufacture of seribantumab and may be required to make milestone payments of up to approximately €900, per licensed product, if certain development and regulatory milestones are achieved. Additionally, Selexis may have the right to obtain a royalty of the greater of €0.2 million annually and less than one percent on net sales of seribantumab. The obligation to pay royalties with respect to each product sold in a country continues until the expiration of the patent rights covering the product in such country. Either party may terminate the agreement in the event of an uncured material breach by the other party. The Company also has the right to terminate the agreement at any time upon 60 days' prior written notice. In November of 2021, the Selexis agreement was assigned to Ligand Pharmaceuticals Incorporated.

- *National Institute of Health*—The Company assumed all rights and obligations provided for under the amended commercial license agreement executed between the U.S. Public Health Service, a division of the U.S. Department of Health and Human Services (the "NIH") and the previous sponsor (the "NIH Agreement"). Pursuant to the NIH Agreement, the Company received non-exclusive rights in the United States to patents related to certain antibodies associated with seribantumab. If certain development and regulatory milestones are achieved, the Company may be obligated to pay NIH additional milestone payments of up to approximately $0.4 million per licensed product.

The Company evaluated the asset purchase agreement with the previous sponsor under ASC Topic 805, *Business Combinations*, and concluded that the transaction did not meet the requirements to be accounted for as a business combination and therefore was accounted for as an asset acquisition. Accordingly, the upfront payment of $3.5 million was expensed as research and development expenses in the statement of operations for the year ended December 31, 2019. Additionally, the Company concluded that all consideration to be paid under the asset purchase agreement is contingent in nature and will be recognized when the respective contingency is resolved. The Company assessed the contingent events which would result in the payment of a milestone as of December 31, 2021 and 2020, and concluded no such payments were required.

Other Research Arrangements

In June 2021, the Company entered into a collaboration agreement with Caris, or the Caris Agreement. Under the terms of the Caris Agreement, Caris will identify targets for the collaboration and provide those targets to the Company at regular intervals for review and approval. Once a target is selected by the collaboration's joint steering committee, the collaboration will retain access to the selected targets.

The financial terms surrounding development and commercialization of each product candidate identified for the collaboration and included in the Caris Agreement vary based on the level of participation elected by each party in the development and commercialization efforts following identification of a target. There are no upfront or milestone payments or royalties due to either party under the collaboration. With respect to proceeds from any potential commercial transaction related to a product resulting from the collaboration, Caris will be entitled to a tiered initial percentage ranging from the mid-single digits to low teens based on the product candidate's potential peak sales revenue with the remaining proceeds allocated based on each party's pro rata share of expenses incurred in development of the product. In the case of an out-licensing transaction of an asset instead of a sale, Caris and the Company will split all consideration received in the transaction in a similar manner. The Caris Agreement provides flexibility for Caris and the Company to jointly develop and commercialize, or for either the Company or Caris to incur development and commercialization expenses. The ultimate percentage of proceeds payable to the Company and Caris will depend on the level of development and commercialization participation elected by each party.

The Company will own the intellectual property rights to the therapeutics developed under the collaboration, and Caris will own the intellectual property rights to the diagnostics developed under the collaboration.

Either party may terminate the Caris Agreement for uncured material breach by the other party or in the case of the other party's insolvency. The term of the Caris Agreement is three years, automatically renewing for one-year terms. Either party may terminate the agreement at the end of a term by written notice to the other, subject to the continuation of exclusivity with respect to any target selected by the Joint Steering Committee, so long as commercially reasonable efforts are used to discover, identify, develop and/or commercialize a therapeutic related to such target.

10. COMMITMENTS AND CONTINGENCIES

The Company, from time to time, may be involved in legal proceedings, regulatory actions, claims and litigation arising in the ordinary course of business. The Company was not a defendant in any lawsuits from Inception to the date of these consolidated financial statements.

11. INCOME TAXES

No provision for income taxes was recorded for the years ended December 31, 2021 and 2020. The Company has incurred net pre-tax losses in the United States only for all periods presented. The Company has not reflected any benefit of such net operating loss ("NOL") carryforwards in the accompanying consolidated financial statements. The provision for income taxes differs from the amount expected by applying the federal statutory rate to the loss before taxes as follows:

	Year Ended December 31,	
	2021	2020
Profit before tax at federal statutory rate	21.0 %	21.0 %
State tax benefit, net of federal benefit	0.4 %	0.3 %
Research and development credit carryovers	4.4 %	1.7 %
Permanent differences	(1.4)%	(0.6)%
Return to Provision True Ups	0.1 %	— %
Change in valuation allowance	(24.5)%	(22.4)%
Effective income tax rate	— %	— %

In assessing the realizability of the net deferred tax assets, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the NOL carryforwards. The Company has recorded a valuation allowance against its deferred tax assets on December 31, 2021 and 2020 because the Company's management believes that it is more likely than not that these assets will not be fully realized in the near future. The increase in the valuation allowance of approximately $7.9 million in the year ended December 31, 2021 primarily relates to the generation of net operating losses and research and development credits.

As of December 31, 2021, the Company had federal NOL carryforwards of approximately $48.2 million, all of which can be carried forward indefinitely, and state NOL carryforwards of $3.5 million, which begin to expire in 2040. The Company also has federal tax credits of $1.5 million and state tax credits of $0.2 million which may be used to offset future tax liabilities and will begin to expire in 2040. NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities.

Net deferred tax asset (liability) in the accompanying consolidated balance sheets consists of the following (in thousands):

	December 31,	
	2021	2020
	(in thousands)	
Deferred tax assets and (liabilities)		
Net operating losses	$ 10,303	$ 4,138
Research and development credit	1,697	295
Accrued expenses	130	—
Stock-based compensation	151	—
Intangible assets	666	664
Gross deferred tax asset	12,947	5,097
Valuation allowance	(12,945)	(5,083)
Net deferred tax asset	2	14
Stock based compensation	—	(2)
Fixed assets	(2)	(12)
Deferred tax liabilities	(2)	(14)
Net deferred tax asset (liability)	$ —	$ —

Subsequent ownership changes may further affect the limitation in future years. The Company has not conducted a study to assess whether a change of ownership has occurred or whether there have been multiple changes of ownership since Inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of ownership, as defined by Section 382 and 383 of the Internal Revenue Code, at any time since Inception, utilization of the NOL carryforwards or research and development tax credit carryforwards would be subject to the annual limitations under Section 382 and 383 of the Internal Revenue Code.

The Company will recognize both accrued interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2021, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available. As of December 31, 2021, all tax returns remain open.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security Act ("the CARES Act"), was signed into law in March 2020. The CARES Act lifts certain deduction limitations originally imposed by the Tax Cuts and Jobs Act of 2017 ("2017 Tax Act"). Corporate taxpayers may carryback NOLs originating during 2018 through 2020 for up to five years, which was not previously allowed under the 2017 Tax Act. The CARES Act also eliminates the 80% of taxable income limitations by allowing corporate entities to fully utilize NOL carryforwards to offset taxable

income in 2018, 2019 or 2020. Taxpayers may generally deduct interest up to the sum of 50% of adjusted taxable income plus business interest income (30% limit under the 2017 Tax Act) for tax years beginning January 1, 2019 and 2020. The CARES Act allows taxpayers with alternative minimum tax credits to claim a refund in 2020 for the entire amount of the credits instead of recovering the credits through refunds over a period of years, as originally enacted by the 2017 Tax Act. The Company notes that these provisions did not have a material impact to the amounts recorded within this footnote.

12. NET LOSS PER SHARE

The following table summarizes the computation of basic and diluted net loss per share of the Company (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2021	2020
Net loss	$ (32,039)	$ (17,265)
Weighted average common stock outstanding, basic and diluted	12,132,610	791,821
Net loss per share, basic and diluted	$ (2.64)	$ (21.80)

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

	December 31,	
	2021	2020
Convertible preferred shares	—	15,736,053
Outstanding stock options	3,021,799	1,761,062
Unvested restricted stock	19,721	34,498
Unvested RSUs	200,996	—
	3,242,516	17,531,613

13. DEFINED CONTRIBUTION PLAN

The Company has a defined-contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. As currently established, the Company is not required to make contributions to the 401(k) Plan. The Company made matching contributions of $0.1 million for the year ended December 31, 2021. No contributions were made for the year ended December 31, 2020.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with GAAP. This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies. We will be required, under Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ending December 31, 2022. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The SEC defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim consolidated financial statements will not be detected or prevented on a timely basis.

In accordance with the provisions of the Sarbanes-Oxley Act, neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period included in this annual report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended December 31, 2021 that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Except to the extent provided below, the information required by this Item 10 will be included in the section captioned "Corporate Governance Matters" and the subsections thereof, "Class I Director Nominees," "Class II Directors," "Class III Directors," "Executive Officers," and "Section 16(a) Beneficial Ownership Reporting Compliance," in our definitive proxy statement to be filed with the Securities and Exchange Commission ("SEC") with respect to our 2022 Annual Meeting of Stockholders within 120 days of the end of the fiscal year to which this report relates, which information is incorporated herein by reference

We post our code of business conduct and ethics, which applies to all employees, including all executive officers, senior financial officers and directors, in the "Governance" sub-section of the "Investor Relations" section (https://investors.elevationoncology.com) of our corporate website at www.elevationoncology.com. Our code of business conduct and ethics complies with Item 406 of SEC Regulation S-K and the rules of Nasdaq. We intend to disclose any changes to the code that affect the provisions required by Item 406 of Regulation S-K, and any waivers of the code of ethics for our executive officers, senior financial officers or directors, on our corporate website.

Item 11. Executive Compensation

The information required by this Item 11 will be included in the section captioned "Executive Compensation" in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders within 120 days of the end of the fiscal year to which this report relates, which information is incorporated herein by reference.

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

The information required by this Item 12 will be included in the sections captioned "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans" in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders within 120 days of the end of the fiscal year to which this report relates, which information is incorporated herein by reference.

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

The information required by this Item 13 will be included in the sections captioned "Related Person Transactions," "Policies and Procedures for Related Person Transactions" and "Board Determination of Independence" in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders within 120 days of the end of the fiscal year to which this report relates, which information is incorporated herein by reference.

Item 14. Principal Accountant's Fees and Services

The information required by this Item 14 will be included in the section captioned "Audit Fees and Services" and the subsection thereof in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders within 120 days of the end of the fiscal year to which this report relates, which information is incorporated herein by reference.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(1) Consolidated Financial Statements

See Index to Consolidated Financial Statements at Item 8 herein.

(2) Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit No.	Description	Incorporated by Reference				Filed herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation.	10-Q	001-40523	3.1	August 12, 2021	
3.2	Restated Bylaws.	10-Q	001-40523	3.2	August 12, 2021	
4.1	Form of Common Stock Certificate.	S-1/A	333-256787	4.1	June 21, 2021	
4.2	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.					X
4.3	Amended and Restated Investors' Rights Agreement, dated November 10, 2020 by and among Elevation Oncology, Inc. and certain of its stockholders.	S-1	333-256787	4.2	June 4, 2021	
10.1#	Form of Indemnity Agreement.	S-1/A	333-256787	10.1	June 21, 2021	
10.2#	2019 Equity Incentive Plan, as amended, and forms of award agreements.	S-1	333-256787	10.2	June 4, 2021	
10.3#	2021 Equity Incentive Plan, and forms of award agreements.	S-1/A	333-256787	10.3	June 21, 2021	
10.4#	2021 Employee Stock Purchase Plan, and forms of award agreements.	S-1/A	333-256787	10.4	June 21, 2021	
10.5^†	Asset Purchase Agreement dated May 28, 2019, by and between the Registrant and Merrimack Pharmaceuticals, Inc., as amended.	S-1	333-256787	10.5	June 4, 2021	
10.6^†	Amended and Restated Collaboration Agreement dated January 24, 2007 between Dyax Corp. and Merrimack Pharmaceuticals, Inc., as amended.	S-1	333-256787	10.6	June 4, 2021	
10.7^†	Commercial License Agreement dated June 4, 2008 between Selexis SA and Merrimack Pharmaceuticals, Inc..	S-1	333-256787	10.7	June 4, 2021	

10.9#	Employment Agreement dated July 12, 2019 by and between Elevation Oncology, Inc. and Shawn Leland, as amended.	S-1/A	333-256787	10.9	June 21, 2021	
10.10#	Employment Agreement dated June 6, 2021 by and between Elevation Oncology, Inc. and Joseph J. Ferra, Jr..	S-1/A	333-256787	10.10	June 16, 2021	
10.11#	Employment Agreement dated February 2, 2021 by and between Elevation Oncology, Inc. and Valerie Malyvanh Jansen, as amended.					X
10.12#ˆ†	Collaboration Agreement dated June 14, 2021, between Caris MPI, Inc. and Elevation Oncology, Inc..	S-1/A	333-256787	10.11	June 23, 2021	
10.13	Form of Change in Control and Severance Agreement.	8-K	001-40523	99.1	August 6, 2021	
21.1	Subsidiaries of Registrant.					X
23.1	Consent of CohnReznick LLP, Independent Registered Public Accounting Firm					X
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.					X
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.					X
32*	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.					X
101.INS	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X

101.SCH	XBRL Taxonomy Extension Schema Document.	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).	X

*	This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.
^	Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulations S-K.
†	Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.
#	Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

ELEVATION ONCOLOGY, INC.

Date: March 3, 2022

By: /s/Shawn Leland
Shawn Leland
President, Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on March 3, 2022 by the following persons on behalf of the registrant and in the capacities indicated:

Signature	Title
/s/ Shawn Leland, Pharm.D., R.Ph. Shawn Leland, Pharm.D., R.Ph.	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Joseph J. Ferra, Jr. Joseph J. Ferra, Jr.	Chief Financial Officer and Corporate Secretary (Principal Financial and Accounting Officer)
/s/ Steven A. Elms Steven A. Elms	Chairman of the Board
/s/ R. Michael Carruthers R. Michael Carruthers	Director
/s/ Timothy Clackson, Ph.D. Timothy Clackson, Ph.D.	Director
/s/ Lori Hu Lori Hu	Director
/s/ Colin Walsh, Ph.D. Colin Walsh, Ph.D.	Director