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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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 001-38459

SURFACE ONCOLOGY, INC.
(Exact name of Registrant as specified in its Charter)

Delaware	**46-5543980**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
50 Hampshire Street, 8th Floor Cambridge, MA	**02139**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 714-4096

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common stock, $0.0001	SURF	The Nasdaq Global Market

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

None

(Title of class)

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

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

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

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

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

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

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

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 x

The aggregate market value of the registrant's common stock, $0.0001 par value per share ("Common Stock"), held by non-affiliates of the registrant, based on the last sale price of the Common Stock at the close of business on June 30, 2021, was $308,676,299. For purposes of foregoing calculation only, all directors and executive officers of the registrant are assumed to be affiliates of the registrant.

The number of shares of registrant's Common Stock outstanding as of February 28, 2022 was 46,958,984.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement relating to the Annual Meeting of Shareholders, scheduled to be held on June 8, 2022, are incorporated by reference into Part III of this Report.

Auditor Firm Id:	238	Auditor Name:	PricewaterhouseCoopers LLP	Auditor Location:	Boston, Massachusetts

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Summary of Risk Factors

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks include, among others, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.
- We will require substantial additional financing, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.
- The regulatory approval processes of the FDA, the EMA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Our current or future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could halt their clinical development, prevent their marketing approval, limit their commercial potential or result in significant negative consequences.
- We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.
- We rely on third parties, and will continue to rely on third parties, to conduct our ongoing and planned clinical trials for the product candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize any product candidates we develop and our business could be substantially harmed.
- We rely on third parties to manufacture product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- Intellectual property is critical to our business and our success in part depends on our ability to maintain, protect, and expand our portfolio of intellectual property rights.
- The price of our common stock may be volatile and fluctuate substantially.
- Our business may be adversely affected by the ongoing COVID-19 pandemic.

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

PART I

Item 1. Business.

Overview

We are a clinical-stage immuno-oncology company focused on using our specialized knowledge of the biological pathways critical to the immunosuppressive tumor microenvironment, or the TME, for the development of next-generation cancer therapies. While first-generation immuno-oncology therapies, such as checkpoint inhibitors, represented a remarkable therapeutic advancement, we believe most patients do not achieve durable clinical benefit primarily because these therapies focus on only one element of the complex and interconnected immunosuppressive TME. We believe there is a significant opportunity to more broadly engage both the innate and adaptive arms of the immune system in a multi-faceted, coordinated and patient-specific approach, to meaningfully improve cure rates for patients with a variety of cancers. We aim to identify key components within the TME to gain a deep understanding of its biology, leverage this understanding to define the optimal therapeutic targets and the patients most likely to benefit, and develop novel antibody therapeutics with differentiated biologic activity. By utilizing our expertise in immunology, oncology, assay development, antibody selection and characterization, and translational research, we are developing and advancing a broad pipeline of TME-focused programs that we believe are the next generation of immuno-oncology therapies. Our programs demonstrate our multi-faceted approach by targeting several critical components of the immunosuppressive TME.

NZV930 (formerly SRF373) and SRF617 are antibodies designed to inhibit cluster of differentiation (or CD) 73 and CD39, respectively, and illustrate how our specialized knowledge of TME biology can be leveraged across programs. CD73 and CD39 are both critical enzymes involved in the production of extracellular adenosine, a key metabolite with strong immunosuppressive properties within the TME. NZV930 and SRF617 each aim to reduce the production of immunosuppressive adenosine, but target different points of the adenosine pathway. In addition to reducing the production of adenosine, we believe SRF617 will also stimulate anti-tumor immunity because of its ability to maintain levels of extracellular adenosine triphosphate, or ATP. In June 2018, a Phase 1 trial of NZV930 was initiated by our partner, Novartis Institutes for Biomedical Research, Inc., or Novartis. We initiated a Phase 1/1b dose escalation trial of SRF617 in March 2020, and initiated combination cohorts of the ongoing trial in January 2021. SRF617 received orphan drug designation from the U.S. Food and Drug Administration, or FDA for the treatment of pancreatic cancer in March 2021. In December 2021, we presented initial clinical data demonstrating SRF617's potential in combination with chemotherapy and other immuno-oncology therapies.

SRF388 is an antibody targeting interleukin 27, or IL-27, an immunosuppressive cytokine, or protein that is overexpressed in certain cancers, including hepatocellular, lung and renal cell carcinoma. IL-27 is a cytokine secreted by macrophages and antigen presenting cells that plays an important physiologic role in suppressing the immune system, as evidenced by its ability to resolve tissue inflammation. In addition, one of the subunits of IL-27, EBI3, is highly expressed during pregnancy and its expression is correlated with maternal-fetal tolerance. Due to its immunosuppressive nature, there is a rationale for inhibiting IL-27 to treat cancer, as this approach will influence the activity of multiple types of immune cells that are necessary to recognize and attack a tumor. We initiated a Phase 1 dose escalation clinical trial of SRF388 in April 2020, and initiated expansion stages of the ongoing trial in June 2021. SRF388 received orphan drug designation and fast track designation from the FDA for the treatment of hepatocellular carcinoma in November 2020. In June 2021, we presented initial clinical data demonstrating monotherapy activity.

GSK4381562 (formerly SRF813) is an antibody targeting CD112R, also known as PVRIG, an inhibitory protein expressed on natural killer, or NK, and T cells. GSK4381562 blocks the interaction of CD112R with CD112, its binding partner that is expressed on tumor cells. GSK4381562 can promote the activation of both NK and T cells, with potential to elicit a strong anti-tumor response and promote immunological memory. On December 16, 2020, we granted GlaxoSmithKline Intellectual Property (No. 4) Limited, or GSK, an exclusive license to worldwide development and commercialization rights of SRF813. GSK received clearance from the FDA for GSK4381562 to proceed into a first-in-human clinical trial in November 2021.

SRF114 is designed as a highly specific afucosylated IgG1 antibody targeting CCR8, a chemokine receptor highly expressed on regulatory T cells, or Treg cells, in the TME. SRF114 causes depletion of intra-tumoral Treg cells, important regulators of immune suppression and tolerance, through antibody-dependent cellular cytotoxicity, or ADCC, leading to anti-tumor activity in preclinical models. In March 2021, we initiated IND-enabling activities for SRF114, with an IND filing planned for the second half of 2022.

We expect that the unique insights generated in any one of our product programs will accelerate the development of the other programs in a synergistic fashion due to the interconnections between these TME pathways.

In January 2016, we entered into a strategic collaboration agreement with Novartis, or the Novartis Agreement, to develop next-generation cancer therapies. Upon entering into the agreement, we received an upfront payment of $70.0 million from Novartis and granted Novartis a worldwide exclusive license to research, develop, manufacture, and commercialize antibodies that target CD73. Under the Novartis Agreement, we are currently entitled to potential development milestones of $325.0 million, potential sales milestones of $200.0 million, as well as tiered royalties on annual net sales of NZV930 by Novartis ranging from high single-digit to mid-teens percentages. Such amount of potential milestone payments assumes the successful clinical development and achievement of all sales milestones for NZV930.

In December 2020, we entered into a license agreement with GSK, or the GSK Agreement. Upon entering into the agreement, we received an upfront payment $85.0 million and granted GSK an exclusive worldwide license to develop, manufacture, and commercialize antibodies that target PVRIG. Under the GSK Agreement, we are eligible to receive up to $90.0 million in clinical and $155.0 million in regulatory milestones. In addition, we may receive up to $485.0 million in sales milestone payments. We are also eligible to receive royalties on global net sales of any approved products based on the licensed antibodies, ranging in percentages from high single digits to mid-teens upon successful commercialization of GSK4381562.

We have assembled an outstanding team, including our world-class scientific advisory board, to execute on our mission to create next-generation immuno-oncology therapies to help patients suffering with cancer. Our scientific founders and members of our management team have extensive experience in drug discovery and development and are leaders in the immuno-oncology field. Members of our leadership team have helped develop a number of commercialized therapies, including cancer treatments such as Avastin, Copiktra and Velcade. Our scientific advisory board is co-chaired by leading immuno-oncology researchers Alexander Y. Rudensky, Ph.D., a world leader in regulatory T cell biology, and Arlene H. Sharpe, M.D., Ph.D., who led pioneering work related to the ligands for PD-1, including the co-discovery of PD-L2, and has defined functions of the PD-1 pathway as well as other costimulatory and immune checkpoint molecules. Collectively, we believe our team, industry-leading capabilities and collaborations with Novartis and GSK, position us to build the leading TME company focused on developing next-generation immunotherapies for the tens of millions of cancer patients worldwide.

The Tumor Microenvironment

The TME presents a complex interplay of immunosuppressive biological pathways, cells and other components surrounding the tumor. It comprises several key components that often act together to profoundly suppress the body’s anticancer immune response through a variety of different biological mechanisms, allowing the tumor to evade the immune system. Given the complexity of the TME, we believe it is imperative to target more than one component of this environment in order to provide durable clinical benefit to patients suffering with cancer.

Checkpoint inhibitors are a drug class designed to counteract certain defenses a tumor has against the immune system. Currently approved checkpoint inhibitors were developed for the treatment of cancer because of the initial belief that inactivation of the immune system by checkpoint proteins could be reversed to reactivate the immune system to recognize and attack the tumor. These therapies against checkpoint proteins, such as cytotoxic T-lymphocyte antigen 4, or CTLA-4, programmed cell death protein 1, or PD-1, and programmed death-ligand 1, or PD-L1, have produced impressive results in the clinic across an array of cancers and have been approved for a number of malignancies. However, a durable clinical benefit has been observed in only a limited subset of patients and tumor types. For example, PD-1 inhibition has doubled three-year survival rates in previously treated non-small cell lung cancer patients, but more than 80% of patients do not achieve a durable clinical benefit. We believe the primary reason only a relatively modest number of patients achieve durable response with checkpoint inhibitors is because only one component of the TME, the effector T lymphocyte, is reactivated while other elements of the TME, including suppressive metabolites and cytokines, macrophages, regulatory T cells, and NK cells, remain unaffected.

Adenosine is a key metabolite within the TME that accumulates and inhibits the function of important immune cells, including T cells and NK cells, leading to an environment conducive to tumor growth. CD39 and CD73, two of the enzymes involved in the production of extracellular adenosine, are both attractive therapeutic targets because inhibiting either of them will reduce the amount of adenosine in the TME. We believe inhibiting CD39 may have further immunostimulatory effects because this inhibition will also increase local amounts of ATP in the TME.

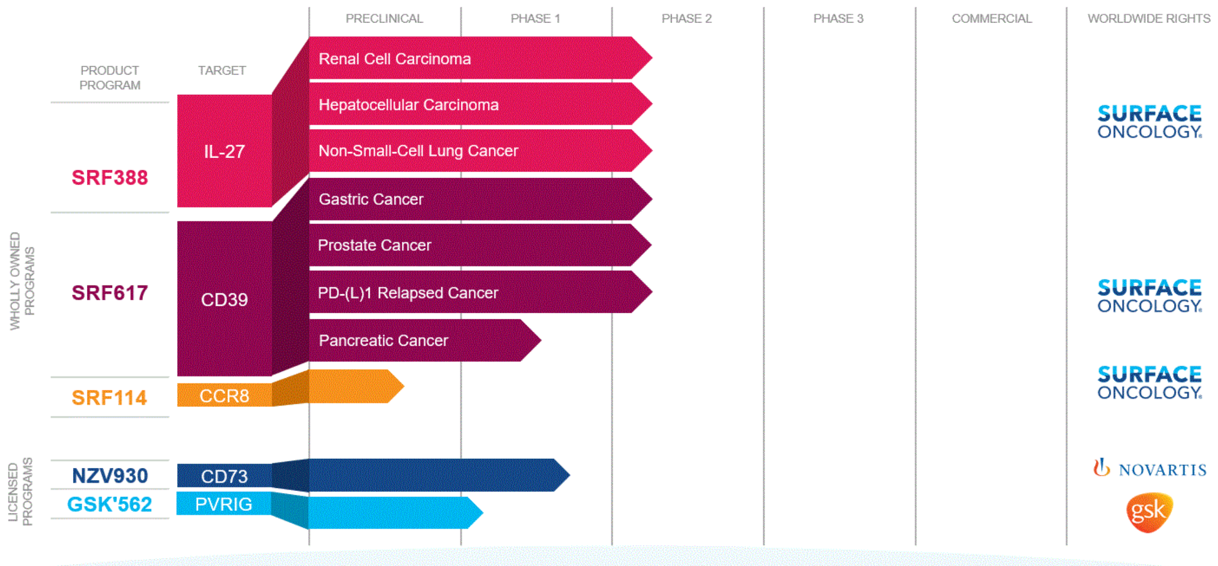
IL-27 is a cytokine that plays an important physiologic role in suppressing the immune system. In preclinical studies, the IL-27 pathway has been observed to suppress T cell activation within the TME, which may prevent the immune system from recognizing, attacking and killing cancer cells. Due to its immunosuppressive nature, there is a rationale for inhibiting IL-27 to treat cancer, as this approach influences the activity of multiple types of immune cells, including the reactivation of T cells, that are necessary to recognize and attack the tumor.

NK cells are a type of immune cell that can recognize and lyse, or kill, other cells that need to be destroyed, including cancer cells. These immune cells are a key component of the immune system that provide a rapid, non-specific response to pathogens. NK and T cells express CD112R (PVRIG), an inhibitory protein that helps block NK and T cell activation when bound to its binding partner, CD112. Targeting CD112R is an attractive therapeutic strategy for activating NK and T cells so that they can effectively kill tumor cells.

Regulatory T cells, or Tregs, play an essential role in controlling autoimmunity and maintaining immune tolerance and homeostasis. Treg cells are also recruited to sites of tumor growth where they suppress antitumor immune responses and facilitate tumor growth. Treg cells are associated with poor prognosis in many human cancers. Depletion of Treg cells in published experimental murine models of cancer has been shown to reduce primary and metastatic tumor growth. Although Treg cell depletion is a promising therapeutic strategy in cancer, current therapies aimed at depletion of Treg cells in humans fail to distinguish systemic Treg cells from tumor infiltrating Treg cells, resulting in undesirable inflammatory side-effects outside of the TME. The chemokine receptor CCR8 was recently reported to be highly expressed on intratumoral Treg cells in breast carcinomas but not on peripheral Treg cells or effector T cells. As such, we believe that the depletion of tumor infiltrating Treg cells while sparing peripheral Treg cells via targeting CCR8 is an attractive approach to enhance anti-tumor immunity.

Our Pipeline

We believe next-generation immuno-oncology therapies need to encompass a multi-faceted, coordinated and patient-specific approach to treating cancer in order to achieve meaningful increases in patient cure rates. We have developed a pipeline of multiple therapeutic programs to address the complexity of the TME, as shown in the table below.



Our Programs

Modulating the Adenosine Pathway to Treat Cancer with NZV930 and SRF617

Overview of NZV930 and SRF617

Based on our understanding of the adenosine pathway and its role in the TME, we are advancing two programs targeting different enzymes in the adenosine pathway to reduce the immunosuppressive effects of adenosine production in the TME.

NZV930 (formerly SRF373) is designed to inhibit CD73, an enzyme critical to the production of extracellular adenosine. By reducing the amount of adenosine in the TME, we believe the immune system will be able to better recognize and attack tumors. In our preclinical studies, NZV930 exhibited potent CD73 enzymatic inhibition, resulting in a reduction of adenosine and increased activity of immune cells, particularly T cells. Further, in combination with a PD-1 inhibitor, our antibodies against CD73 demonstrated potent anti-tumor effects in preclinical animal studies. CD73 is overexpressed in many tumors and can be shed from the cell surface. We therefore believe CD73 overexpression could be a useful biomarker to identify those patients most likely to benefit from NZV930. We have granted Novartis a worldwide exclusive license to develop and commercialize NZV930. Novartis advanced NZV930 into clinical development in June of 2018.

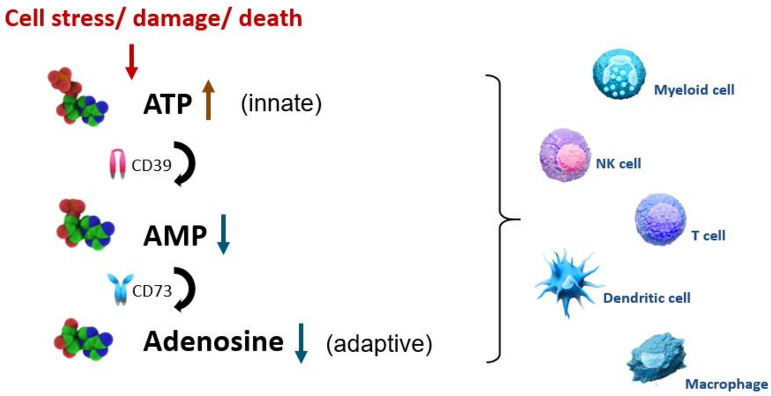
SRF617 is designed to inhibit CD39, an enzyme critical both to the production of adenosine and the breakdown of ATP. We believe targeting CD39 will not only reduce extracellular adenosine, but will also maintain extracellular levels of immunostimulatory ATP, both of which have been observed to promote anti-tumor immunity. In preclinical studies, SRF617 exhibited potent CD39 enzymatic inhibition, leading to increased activity of T cells and maturation of antigen presenting cells. Further, in combination with chemotherapy or a PD-1 inhibitor, our antibodies against CD39 demonstrated potent anti-tumor effects in preclinical animal studies. We initiated a Phase 1/1b dose escalation trial of SRF617 in March 2020, and initiated combination cohorts of the ongoing trial in January 2021.

CD73 and CD39 Background

Within the TME, the adenosine pathway refers to the extracellular conversion of ATP to adenosine and the signaling of adenosine through the A2A/A2B adenosine receptors on immune cells. Under normal conditions, CD39 and CD73 maintain the balance of extracellular levels of immunosuppressive adenosine and immunostimulatory ATP. In healthy tissue, ATP is barely detectable in the extracellular environment because ATP is rapidly broken down by CD39 to generate adenosine monophosphate, or AMP, which is then converted to adenosine by CD73. Under conditions of cellular stress, including cancer, extracellular ATP levels rise significantly, but ATP is rapidly broken down, subsequently hindering the ability of the immune system to recognize and attack the tumor due to lower levels of ATP and higher levels of adenosine.

We believe inhibiting CD73 will reduce levels of immunosuppressive adenosine in the TME and allow key immune cells, including T cells, to attack the tumor. In addition, we believe inhibiting CD39 will maintain extracellular levels of immunostimulatory ATP as well as reduce the amount of extracellular adenosine in the TME. Because of its role in regulating the immune system, we believe a multi-faceted approach targeting components of the adenosine pathway is attractive for the treatment of cancer.

Inhibiting the Adenosine Pathway in the TME



Landscape of Competitive Agents and the Opportunity

There are multiple third-party programs evaluating targets in the adenosine pathway, including inhibitors of CD73, CD39 and the key adenosine receptors. Due to the relatively high amounts of adenosine in the TME, we believe achieving inhibition of adenosine receptors sufficient to result in a meaningful clinical response as a monotherapy could prove challenging. CD73 and CD39 are overexpressed in a variety of tumors, making them attractive targets for cancer therapies. Recently published randomized Phase 2 clinical data of a CD73 antibody in combination with a PD-1 antibody provide further support for the potential benefit of adenosine pathway inhibition in patients with cancer. We believe that the potency of CD73 and CD39 enzymatic inhibition will be an important differentiator and may lead to improved clinical efficacy by reducing adenosine levels in the TME to a greater extent.

Our Adenosine Pathway Programs

NZV930

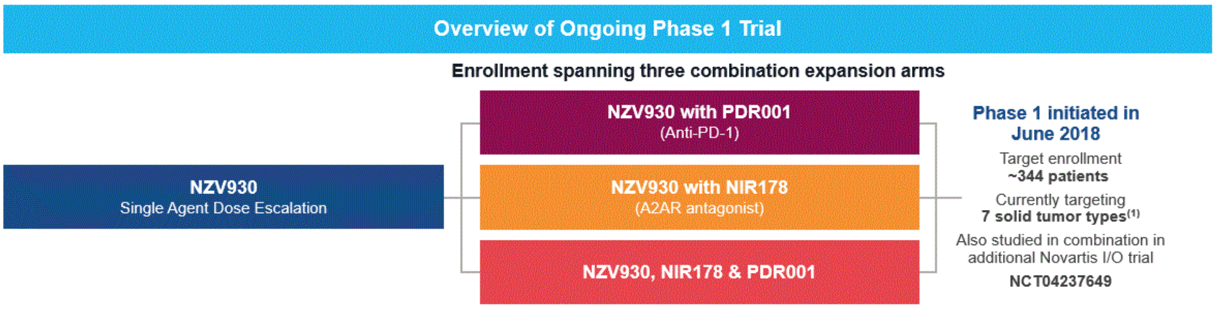
NZV930 is a fully human immunoglobulin isotype G4, or IgG4, monoclonal antibody that is designed to be a potent inhibitor of CD73. We selected NZV930 for clinical development based on the following key attributes observed in preclinical development:

- Potent enzymatic inhibition of soluble and membrane bound CD73, resulting in reduced adenosine levels;
- Increased T cell proliferation; and
- Inhibition of tumor growth.

Clinical Trial

We have granted Novartis worldwide development and commercialization rights to NZV930. An IND for NZV930, was sponsored and filed by Novartis with the FDA in February 2018, and NZV930 entered clinical trials in June 2018. As depicted below, the Phase 1 trial is anticipated to enroll approximately 344 patients. Following a monotherapy dose escalation, NZV930 will be tested in combination with a PD-1 inhibitor, Novartis' PDR001 and an A2A receptor antagonist, Novartis' NIR178. A triplet therapeutic regimen, including NZV930, PDR001 and NIR178 will also be tested.

Overview of NZV930 Phase 1 Trial



SRF617

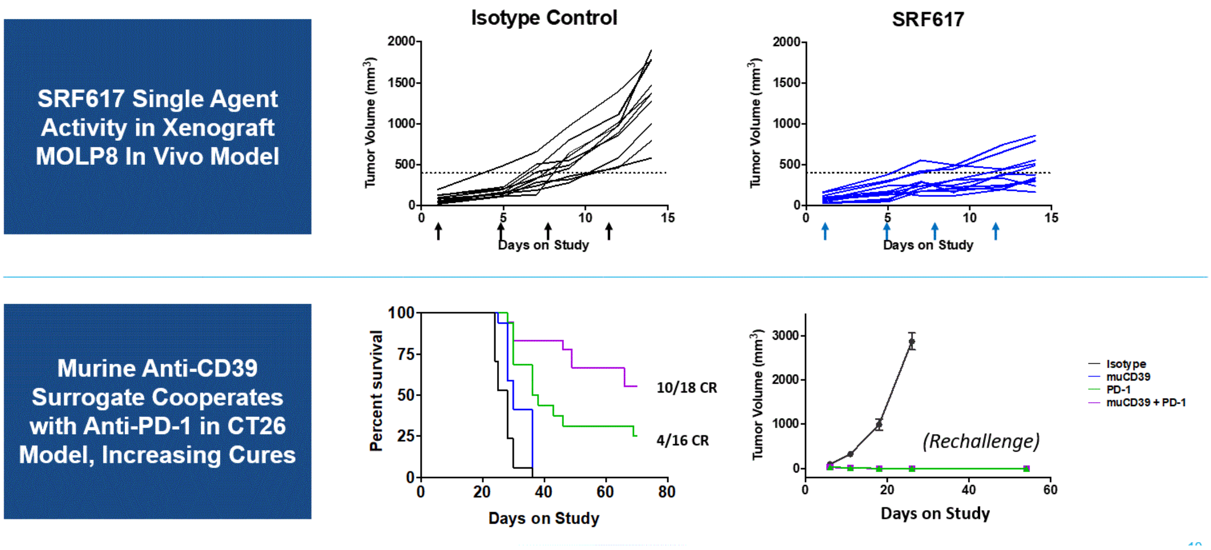
SRF617 is a fully human IgG4 monoclonal antibody that is designed to be a potent inhibitor of CD39 enzymatic activity. We selected SRF617 for clinical development based on the following key attributes observed in preclinical development:

- Potent enzymatic inhibition of CD39;
- Maintenance of immunostimulatory levels of ATP despite the presence of CD39; and
- Inhibition of tumor growth as a monotherapy

Our Preclinical Studies

We have seen preclinical anti-tumor activity with SRF617. In the study shown below, we observed that SRF617 monotherapy was associated with significantly inhibited tumor growth, as compared to a control antibody. Also, in the study below, an anti-mouse CD39 antibody in combination with an anti-PD-1 antibody significantly extended survival in tumor-bearing mice and resulted in immunological memory.

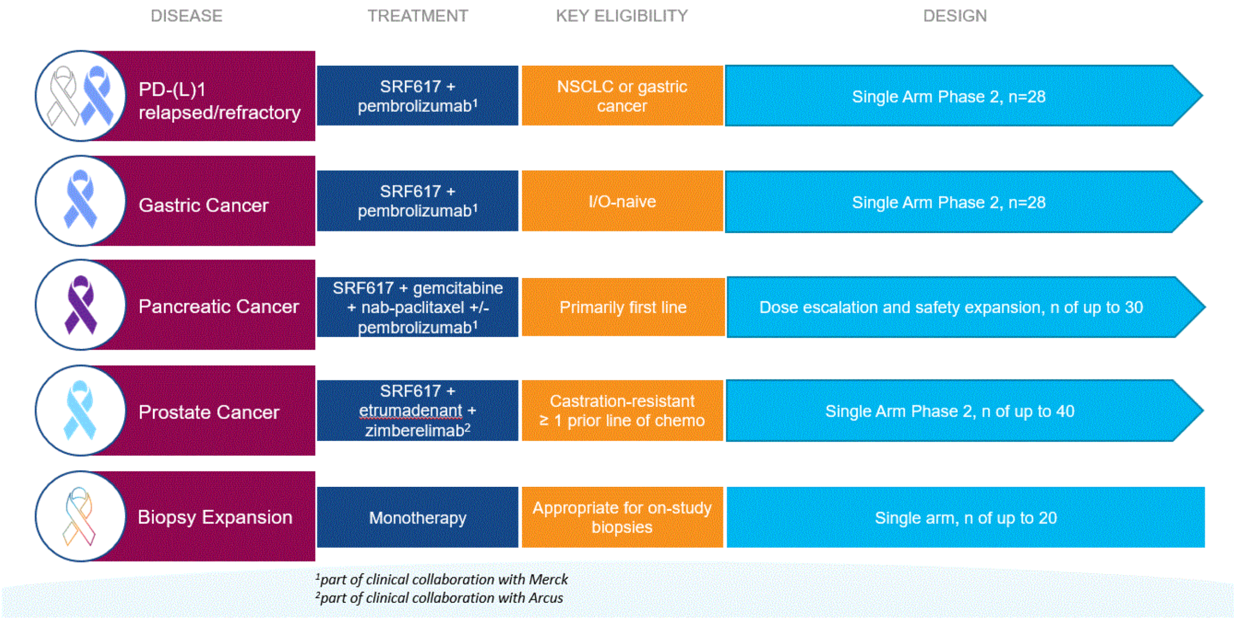
CD39 Inhibition Observed to Have Potent Anti-tumor Activity



Clinical Trial

We initiated a Phase 1/1b dose escalation trial of SRF617 in March 2020. We initiated the Phase 1b combination expansion part of the trial in January 2021 in which SRF617 is being tested in combination with a PD-1 inhibitor and with chemotherapy. SRF617 received orphan drug designation from the FDA for the treatment of pancreatic cancer in March 2021. We plan to evaluate SRF617 in combination with an adenosine receptor inhibitor and a PD-1 inhibitor in a Phase 2 trial in patients with advanced prostate cancer and anticipate initiation of that study in early 2022. In December 2021, we presented initial clinical data demonstrating SRF617's potential in combination with chemotherapy and other immuno-oncology therapies at the ESMO Immuno-Oncology conference.

SRF617 Clinical Development Plan



Inhibiting the Immunosuppressive Cytokine IL-27 to Activate the Immune System

Overview of SRF388

SRF388 is a fully human IgG1 monoclonal antibody that is designed to bind to the p28 subunit of IL-27 and inhibit IL-27's activity by blocking its binding to the IL-27 receptor. We identified SRF388 using our proprietary suite of research tools, which have allowed us to enhance our deep biological understanding of IL-27 and its receptor. We selected SRF388 for clinical development based on the following key observations in our preclinical studies:

- Potent reduction of IL-27 driven immune cell suppression;
- Potential for combination therapy including checkpoint inhibitors; and
- Strong translational rationale for targeting IL-27 in certain types of cancer.

IL-27 Background

IL-27 is a multi-subunit cytokine (subunits P28 and EBI3) secreted by macrophages and antigen presenting cells that plays an important physiologic role in suppressing the immune system, as evidenced by its role in resolving tissue inflammation and its association with maternal-fetal tolerance. Due to its immunosuppressive nature, there is an emerging rationale for inhibiting IL-27 to treat cancer, as this approach influences the activity of multiple types of immune cells that are necessary to recognize and attack the tumor. As shown in the diagram below, IL-27 suppresses T cell activation, which we believe will prevent the immune system from recognizing, attacking and killing cancerous cells.

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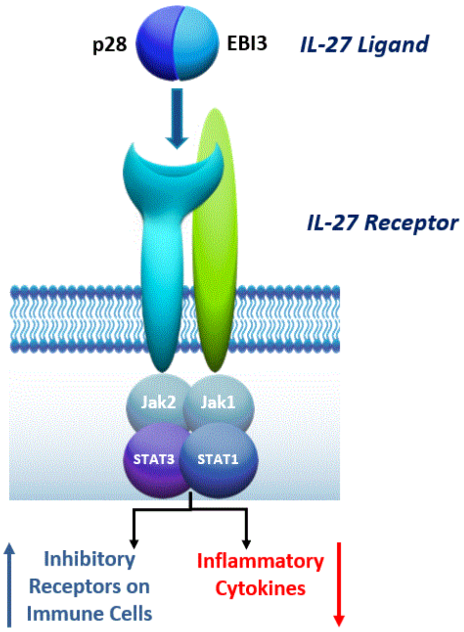
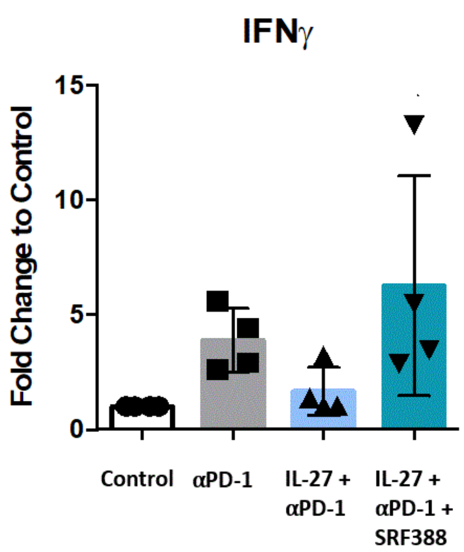
IL-27 Upregulates Inhibitory Receptors, Downregulates Proinflammatory Cytokines



Our Preclinical Studies

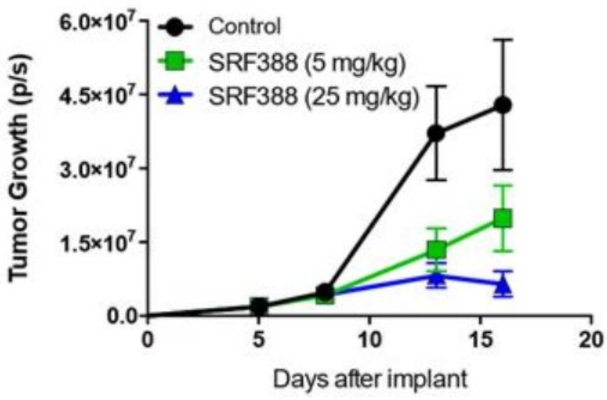
In several preclinical studies conducted by us, we observed that the treatment of human T cells and monocytes with IL-27 resulted in the induction of an immunosuppressive phenotype, including increased expression of the checkpoint proteins PD-L1 and TIM3 and a decrease in pro-inflammatory cytokines such as TNFα and IFNγ. In the preclinical study below, SRF388 restores INFγ production in PBMCs when combined with PD-1 antibody treatment in the presence of IL-27.

SRF388 Restored Cytokine Production in Combination with anti-PD-1 in Presence of Recombinant IL-27 in Activated Healthy Donor PBMCs

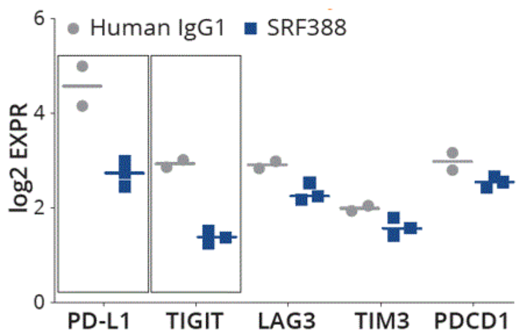


In the preclinical study below, SRF388 monotherapy resulted in a significant reduction in the growth of hepatocellular, or HCC, tumors in the liver, as compared to a control antibody. In addition, SRF388 reduced the expression of immune-inhibitory receptors in this HCC model.

SRF388 Inhibited Tumor Growth in the Orthotopic Hepa 1-6 Mouse Model of Hepatocellular Carcinoma



SRF388 Modulated Gene Expression in the Hepa1-6 Mouse Model of HCC



Clinical Trial

We initiated a Phase 1 dose escalation trial of SRF388 in April 2020, and initiated expansion stages of the ongoing trial in June 2021. SRF388 received orphan drug designation and fast track designation from the FDA for the treatment of hepatocellular carcinoma in November 2020. As depicted below, the Phase 1 trial is anticipated to enroll approximately 100 patients. Following a monotherapy dose escalation, SRF388 will be tested in specific cohorts of patients with renal cell carcinoma, hepatocelluar carcinoma, and non-small cell lung cancer. In June 2021, we presented initial clinical data at the American Society of Clinical Oncology Annual Meeting demonstrating monotherapy activity. In October 2021, we announced our plans to evaluate SRF388 in combination with anti-PD-L1 and anti-VEG-F therapy in a randomized Phase 2 trial of patients with first-line HCC and anticipate an initial data read out from this trial in 2024.

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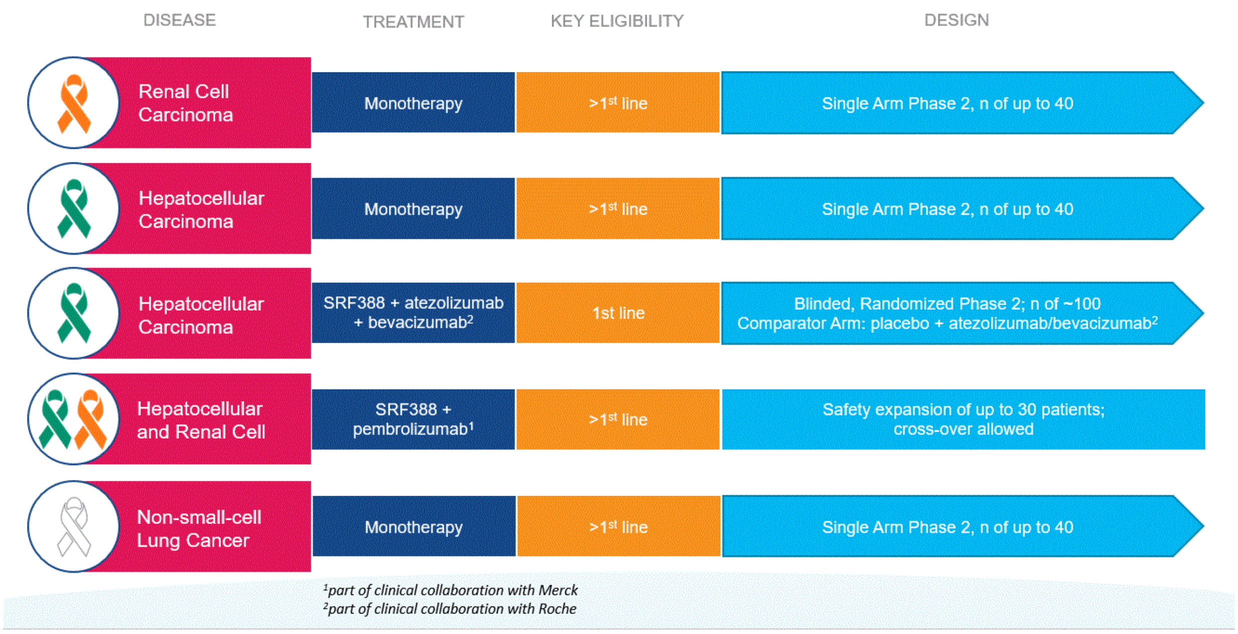
SRF388 Clinical Development Plan



Blocking the Inhibitory Receptor CD112R to Promote Immune Cell Activation in the Tumor Microenvironment

Overview of GSK4381562

GSK4381562 (formerly SRF813) is a fully human IgG1 monoclonal antibody that binds to the inhibitory receptor CD112R, also known as PVRIG, and antagonizes its function on immune cells. We selected GSK4381562 for clinical development based on the following key observations in our preclinical studies:

- Potent blockade of CD112R interaction with its ligand CD112;
- Enhancement of NK and T cell activation; and
- Inhibition of tumor growth.

CD112R Background

CD112R is an inhibitory receptor primarily expressed on NK cells and T cells. CD112R suppresses immune cell activation through its binding with CD112. Because CD112 is commonly overexpressed on tumor cells, there is an emerging rationale for disrupting the CD112:CD112R interaction to promote antitumor immune responses. On December 16, 2020, we granted GSK an exclusive license to worldwide development and commercialization rights of GSK4381562. GSK received clearance from the FDA for GSK4381562 to proceed into a first-in-human clinical trial in November 2021.

Targeting CCR8 to Deplete Intra-tumoral Regulatory T Cells

Overview of SRF114

SRF114 is a highly specific afucosylated IgG1 monoclonal antibody targeting the chemokine receptor CCR8, which is expressed at high levels on Treg cells within the TME. SRF114 causes depletion of intra-tumoral Treg cells, important regulators of immune suppression and tolerance, through antibody-dependent cellular cytotoxicity, or ADCC. We selected SRF114 for further development based on the following key observations in our preclinical studies:

- Highly specific for human CCR8;
- Activation of NK cells; and
- Preferentially depletes tumor Treg cells.

CCR8 Background

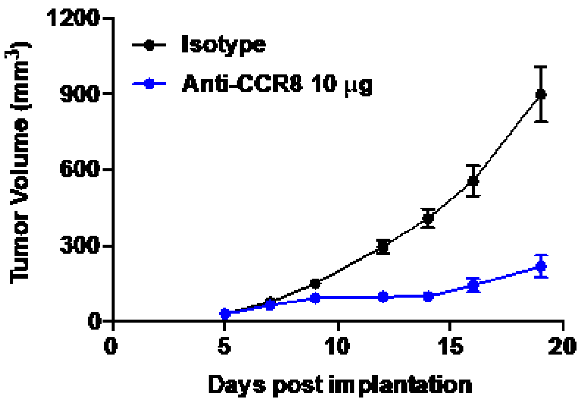
Selectively targeting tumor Treg cells for depletion while sparing those Treg cells that control immune responses in other healthy tissues is an attractive strategy for cancer immunotherapy. Preclinical data in mouse models of cancer evaluating Treg cell-depleting strategies support this hypothesis.

Studies characterizing the gene expression signature of tumor-infiltrating immune cells have identified CCR8 as highly expressed and enriched on Treg cells as compared to other immune cells present in the TME. CCR8 is a G-protein coupled chemokine receptor that is involved in the chemotaxis of immunocytes to sites of inflammation. Importantly, CCR8 protein expression was shown to be highly upregulated on tumor Treg cells isolated from several different tumor types, whereas expression on tumor infiltrating effector T cells (Teff cells) or peripheral Teff and peripheral Treg cells was significantly lower and only present on minor subsets of these cells. This expression profile increases the likelihood of preferentially targeting and depleting tumor-infiltrating Treg cells with SRF114 and has the potential to unleash antitumor immune responses in the TME.

Our Preclinical Studies

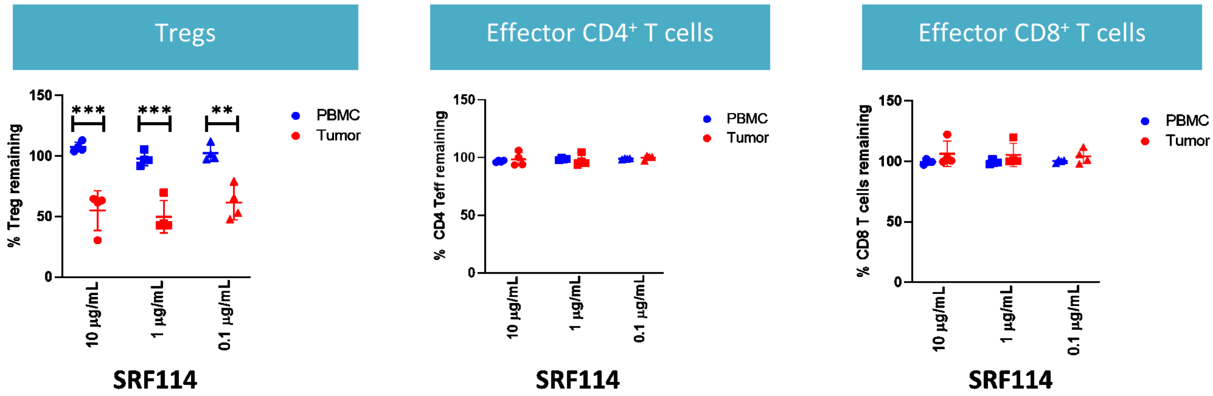
In preclinical studies, we observed that targeting CCR8 in mouse tumor models can strongly inhibit tumor growth. In the study shown below, we observed that treatment with an anti-murine CCR8 antibody was associated with significant tumor growth inhibition, as compared to a control antibody.

Anti CCR8 Antibody Inhibited Tumor Growth in CT26 Model of Colorectal Cancer



We also observed that SRF114 can preferentially deplete Treg cells in human tumor samples. The study below tested the ability of SRF114 to deplete different lymphocyte populations from dissociated cell cultures taken from human tumors or peripheral blood mononuclear cells (PBMC) while cocultured with activated NK cells. SRF114 preferentially depleted tumor Treg cells as compared to effector $CD4^+$ and $CD8^+$ T cell populations or circulating Treg cells from PBMCs.

SRF114 preferentially depletes tumor-infiltrating CCR8+ Treg cells



IND-enabling studies are ongoing to support an IND filing to the FDA planned for the second half of 2022.

We expect that the unique insights generated in any one of our product programs will accelerate the development of the other programs in a synergistic fashion due to the interconnection between the pathways of the TME.

Collaboration Agreement with Novartis

Overview

In January 2016, we entered into a strategic collaboration with Novartis to develop next-generation cancer therapies. The Novartis Agreement was subsequently amended in May 2016, July 2017, September 2017 and October 2018. Upon entering into the agreement, we received an upfront payment of $70.0 million from Novartis and granted Novartis a worldwide exclusive license to research, develop, manufacture and commercialize antibodies that target CD73. In addition, we initially granted Novartis the right to purchase exclusive option rights, each an Option for up to four specified targets, including certain development, manufacturing and commercialization rights. In January 2020, Novartis did not purchase and exercise its single remaining Option under the Novartis Agreement and, as a result, the option purchase period expired. Therefore, there are no Options remaining eligible for purchase, and potential exercise, and the Company's performance obligations under the Novartis Agreement have ended. Under the Novartis Agreement, we are currently entitled to potential development milestones of $325.0 million, potential sales milestones of $200.0 million, as well as tiered royalties on annual net sales of NZV930 by Novartis ranging from high single-digit to mid-teens percentages. Such amount of potential milestone payments assumes the successful clinical development and achievement of all sales milestones for NZV930. Through December 31, 2021, we had received an aggregate of $150.0 million from Novartis in upfront payments, milestone payments, and option purchase payments. In January 2016 and April 2018, we also received equity investments of $13.5 million and $11.5 million, respectively, from Novartis.

Development and Commercialization of CD73 Products

Novartis has the sole right to develop and commercialize CD73 antibody candidates and corresponding licensed products worldwide pursuant to a development plan and a commercialization plan, respectively. Novartis is obligated to use commercially reasonable efforts to develop the CD73 antibody candidates and corresponding licensed products, obtain regulatory approval of such products, including within certain defined markets, and to commercialize such products following regulatory approval. Novartis is responsible for all costs and expenses of such development and commercialization and is obligated to provide us with updates on its development and commercialization activities through the joint development committee.

Exclusivity

Neither party may, alone or with any affiliate or third party, develop or commercialize any antibody that specifically binds to CD73. The October 2018 Amendment clarified that Novartis is permitted to research, develop, manufacture or commercialize any diagnostic product that specifically binds to CD73, subject to Novartis' compliance with its rights and obligations under the Novartis Agreement, and provided that where such diagnostic product is an Adimab diagnostic product, Novartis may research, develop, manufacture or commercialize such Adimab diagnostic product solely for the purpose of research, development or commercialization of a therapeutic or prophylactic licensed product that specifically binds to the same licensed target.

Termination

Unless terminated earlier, the Novartis Agreement will continue in effect until neither we nor Novartis is researching, developing, manufacturing or commercializing any antibody candidate that binds to CD73. Novartis may terminate the Novartis Agreement for any reason upon prior notice to us within a specified time period. Either party may terminate the Novartis Agreement if an undisputed material breach is not cured within a certain period of time or upon notice of insolvency of the other party. To the extent Novartis terminates for convenience, or we terminate for Novartis' material breach, Novartis will grant us, on mutually agreeable financial terms, an exclusive, worldwide, irrevocable, perpetual and royalty-bearing license with respect to intellectual property controlled by Novartis that is reasonably necessary to research, develop, manufacture or commercialize NZV930.

License Agreement with GSK

Overview

In December 2020, we entered into the GSK Agreement, under which we granted GSK a worldwide, exclusive, sublicensable license to develop and commercialize specified antibodies targeting CD112R, also known as PVRIG, or the Licensed Antibodies. GSK will be responsible for the development, manufacturing and commercialization of the Licensed Antibodies and joint development and joint patent committees will be formed to facilitate information sharing between us and GSK. Under the terms of the GSK Agreement, GSK is obligated to use commercially reasonable efforts to develop and commercialize the Licensed Antibodies. Under the terms of the agreement, GSK made a one-time upfront payment of $85.0 million and is required to make additional payments to us for supply services and transition services initially estimated to be $4.3 million and $1.0 million, respectively. We are eligible to receive up to $90.0 million in clinical and $155.0 million in regulatory milestones. In addition, we may receive up to $485.0 million in sales milestone payments. We are also eligible to receive royalties on global net sales of any approved products based on the licensed antibodies, ranging in percentages from high single digits to mid-teens.

In November 2021, GSK received clearance from the FDA for GSK4381562 to proceed into a first-in-human clinical trial and as a result our performance obligations under the GSK Agreement have ended. Through December 31, 2021, we have received $85.0 million from GSK in upfront payments and $4.5 million for the transition and supply services performed.

Development, Manufacturing and Commercialization of Licensed Antibodies

GSK has the sole right to develop, manufacturer and commercialize the Licensed Antibodies and corresponding licensed products worldwide. GSK is obligated to use commercially reasonable efforts to develop the Licensed Antibodies and corresponding licensed products. GSK is responsible for all costs and expenses of such development, manufacturing and commercialization and is obligated to provide the Company with updates on its development, manufacturing and commercialization activities through the joint development committee.

Exclusivity

During the term of the GSK Agreement, neither the Company, nor any affiliates, will research, develop, manufacture, or commercialize any alternative product.

Termination

Unless terminated earlier, the GSK Agreement expires on a licensed product-by-licensed product and country-by-country basis on the later of ten years from the date of first commercial sale or when there is no longer a valid patent claim or regulatory exclusivity covering such licensed product in such country. Either party may terminate the GSK Agreement for an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party. GSK may terminate the GSK Agreement for its convenience. The Company may terminate the GSK Agreement if GSK institutes certain actions related to the licensed patents or if GSK ceases development activities, other than for certain specified technical or safety reasons. In the event of termination, the Company would regain worldwide rights to the terminated program.

Other Collaborations and License Agreements

Memorial Sloan Kettering Cancer Center License Agreement

In November 2020, we entered into a license agreement, or the MSK Agreement, with Memorial Sloan Kettering Cancer Center, or MSK. Under the agreement, MSK granted us a non-exclusive license to certain U.S. patent rights relating to methods of treating cancer with CCR8 antibodies to research, develop, make, use, sell, offer for sale, and import CCR8 antibodies intended to treat cancer. The upfront license execution fee due to MSK was $0.1 million. As of December 31, 2020, we paid half of the upfront license execution fee, with the remaining portion due on the first anniversary. Under the MSK Agreement, each of these CCR8 antibodies is a licensed product and we are obligated to make milestone payments of up to an aggregate of $7.5 million for each licensed product, as well as reimburse MSK for a portion of past and future patent-related expenses. For any licensed product that is commercialized, we are obligated to pay MSK a low single-digit percentage royalty on net U.S. sales of such product.

The MSK License will remain in effect on a licensed product-by-licensed product basis until the later of when there is no longer a valid patent claim covering the composition, manufacture or use of such licensed product or ten years from the date of first commercial sale of such licensed product in the U.S. We may terminate the MSK License for any reason with thirty days prior written notice to MSK. MSK may terminate the MSK License immediately upon written notice if we are convicted of a felony relating to the manufacture, use or sale of a licensed product anywhere we may manufacture, use or sell the licensed product, or, with a specified notice period, in the event of our insolvency, bankruptcy, or cessation of business operations. MSK may also terminate the MSK License for nonpayment of any fees, milestones or royalties if such payment(s) remain past due for a specified period of time, and for an uncured material breach.

Vaccinex Exclusive Product License Agreement

In March 2021, we and Vaccinex, Inc., or Vaccinex, entered into an exclusive product license agreement, or the Vaccinex License Agreement, to exclusively license certain antibodies, including SRF114. Pursuant to the terms of the Vaccinex License Agreement, we have a worldwide, exclusive, sublicensable license to make, have made, use, sell, offer to sell, have sold, import, and otherwise exploit licensed products that incorporate certain Vaccinex intellectual property which covers certain antibodies, including the antibody SRF114 targeting CCR8, each a “Licensed Product.”

Under the Vaccinex License Agreement, we are obligated to use commercially reasonable efforts to develop, clinically test, achieve regulatory approval, manufacture, market and commercialize at least one Licensed Product and have the sole right to develop, manufacture and commercialize the licensed products worldwide. We are responsible for all costs and expenses of such development, manufacturing and commercialization. Pursuant to the Vaccinex License Agreement, we paid Vaccinex a one-time fee of $0.9 million. Vaccinex is eligible to receive up to an aggregate of $3.5 million based on achievement of certain clinical milestones and up to an aggregate of $11.5 million based on achievement of certain regulatory milestones per Licensed Product. We also owe low single digit royalties on global net sales of any approved licensed products. Commencing on the third anniversary of the date of the Vaccinex License Agreement and continuing until the first dosing of a Licensed Product in a clinical trial, we will be required to pay Vaccinex a nominal yearly maintenance fee.

We may terminate the Vaccinex License Agreement for convenience upon the notice period specified in the Vaccinex License Agreement. Either party may terminate the agreement for an uncured material breach by the other party. Vaccinex may terminate the Vaccinex License Agreement if we default on any payments owed to Vaccinex under the agreement, if we are in material breach of, and fail to cure, our development obligations, or institute certain actions related to the licensed patents. In the event of termination, all rights in the licensed intellectual property would revert to Vaccinex.

Adimab Development and Option Agreement

In October 2018, we and Adimab LLC, or Adimab, entered into an amended and restated development and option agreement, or the A&R Adimab Agreement, which amended and restated the development and option agreement with Adimab dated July 2014, as amended, or the Original Adimab Agreement, for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the A&R Adimab Agreement, we will select biological targets against which Adimab will use its proprietary platform technology to research and develop antibody proteins using a mutually agreed upon research plan. The A&R Adimab Agreement, among other things, extended the discovery term of the Original Adimab Agreement, provided access to additional antibodies, and expanded our right to evaluate and use antibodies that were modified or derived using Adimab technology for diagnostic purposes.

Upon our selection of a target, we and Adimab will initiate a research plan and the discovery term begins. During the discovery term, Adimab will grant us a non-exclusive, non-sublicensable license under its technology with respect to the target, to research, design and preclinically develop and use antibodies that were modified or derived using Adimab technology, solely to evaluate such antibodies, perform our responsibilities under the research plan, and use such antibodies for certain diagnostic purposes. We also will grant to Adimab a non-exclusive, nontransferable license with respect to the target under our technology that covers or relates to such target, solely to perform its responsibilities under the research plan during the discovery period. We are required to pay Adimab at an agreed upon rate for its full-time employees during the discovery period while Adimab performs research on each target under the applicable research plan.

Adimab granted us an exclusive option to obtain a non-exclusive, worldwide, fully paid-up, sublicensable license under Adimab's platform patents and other Adimab technology solely to research up to ten antibodies, chosen by us against a specific biological target for a specified period of time, or the Research Option. In addition, Adimab granted us an exclusive option to obtain a worldwide, royalty-bearing, sublicensable license under Adimab platform patents and other Adimab technology to exploit, including commercially, 20 or more antibodies against specific biological targets, or the Commercialization Option. Upon the exercise of a Commercialization Option, and payment of the applicable option fee to Adimab, Adimab will assign us the patents that cover the antibodies selected by such Commercialization Option. We will be required to use commercially reasonable efforts to develop, seek market approval of, and commercialize at least one antibody against the target covered by the Commercialization Option in specified markets upon the exercise of a Commercialization Option.

We are obligated to make milestone payments and specified fees upon the exercise of the Research or Commercialization Options. During the discovery term, we may be obligated to pay Adimab up to $250,000 for technical milestones achieved against each biological target. Upon exercise of a Research Option, we are obligated to pay a nominal research maintenance fee on each of the next four anniversaries of the exercise. Upon the exercise of each Commercialization Option, we will be required to pay an option exercise fee of a low seven-digit dollar amount, and we may be responsible for milestone payments of up to an aggregate of $13.0 million for each licensed product that receives marketing approval. For any licensed product that is commercialized, we are obligated to pay Adimab tiered royalties of a low to mid single-digit percentage on worldwide net sales of such product. We may also partially exercise a Commercialization Option with respect to ten antibodies against a biological target by paying 65% of the option fee and later either (i) paying the balance and choosing additional antibodies for commercialization, up to the maximum number under the Commercialization Option, or (ii) forgoing the Commercialization Option entirely. For any Adimab diagnostic product that is used with or in connection with any compound or product other than a licensed antibody or licensed product, we are obligated to pay Adimab up to a low seven digits in regulatory milestone payments and low single-digit royalties on net sales. No additional payment is due with respect to any companion diagnostic or any diagnostic product that does not contain any licensed antibody. Any payments payable to Adimab as a result of any product candidates being developed pursuant to the GSK Agreement, will be payable to Adimab directly by GSK.

The A&R Adimab Agreement will remain in effect until the later of (a) the earlier of (i) the expiration of the Research and Commercialization Options (if they expire without exercise) and (ii) 12 months from the effective date without us providing materials that pass Adimab's quality control; or (b) if a Research Option is exercised but the Commercialization Option is not, then upon the expiration of the last to expire research license term; or (c) upon commercialization of a product, until the end of the royalty term, which will vary on a product-by-product and country-by-country basis, ending on the later of (y) the expiration of the last valid claim covering the product in such country as the product is manufactured or sold or (z) ten years after the first commercial sale of the product in such country.

Either party may terminate the A&R Adimab Agreement for material breach if such breach remains uncured for a specified period of time, however, if a Research Option or Commercialization Option has been exercised and the breach only applies to the applicable target of such Research Option or Commercialization Option, then the termination right will only apply to such target. We may also terminate the A&R Adimab Agreement for any reason with prior notice to Adimab. If Adimab is bankrupt, we will be entitled to a complete duplicate of, or complete access to, all rights and licenses granted under or pursuant to the A&R Adimab Agreement.

Manufacturing

We rely on and will continue to rely on our contract manufacturing organizations, or CMOs, for both drug substance and drug product. While we do not plan to develop our own full-scale manufacturing capabilities, we may consider establishing a small, flexible facility for supporting preclinical IND-enabling studies and early clinical studies. Currently, all of our manufacturing is outsourced to well-established third-party manufacturers. We have entered into contracts with CMOs for SRF617, SRF388, and SRF114 related to production of drug substance and drug product for our clinical trials and plan to enter into additional contracts with these or other manufacturers for additional supply.

Our outsourced approach to manufacturing relies on CMOs to first develop cell lines and manufacturing processes that are compliant with current Good Manufacturing Practice, or cGMP, then produce material for preclinical and clinical studies. Our agreements with CMOs may obligate them to develop a production cell line, establish master and working cell banks, develop and qualify upstream and downstream processes, develop drug product process, validate (and in some cases develop) suitable analytical methods for test and release as well as stability testing, produce drug substance for preclinical testing, produce cGMP-compliant drug substance, or produce cGMP-compliant drug product. We conduct audits of CMOs prior to initiation of activities under these agreements and monitor operations to ensure compliance with the mutually agreed process descriptions and to cGMP regulations.

Competition

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

Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products and the ease of use and effectiveness of any complementary diagnostics and/or companion diagnostics. Our competitors fall primarily into the following groups of treatment:

- Programs in development targeting the adenosine axis, including those by AbbVie, Arcus Biosciences, Inc., AstraZeneca PLC, Bristol-Myers Squibb Company, Corvus Pharmaceuticals, Inc., Gilead, Innate Pharma, S.A., iTeos, Palobiofarma SL, Trishula Therapeutics (formerly known as Tizona), and TRACON Pharmaceuticals, Inc.
- Programs in development targeting CCR8, including those by Bristol-Myers Squibb Company, Gilead/Jounce, Shionogi and Five Prime/Amgen;
- Traditional cancer therapies, including chemotherapy, targeted therapies; and
- Approved immunotherapy antibodies such as those targeting CTLA-4 (Yervoy, marketed by Bristol-Myers Squibb Company) and PD-1/PD-L1 (Opdivo, Keytruda and Tecentriq, marketed by Bristol-Myers Squibb Company, Merck & Co. and Genentech, Inc., respectively).

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

Many of the companies against which we may compete 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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Intellectual Property

Our patents and patent applications are directed to our antibodies and accompanying technologies. We seek patent protection for our development programs, product candidates and related alternatives by filing and prosecuting patent applications in the U.S. and other countries as appropriate.

As of February 28, 2022, we co-own and have exclusively licensed to Novartis our rights in two patent families that cover compositions of matter and methods of use for our CD73 therapeutic antibody candidate, NZV930. The first patent family includes two expired U.S. provisional patent applications, one pending U.S. non-provisional patent application, one expired international Patent Cooperation Treaty ("PCT") patent application, and forty-eight (48) ex-US applications. The second patent family includes two expired U.S. provisional patent applications, one pending U.S. non-provisional patent application and one expired PCT patent application. Any patents issuing from the first and second patent families would be expected to expire in 2038 or 2039, respectively, absent any applicable patent term adjustment or extension.

As of February 28, 2022, we solely own three patent families related to compositions of matter and methods of use for our CD39 therapeutic antibody candidates, including SRF617, and co-own one patent family related to methods of treating cancer with SRF617. The first solely owned patent family includes two issued U.S. patents, U.S. 10,738,128 and U.S. 10,793,637, two pending U.S. non-provisional patent applications, one expired PCT patent application and twenty-one (21) pending ex-U.S. applications, each claiming priority to two expired U.S. provisional patent applications. The second solely owned patent family includes a pending U.S. non-provisional patent application, a pending PCT patent application and nine ex-US applications with additional national phase filings in progress, each claiming priority to seven expired U.S. provisional patent applications. Any patents issuing from these applications would be expected to expire in 2039 and 2040, absent any applicable patent term adjustment or extension. The third solely owned patent family includes three pending U.S. provisional patent applications and the co-owned patent family includes two pending U.S. provisional patent applications. Any patents issuing from these applications would be expected to expire in 2042, absent any applicable patent term adjustment or extension.

With respect to our IL-27 therapeutic antibody program, as of February 28, 2022, we own four patent families related to compositions of matter and methods of use for various antibodies, including SRF388. The first patent family includes one pending U.S. non-provisional patent application, one expired PCT patent application and thirteen (13) pending ex-U.S. applications, each claiming priority to one expired U.S. provisional patent application. The second patent family includes one pending U.S. non-provisional patent application, one expired PCT patent application and fourteen (14) pending ex-U.S. applications, each claiming priority to one expired U.S. provisional patent application. The third patent family includes one pending U.S. non-provisional patent application, two pending ex-U.S. patent applications and a pending PCT patent application, each claiming priority to two expired U.S. provisional patent applications. Any patents issuing from these applications would be expected to expire in 2039 and 2040, absent any applicable patent term adjustment or extension. The fourth patent family includes three pending U.S. provisional patent applications; any patents issuing from these applications would be expected to expire in 2042, absent any applicable patent term adjustment or extension.

As of February 28, 2022, we own and have exclusively licensed to GSK our rights in two patent families that cover compositions of matter and methods of use for our CD112R therapeutic antibody candidates, including GSK4381562. The first patent family includes one allowed U.S. patent application, two pending U.S. non-provisional patent applications, one expired PCT patent application, and twenty-six (26) ex-U.S. applications, each claiming priority to two expired U.S. provisional patent applications. The second family includes a pending PCT patent application claiming priority to an expired U.S. provisional patent application. Any patents issuing from these applications would be expected to expire in 2039 and 2040, absent any applicable patent term adjustment or extension.

As of February 28, 2022, we have exclusively licensed from Vaccinex rights to a patent family that covers compositions of matter and methods of use for our CCR8 therapeutic antibody candidates, including SRF114. This patent family includes one pending U.S. non-provisional patent application, two pending ex-U.S. patent applications and a pending PCT patent application, each claiming priority to three expired U.S. provisional patent applications. Any patents issuing from these applications would be expected to expire in 2041, absent any applicable patent term adjustment or extension.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, including any product candidates we develop. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or PHSA, and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

All product candidates we develop must be approved by the FDA through either a New Drug Application, or NDA, or Biologics License Application, or BLA, process before they may be legally marketed in the United States. The process generally involves the following:

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Approval by an Institutional Review Board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- Submission to the FDA of an NDA or BLA;
- Payment of user fees for FDA review of an NDA or BLA;
- A determination by the FDA within 60 days of its receipt of an NDA or BLA to accept the filing for review;
- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic's identity, strength, quality and purity;
- Potential FDA audit of the clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug or biologic in the United States.

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

Preclinical Studies and IND

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

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

Clinical Trials

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

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.
- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

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

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

NDA/BLA and FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity and potency for a biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA or BLA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2022, the user fee for an application requiring clinical data, such as an NDA or BLA, is $3,117,218. The sponsor of an approved NDA or BLA is also subject to an annual prescription drug program fee, which for fiscal year 2022 is $369,413. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months, from the filing date, in which to complete its initial review of a new molecular-entity NDA or original BLA and respond to the applicant, and six months from the filing date of a new molecular-entity NDA or original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it consider such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan Drug Designation

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

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

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

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biologic designated for priority review in an effort to facilitate the review.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify and describe the product's clinical benefit. If the FDA concludes that a drug or biologic being considered for accelerated approval that is shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. All promotional materials for product candidates approved under accelerated approval are subject to prior review by the FDA unless the FDA informs the applicant otherwise.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program.

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

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, as amended, an NDA or BLA or supplement to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The FDCA requires that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Unless otherwise required by regulation, PREA does not apply to a drug or biologic for an indication for which orphan designation has been granted, except that PREA will apply to an original NDA or BLA for a new active ingredient that is orphan-designated if the drug or biologic is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

Post-Marketing Requirements

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

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Manufacturers and other parties involved in the drug supply chain for prescription drugs and biologics must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stole and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including recall.

Companion Diagnostics and Complementary Diagnostics

We believe that the success of any product candidates we develop will depend, in part, on the development and commercialization of either a companion diagnostic or complementary diagnostic. Companion diagnostics and complementary diagnostics can identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics and complementary diagnostics are regulated as medical devices by the FDA and, as such, require either clearance or approval prior to commercialization. The level of risk combined with available controls to mitigate risk determines whether a companion diagnostic device requires Premarket Approval Application, or PMA, approval or is cleared through the 510(k) premarket notification process. For a novel therapeutic product for which a companion diagnostic device is essential for the safe and effective use of the product, the companion diagnostic device should be developed and approved or 510(k)-cleared contemporaneously with the therapeutic. The use of the companion diagnostic device will be stipulated in the labeling of the therapeutic product. This is also true for a complementary diagnostic, although it is not a prerequisite for receiving the therapeutic.

Other Healthcare Laws and Compliance Requirements

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In addition, transparency laws and patient privacy regulations by federal and state governments and by governments in foreign jurisdictions can apply to the manufacturing, sales, promotion and other activities of pharmaceutical manufactures. The applicable federal, state and foreign healthcare laws and regulations that can affect a pharmaceutical company’s operations include:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement, including providing inaccurate billing or coding information to customers or promoting a product off-label, material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- The federal legislation commonly referred to as the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, or ACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain nonphysician providers such as physician assistants and nurse practitioners;
- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

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

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

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the Affordable Care Act, or the ACA, was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; 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 established the Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

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

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the temporary suspension, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022.
- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates would have been be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021 CMS rescinded the Most Favored Nations rule. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of any product candidates we develop, some of our U.S. patents may be eligible for limited patent term extension, or PTE, under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The PTE period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, as part of the ACA. This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial.

European Union Drug Development

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

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the European Union, or EU, Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical.

European Union Drug Review and Approval

In the European Economic Area, or EEA, which is comprised of the 27 Member States of the European Union (including Norway but excluding Croatia), Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States, referred to as the Member States Concerned, for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

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

European Union New Chemical Entity Exclusivity

In the European Union, new chemical entities, sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator’s data to assess a generic application for eight years, after which generic marketing authorization can be submitted, and the innovator’s data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies.

European Union Orphan Designation and Exclusivity

In the European Union, the EMA’s Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the European Union community (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected).

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

European Union Supplementary Protection Certificate

Similar to PTE in the United States, depending upon the timing, duration and specifics of EMA approval of any product candidates we develop, certain issued patents may be eligible for limited patent term extension on a country-by-country basis in the UK and all member states of the European Economic Area (comprising the EU member states, plus Norway, Iceland and Liechtenstein), in accordance with the Council Regulation (EC) No 469/2009 concerning the creation of a supplementary protection certificate (SPC) for medicinal products as codified, or the SPC Regulation. The SPC Regulation permits restoration of the patent term of up to five years as compensation for patent term lost due to the compulsory lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval. The scope of the SPC extends only to the product covered by the applicable EEA marketing EMA authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate. SPC terms cannot be greater than 5 years, and cannot extend the remaining term of a patent beyond a total of 15 years from the product’s approval date (subject to a possible six month extension under the EU Paediatric Regulation). The SPC period is calculated based on the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the period elapsed between patent filing and grant of the first marketing authorization to place the product on the market in the EEA, reduced by a period of five years. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted within six months of either the grant of the marketing authorization in any EEA member state or, if later, the grant of the patent.

Rest of the World Regulation

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

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

Coverage and Reimbursement

Sales of our products, when and if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States, no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products and/or biosimilars for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. This decrease in reimbursement has been challenged in the U.S. District Court for the District of Columbia, and was appealed to the U.S. Court of Appeals. On July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court); the court denied this Petition on October 16, 2020. On Friday July 2, 2021, the Supreme Court granted the petition. It is unclear how the invalidation of the formula could affect pharmaceutical manufacturers and hospitals who prescribe their products.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

Any of these laws, and future state and federal healthcare reform measures may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and reimbursement. Obtaining coverage and reimbursement for newly approved drugs is a time-consuming and costly process, and coverage may be more limited than the purposes for which a drug is approved by the FDA or comparable foreign regulatory authorities. Assuming coverage is obtained for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use products unless coverage is provided, and reimbursement is adequate to cover all or a significant portion of the cost of prescribed products.

An increasing emphasis on cost containment measures in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Human Capital Management

Employees

As of February 28, 2022, we had 67 employees, all full-time, including 45 employees engaged in research and development. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

Compensation and Benefits

Attracting and retaining high-performing talent, while providing meaningful growth and development opportunities to Surface's employees is critical to the Company's mission of delivering transformative outcomes for people with cancer. Surface leverages numerous resources to identify and enhance leadership capability and foster an energetic and highly collaborative culture that emphasizes collective learning. Surface is focused on pay equity and regularly monitors our compensation practices among similar roles and responsibilities throughout our organization. In addition to offering a comprehensive suite of benefits ranging from medical and dental coverage to retirement, disability and life insurance programs, Surface also provides and promotes health and wellness programs, as well as employee assistance programs. Surface continuously cultivates and enhances its culture and embraces equality, diversity and inclusion as fundamental to its mission.

Equity, Equality, Diversity & Inclusion (EED&I)

At the foundation of achieving its mission, is the ability for Surface to foster an inclusive and diverse workforce. Surface defines key focus areas and objectives and includes implementation plans related to equity, equality, diversity and inclusion. Surface’s leadership, including its board of directors, is committed to ensuring that equity, equality, diversity and inclusion remain essential to the core values of the Company. As of December 31, 2021, women represented 61% of Surface employees and 50% of leadership positions. Additionally, 22% of Surface’s workforce was comprised of members who are racially or ethnically diverse. Surface’s equity, equality, diversity and inclusion principles are reflected in our employee training and policies.

COVID-19 Health and Safety

Surface prioritized the health and safety of its employees during the COVID-19 pandemic by implementing temporary office and facility closures; establishing new safety and cleaning protocols and procedures; providing regular communication regarding the effect of the pandemic on Surface's operations and employees; establishing physical distancing procedures, modification of workspaces and provision of personal protective equipment and cleaning supplies for employees; and providing remote working accommodations and related services to support employees' needs for flexibility.

Corporate Information

We were incorporated in Delaware in April 2014. The Company's website address is www.surfaceoncology.com. The Company's annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge through the Financial Information – SEC Filings section of its website, as soon as reasonably practicable after the reports are electronically filed or furnished with the SEC. The SEC maintains a file that contains these reports as well as proxy statements and other information regarding issuers that file electronically. The SEC's website is www.sec.gov. The Company's website and its contents are not deemed incorporated by reference into this report.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Results of Operations and Financial Condition," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related To Our Financial Position And Need For Additional Capital

We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

We have incurred significant net losses since inception,. Our net losses were $78.5 million and $54.8 million for the years ended December 31, 2021 and 2019, respectively. We earned net income of $59.3 million for the year ended December 31, 2020, primarily as a result of revenue recognized under the GSK Agreement. As of December 31, 2021 we had an accumulated deficit of $140.7 million. We have funded our operations to date primarily with proceeds from public and private sales of our securities, payments received under our collaboration agreement with Novartis, upfront fees received in connection with our license agreement with GSK, and a debt financing. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring and discovering development programs, securing related intellectual property rights and conducting discovery, research and development activities for our programs. We have not yet demonstrated our ability to successfully complete any clinical trials, including pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. We expect that it will be several years, if ever, before we have a commercialized product. We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if, and as, we:

- pursue the clinical development of product candidates;
- leverage our programs to advance product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly; and

- acquire or in-license other product candidates and technologies.

To become and remain profitable, we, Novartis, GSK, or any potential future collaborator must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our development programs. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate future revenue from product sales depends heavily on our, Novartis', GSK's or any potential future collaborators' success in:

- completing clinical and preclinical development of product candidates and programs and identifying and developing new product candidates;
- seeking and obtaining marketing approvals for any product candidates that we develop;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving adequate coverage and reimbursement by hospitals, government and third-party payors for product candidates that we develop;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for product candidates that we develop, if approved;
- obtaining market acceptance of product candidates that we develop as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference or infringement claims, if any; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies to perform clinical trials or studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will require substantial additional financing, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs. If we are able to gain marketing approval for product candidates that we develop, including SRF617, SRF388 and SRF114, we will require significant additional amounts of cash in order to launch and commercialize such product candidates to the extent that such launch and commercialization are not the responsibility of Novartis, GSK or another collaborator that we may contract with in the future. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates and programs, and of conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for our current product candidates and any future product candidates we develop if clinical trials are successful;
- the success of our collaborations with Novartis and GSK;
- the cost of commercialization activities for our current product candidates and any product candidates we develop, whether alone or with a collaborator, if any product candidate we develop is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our current product candidates for clinical trials in preparation for marketing approval and in preparation for commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any;
- the emergence of competing cancer therapies and other adverse market developments; and
- the requirement for, and cost of, developing complementary diagnostics and/or companion diagnostics.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Based on our research and development plans, we expect that the net proceeds from our initial public offering and the concurrent private placement, together with our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the second half of 2023, excluding any future milestone payments from Novartis or GSK.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain additional funding on favorable terms when needed, we may have to delay, reduce the scope of or suspend one or more of our research and development programs or clinical trials.

Our Loan and Security Agreement, as amended, contains restrictive and financial covenants that may limit our operating flexibility.

Our Loan and Security Agreement, as amended, or the Loan Amendment, with K2 HealthVentures LLC, or K2 Health Ventures, contains certain restrictive covenants that either limit our ability to, or require a mandatory prepayment in the event that, we engage in new lines of business, incur additional indebtedness or liens, make certain investments, make certain payments, pay cash dividends, merge with other companies or consummate certain changes of control, acquire other companies, transfer or dispose of certain assets, liquidate or dissolve, amend certain material agreements, enter into various other specified transactions, executive office or executive management without notice. We, therefore, may not be able to engage in any of the foregoing transactions unless we obtain the consent of K2 Health Ventures or prepay the outstanding amount under the Loan Amendment. Our obligations under the Loan Amendment are secured by all of our property, with certain exceptions. We may not be able to generate sufficient cash flow to pay the principal and interest under the Loan Amendment.

Risks Related To Product Development And Regulatory Process

If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts. Three of our product candidates, SRF617, SRF388, and NZV930 (formerly SRF373), are being investigated in ongoing Phase 1 clinical trials. The rest of our product candidates are all in preclinical development. We have invested substantially all of our efforts and financial resources into our clinical studies as well as the identification of targets and preclinical development of antibodies.

Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales. The success of our current and future product candidates will depend on several factors, including the following:

- successful completion of clinical trials and preclinical studies;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of INDs for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of regulatory and marketing approvals from applicable regulatory authorities;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;
- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- successfully launching commercial sales of our product candidates, if and when approved;
- acceptance of the product candidate’s benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of the product candidates following approval;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- enforcing and defending intellectual property rights and claims.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for any of our product candidates that we develop, we may not be able to continue our operations.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain FDA approval to market a new biological product we must demonstrate proof of safety, purity and potency or efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the preclinical testing and studies of programs that are the responsibility of Novartis, GSK or our potential future partners over which we have no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design; and
- the FDA not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, even if clinical trials do begin for our preclinical programs, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety, purity and potency or efficacy to obtain the requisite regulatory approvals for any of product candidates we develop. Even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

The regulatory approval processes of the FDA, the EMA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

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

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that a product candidate is safe, pure and potent or effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application, or BLA, to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA, the EMA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations and prospects. The FDA, the EMA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Further, we have not previously submitted a BLA to the FDA, or a Marketing Authorization Application, or MAA, to the EMA. We cannot be certain that any of our programs will be successful in clinical trials or receive regulatory approval. Further, product candidates we develop may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Clinical product development involves a lengthy and expensive process, with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current and future product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe, pure and potent or effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators or Institutional Review Boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs;
- the number of patients required for clinical trials may be larger than we anticipate;
- it may be difficult to enroll a sufficient number of patients with a predictive biomarker or enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators; and
- the supply or quality of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted or ethics committees, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates being stopped early.

The results of early-stage clinical trials and preclinical studies may not be predictive of future results. Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

We expect that we will need to develop, or enter into a collaboration or partnership to develop complementary diagnostics and/or companion diagnostics for our current or future product candidates. If we, or our future collaborators, are unable to successfully develop such companion diagnostics or complementary diagnostics, or experience significant delays in doing so, we may not realize the full commercial potential of our future product candidates.

As one of the key elements of our product development strategy, we seek to identify cancer patient populations who may derive meaningful benefit from our current or future product candidates. Because predictive biomarkers may be used to identify the right patients for our programs and our current or future product candidates, we believe that our success may depend, in part, on our ability to develop complementary diagnostics and/or companion diagnostics in collaboration with partners.

We have little experience in the development of diagnostics and, as such, we expect to rely on future collaborators in developing appropriate diagnostics to pair with our current or future product candidates. We have not yet begun discussions with any potential partners with respect to the development of complementary diagnostics and/or companion diagnostics and may be unsuccessful in entering into collaborations for the development of companion diagnostics for our programs and our current or future product candidates.

Complementary diagnostics and/or companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval or clearance prior to commercialization. If we, our collaborators, or any third parties that we engage to assist us, are unable to successfully develop complementary diagnostics and/or companion diagnostics for our product candidates and any future product candidates, or experience delays in doing so:

- the development of our product candidates and any other future product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials; and
- we may not realize the full commercial potential of our product candidates and any other future product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify, or it takes us longer to identify, patients who are likely to benefit from therapy with our products, if approved.

If any of these events were to occur, our business would be harmed, possibly materially.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- our ability to enroll a sufficient number of patients with a predictive biomarker, if any;
- the size of the patient population required for analysis of the trial’s primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians’ and patients’ perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents for participation in our clinical trials and, where appropriate, biopsies for future patient enrichment efforts;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they are late-stage cancer patients, will not survive the full terms of the clinical trials; and
- factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g., additional outbreaks of COVID-19 or its variants).

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current and potential future product candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such sites. Moreover, because our current and potential future product candidates may represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in our ongoing or any future clinical trial. We may also engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, furthering the difficulty in identifying patients with the targeted genetic mutations for our clinical trials. We may also engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, furthering the difficulty in identifying patients with the targeted genetic mutations for our clinical trials.

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

Our current or future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could halt their clinical development, prevent their marketing approval, limit their commercial potential or result in significant negative consequences.

Undesirable or clinically unmanageable side effects could occur and cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. For example, in December 2018, we announced the deprioritization of SRF231 as a result of toxicities seen during the dose escalation portion of the then-ongoing Phase 1 trial. We concluded the Phase 1 trial in 2021 and have ceased development of SRF231.

If unacceptable toxicities or other undesirable side effects arise in the development of any of our current or future product candidates, we or our collaborators could suspend or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of the product candidate for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Although our current and future product candidates have undergone and will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Immunotherapy, and its method of action of harnessing the body's immune system, is powerful and could lead to serious side effects that we only discover in clinical trials. Unforeseen side effects could arise either during clinical development or, if such side effects are rarer, after our products have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. So far, we have not demonstrated that any of our product candidates are safe in humans, and we cannot predict if ongoing or future clinical trials will do so. If any of our current or future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain marketing approval, we will not be able to generate revenue and our business will be harmed.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any of our existing or future collaboration partners from obtaining approvals for the commercialization of any product candidate we develop.

Any current or future product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biologic product candidate's safety, purity, efficacy and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any current or future product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not mean that we will be successful in obtaining marketing approval of our current and future product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Adverse events in the field of immuno-oncology could damage public perception of our current or future product candidates and negatively affect our business.

The commercial success of our products will depend in part on public acceptance of the use of cancer immunotherapies. While a number of cancer immunotherapies have received regulatory approval and are being commercialized, our approach to targeting different components of the tumor microenvironment is novel and unproven. Adverse events in clinical trials our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for any product that we may develop. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our products may not be accepted by the general public or the medical community.

Future adverse events in immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for the product candidates we develop.

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

Any marketing approvals that we receive for any current or future product candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval of any product candidate, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import and export and record keeping for the product candidate will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practice, or cGMP, and Good Clinical Practice, or GCP, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with any approved candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. 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.

Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. See the section entitled "*Business — Government Regulation — Coverage and Reimbursement*". The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- adoption of a companion diagnostic and/or complementary diagnostic; and
- the prevalence and severity of any side effects.

The market opportunities for any current or future product candidate we develop, if and when approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect to initially seek approval of any product candidates we develop as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that product candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

We expect to develop our product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop our product candidates in combination with one or more currently approved cancer therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market any product candidate we develop.

We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive. We are currently developing therapeutics that will compete, if approved, with other products and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other products and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval or discovering, developing and commercializing products in our field before we do.

There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. These treatments consist both of large and small molecule drug products. 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 effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain FDA, EMA or other marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidate we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness.

Smaller and other early-stage companies may also prove to be significant competitors. These third parties 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. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our product candidates obsolete, less competitive or not economical.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. 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 candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. See the section entitled “*Business — Government Regulation — Coverage and Reimbursement*”.

Our ability to commercialize any product candidates, whether as a single agent or combination therapy, successfully also will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. 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 programs.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, the level of reimbursement. These third-party payors are also examining the cost-effectiveness of drugs in addition to their safety and efficacy.

Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, as the process is time-consuming and costly, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Additionally, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States, which may result in coverage and reimbursement for drug products that can differ significantly from payor to payor. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may 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. For example, on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. FDA also issued a Final Guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. Since the issuance of final rule, on November 23, 2020, several industry groups filed federal lawsuits in the U.S. District Court for the District of Columbia, requesting injunctive relief to prevent certification from the Secretary of HHS from taking effect and challenging multiple aspects of the final rule. This litigation has not progressed. The regulatory and market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation, regulations or policies allowing the reimportation of drugs could decrease the price we receive for our products and adversely affect our future revenues and prospects for profitability. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

We may not be successful in our efforts to identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

The success of our business depends upon our ability to identify, develop and commercialize product candidates. If we do not successfully develop and eventually commercialize products, we will face difficulty in obtaining product revenue in future periods, resulting in significant harm to our financial position and adversely affecting our share price. Research programs to identify new product candidates require substantial technical, financial and human resources, and we may fail to identify potential product candidates for numerous reasons.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. For example, in December 2018, we announced a significant reduction of the investment in our SRF231 program and later terminated its development. Based on the reallocation of capital, we prioritized SRF617 and SRF388. However, the advancement of SRF617 and SRF388 may ultimately prove to be unsuccessful or less successful than another program in our pipeline that we might have chosen to accelerate with our capital resources. Our estimates regarding the potential market for our product candidates could be inaccurate, and our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. For example, we licensed worldwide development and commercialization rights with respect to NZV930 and GSK4381562 to Novartis and GSK, respectively, and we will receive only milestone payments and royalties on sales of NZV930 and GSK4381562, if approved. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may seek Breakthrough Therapy Designation by the FDA for a product candidate that we develop, and we may be unsuccessful. If we are successful, the designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Breakthrough Therapy Designation for any product candidate that we develop. A breakthrough therapy is defined as a drug 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 currently approved 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 accelerated approval and priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop 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 Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if the product candidates we develop qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification and rescind the designation.

We have received Fast Track Designation from the FDA for SRF388 for the treatment of hepatocellular carcinoma. We may in the future seek Fast Track Designation for other product candidates that we develop, and we may be unsuccessful. Fast Track Designation may not actually lead to a faster development or regulatory review or approval process.

We have received Fast Track Designation from the FDA for SRF388 for the treatment of hepatocellular carcinoma, and we may seek Fast Track Designation for the product candidates we develop. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. We may not experience a faster development process, review or approval compared to conventional FDA procedures for SRF388 or any other product candidates that receive Fast Track Designation. Furthermore, the FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

We have received orphan drug designation from the FDA for SRF388 for the treatment of hepatocellular carcinoma and for SRF617 for the treatment of pancreatic cancer. We may in the future seek orphan drug designation for other product candidates we develop, and we may be unsuccessful. We may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

We have received orphan drug designation from the FDA for SRF388 for the treatment of hepatocellular carcinoma and for SRF617 for the treatment of pancreatic cancer. We may seek orphan drug designation for certain of our other product candidates we develop. However, we may be unsuccessful in obtaining orphan drug designation for certain of our other product candidates and may be unable to maintain the benefits associated with orphan drug designation. Regulatory authorities in some jurisdictions, including the United States and Europe, 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 a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. 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.

Similarly, in the EU, the European Commission grants orphan designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan designation application. Orphan designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the EU and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in its development. In the EU, orphan designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

The exclusivity provided by orphan drug designation may not effectively protect our product candidates from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. 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. While we may seek additional orphan drug designations for applicable indications for our current and any future product candidates, we may never receive such designations. There is no guarantee that we will enjoy the benefits of orphan drug designation for SRF388, SRF617 or any other product candidate for which we may receive orphan drug designation. Additionally, the FDA may reevaluate its regulations and policies under the Orphan Drug Act. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, or business could be adversely impacted.

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

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

- decreased demand for any approved product;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate;
- a decline in our share price; and
- a default under the Loan Amendment.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators.

Insurance coverage is increasingly expensive. We may not be able to maintain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with Novartis or any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

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 Affordable Care Act, or the ACA, was passed, 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, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D. See the section entitled “*Business — Government Regulation — Healthcare Reform*”.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. It is unclear what effect such changes will have on our business and our ability to receive adequate reimbursement for our future products. Some of these proposed measures, including drug importation and pharmacy benefit manager rebate rule changes, face legal challenges from industry groups and participants. We cannot predict whether additional reform initiatives will be adopted in the future or whether initiatives that have been adopted will be repealed or modified, or whether legal challenges will be successful. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- and the level of taxes that we are required to pay.

We expect that changes and challenges to the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for any future approved product.

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

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, 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 Trade 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 negative 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 plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and 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.

We may fail to comply with evolving European and other privacy laws.

In the event we conduct clinical trials in the European Economic Area, or EEA, we may be subject to additional privacy laws. The General Data Protection Regulation, (EU) 2016/679, or GDPR, became effective on May 25, 2018, and deals with the processing of personal data and on the free movement of such data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so we do not expect to operate in a uniform legal landscape in the EU. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty.

In addition, further to the UK's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU's GDPR, the European Commission, or the EC, has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. The UK is not subject to the EC's new standard contractual clauses but has published a draft version of a UK-specific transfer mechanism, which, once finalized, will enable transfers from the UK. We will be required to implement these new safeguards when conducting restricted data transfers under the EU and UK GDPR and doing so will require significant effort and cost.

In addition, many jurisdictions outside of Europe are also considering and/or enacting comprehensive data protection legislation. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

Risks Related To Reliance On Third Parties

We are fully dependent on our collaboration with Novartis for the development of NZV930 and GSK for the development of GSK4381562, and may depend on additional third parties for the development and commercialization of our other programs and future product candidates. Our current and future collaborators may control aspects of our clinical trials, which could result in delays or other obstacles in the commercialization of the product candidates we develop. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

In January 2016, we entered into a strategic collaboration agreement with Novartis, or the Novartis Agreement, to develop next generation cancer therapies. Pursuant to the Novartis Agreement, we granted Novartis a worldwide exclusive license to research, develop, manufacture and commercialize antibodies that target CD73. Similarly, in December 2020, we entered into a license agreement with GSK, the GSK Agreement, pursuant to which we granted GSK a worldwide, exclusive, sublicensable license to develop and commercialize specified antibodies, including GSK4381562. Each of the Novartis Agreement and GSK Agreement involves a complex allocation of rights, provides for milestone payments to us based on the achievement of specified clinical development, regulatory and commercial milestones, and provides us with royalty-based sales revenue. Our lack of control over the clinical development of certain programs with current and future collaborators could result in delays or other difficulties in the development and commercialization of product candidates, which may prevent completion of intended IND filings in a timely fashion, if at all. In particular, Novartis and GSK are solely responsible for the development and commercialization of NZV930 and GSK4381562, respectively, and as such, we are wholly dependent on each of Novartis and GSK for the success of these programs. In the event Novartis terminates the Novartis Agreement, or GSK terminates the GSK Agreement, we would be prevented from receiving any milestone payments, royalty payments and other benefits under that agreement, which would have a materially adverse effect on our results of operations. We cannot provide any assurance with respect to the success of any current or future collaboration or license agreement.

In the future, we may form or seek other strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop.

Our current collaboration and license agreements pose, and potential future collaborations involving our product candidates may pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates. For example, under the Novartis Agreement, for a certain period of time we may not directly or indirectly research or develop, outside of the collaboration, any antibody with specified activity against that program’s collaboration target.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition, and results of operations.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with additional pharmaceutical and biotechnology companies with respect to development and potential commercialization. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. For example, under the Novartis Agreement and the GSK Agreement, we have granted worldwide exclusive rights to Novartis for antibodies targeting CD73 and worldwide exclusive rights to GSK for antibodies targeting PVRIG, respectively, and during the term of the agreements we will be restricted from granting similar rights to other parties. This exclusivity could limit our ability to enter into strategic collaborations with future collaborators.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Novartis, GSK or future collaborators or strategic partners, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our product candidates. Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

We rely on third parties, and will continue to rely on third parties, to conduct our ongoing and planned clinical trials for the product candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize any product candidates we develop and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates. We rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs and other third parties will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and the third parties on which we rely for clinical trials are required to comply with regulations and requirements, including GCP, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or these third parties fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations. Our failure or the failure of these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial’s protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our product candidates, third parties will conduct all of the clinical trials. As a result, many important aspects of our clinical development, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed;
- form relationships with other entities, some of which may be our competitors; or
- experience difficulties or delays from factors we may not be able to control, such as current or potential pandemics that may affect patient recruitment and follow-up or staff or clinic site availability and initiation (e.g., outbreak of COVID-19).

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the third parties do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our product candidates may be delayed, we may not be able to obtain marketing approval and commercialize our product candidates, or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by these third parties, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures. It is possible that our development plans will have to be slowed down or stopped completely at times due to our inability to obtain required raw materials, components, and outsourced processes at an acceptable cost, if at all, or to get a timely response from vendors, particularly as a result of recent labor market and global supply chain constraints.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We rely on third parties to manufacture product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of the product candidates that we are developing or evaluating in our development programs. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We rely on third parties for supply of our product candidates, and our strategy is to outsource all manufacturing of our product candidates and products to third parties.

In order to conduct clinical trials of product candidates, we will need to have them manufactured in potentially large quantities. Our third-party manufacturers (or contract manufacturers, or CMOs) may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. Any inability to manufacture our product candidates or future approved drugs in sufficient quantities when needed would seriously harm our business. For example, recent global supply chain constraints have led to a risk of shortages in lab supplies. If there is a shortage of lab supplies which are critical for our clinical programs, there can be no assurance that we would be able to find alternative suppliers for certain critical materials.

In addition, quality issues may arise during scale-up activities and at any other time. For example, ongoing data on the stability of our product candidates may shorten the expiry of our product candidates and lead to clinical trial material supply shortages, and potentially clinical trial delays. If these third-party manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

Our use of new third-party manufacturers increases the risk of delays in production or insufficient supplies of our product candidates as we transfer our manufacturing technology to these manufacturers and as they gain experience manufacturing our product candidates. Changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating comparability of clinical supplies which could require the conduct of additional clinical trials.

Even after a third-party manufacturer has gained significant experience in manufacturing our product candidates or even if we believe we have succeeded in optimizing the manufacturing process, there can be no assurance that such manufacturer will produce sufficient quantities of our product candidates in a timely manner or continuously over time, or at all.

We may be delayed if we need to change the manufacturing process used by a third party. Further, if we change an approved manufacturing process, then we may be delayed if the FDA or a comparable foreign authority needs to review the new manufacturing process before it may be used. Additionally, we will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates.

We do not currently have any agreements with third-party manufacturers for long-term commercial supply. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of any product candidate that we develop, or may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- 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; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP requirements or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and potentially cause delays to our ongoing clinical trials.

Our future product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP requirements particularly for the development of monoclonal antibodies, and that might be capable of manufacturing for us.

If the third parties that we engage to supply any materials or manufacture product for our preclinical tests and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our third-party manufacturers and clinical reagent suppliers may be subject to damage or interruption from, among other things, fire, natural or man-made disaster, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy and similar events. For example, in December 2019, a novel strain of coronavirus that causes a respiratory disease named coronavirus disease 2019 (COVID-19) was reported to have surfaced in Wuhan, China. We are monitoring the situation closely and our response to the COVID-19 pandemic continues to evolve, including the recent labor market and global supply chain constraints. The extent to which the novel coronavirus may impact our third-party manufacturers and suppliers going forward will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

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

Our future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. See the section entitled "*Business — Government Regulation — Other Healthcare Laws and Compliance Requirements*".

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies, including pharmaceutical manufacturers and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our business arrangements with third parties comply with applicable healthcare laws, as well as responding to investigations by government authorities, can be time- and resource-consuming and can divert management's attention from the business.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could harm our ability to operate our business and our financial results. Further, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. In addition, the approval and commercialization of any product candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

A variety of risks associated with operating internationally could materially adversely affect our business.

We currently have limited international operations, but we rely on and will continue to rely on our CMOs, some of which operate internationally, for both drug substance and drug product, and our business strategy incorporates potentially expanding internationally if any of our product candidates receive regulatory approval. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease (e.g., the novel COVID-19 pandemic), boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions, or its anti-bribery provisions, or other anti-bribery and anti-corruption laws.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

Risks Related To Intellectual Property

Intellectual property is critical to our business and our success in part depends on our ability to maintain, protect, and expand our portfolio of intellectual property rights.

Biotechnology and pharmaceutical companies generally, and we in particular, compete in a crowded competitive space characterized by rapidly evolving technologies and aggressive defense of intellectual property.

Our patents and patent applications are directed to our antibodies and accompanying technologies. We seek patent protection for our development programs, product candidates and related alternatives by filing and prosecuting patent applications in the U.S. and other countries as appropriate.

As of February 28, 2022, we co-own and have exclusively licensed to Novartis our rights in two patent families that cover compositions of matter and methods of use for our CD73 therapeutic antibody candidate, NZV930. The first patent family includes two expired U.S. provisional patent applications, one pending U.S. non-provisional patent application, one expired international Patent Cooperation Treaty ("PCT") patent application, and forty-eight (48) ex-US applications. The second patent family includes two expired U.S. provisional patent applications, one pending U.S. non-provisional patent application and one expired PCT patent application. Any patents issuing from the first and second patent families would be expected to expire in 2038 or 2039, respectively, absent any applicable patent term adjustment or extension.

As of February 28, 2022, we solely own three patent families related to compositions of matter and methods of use for our CD39 therapeutic antibody candidates, including SRF617, and co-own one patent family related to methods of treating cancer with SRF617. The first solely owned patent family includes two issued U.S. patents, U.S. 10,738,128 and U.S. 10,793,637, two pending U.S. non-provisional patent applications, one expired PCT patent application and twenty-one (21) pending ex-U.S. applications, each claiming priority to two expired U.S. provisional patent applications. The second solely owned patent family includes a pending U.S. non-provisional patent application, a pending PCT patent application and nine ex-US applications with additional national phase filings in progress, each claiming priority to seven expired U.S. provisional patent applications. Any patents issuing from these applications would be expected to expire in 2039 and 2040, absent any applicable patent term adjustment or extension. The third solely owned patent family includes three pending U.S. provisional patent applications and the co-owned patent family includes two pending U.S. provisional patent applications. Any patents issuing from these applications would be expected to expire in 2042, absent any applicable patent term adjustment or extension.

With respect to our IL-27 therapeutic antibody program, as of February 28, 2022, we own four patent families related to compositions of matter and methods of use for various antibodies, including SRF388. The first patent family includes one pending U.S. non-provisional patent application, one expired PCT patent application and thirteen (13) pending ex-U.S. applications, each claiming priority to one expired U.S. provisional patent application. The second patent family includes one pending U.S. non-provisional patent application, one expired PCT patent application and fourteen (14) pending ex-U.S. applications, each claiming priority to one expired U.S. provisional patent application. The third patent family includes one pending U.S. non-provisional patent application, two pending ex-U.S. patent applications and a pending PCT patent application, each claiming priority to two expired U.S. provisional patent applications. Any patents issuing from these applications would be expected to expire in 2039 and 2040, absent any applicable patent term adjustment or extension. The fourth patent family includes three pending U.S. provisional patent applications; any patents issuing from these applications would be expected to expire in 2042, absent any applicable patent term adjustment or extension.

As of February 28, 2022, we own and have exclusively licensed to GSK our rights in two patent families that cover compositions of matter and methods of use for our CD112R therapeutic antibody candidates, including GSK4381562. The first patent family includes one allowed U.S. patent application, two pending U.S. non-provisional patent applications, one expired PCT patent application, and twenty-six (26) ex-U.S. applications, each claiming priority to two expired U.S. provisional patent applications. The second family includes a pending PCT patent application claiming priority to an expired U.S. provisional patent application. Any patents issuing from these applications would be expected to expire in 2039 and 2040, absent any applicable patent term adjustment or extension.

As of February 28, 2022, we have exclusively licensed from Vaccinex, Inc. rights to a patent family that covers compositions of matter and methods of use for our CCR8 therapeutic antibody candidates, including SRF114. This patent family includes one pending U.S. non-provisional patent application, two pending ex-U.S. patent applications and a pending PCT patent application, each claiming priority to three expired U.S. provisional patent applications. Any patents issuing from these applications would be expected to expire in 2041, absent any applicable patent term adjustment or extension.

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

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our antibodies and the accompanying technologies we develop that are important to our business. If we are unable to secure or maintain patent protection with respect to our antibody technology and any proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. No consistent policy governing the scope of claims allowable in the field of antibodies has emerged in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

The patent prosecution process is complex, expensive, time-consuming, and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, corporate collaborators, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly 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 their earliest priority date, or in some cases not at all. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications.

The issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even where patent applications we currently own or that we may license in the future issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors or other third parties from competing with us, or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade our patent rights by developing new antibodies, biosimilar antibodies, or alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant and inter partes review, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the United States Patent and Trademark Office, or USPTO, or other foreign patent office. An unfavorable 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 extinguish our ability to manufacture or commercialize products without infringing third-party patent rights.

In addition, 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. 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 owned and in-licensed patents and patent applications are, and 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 or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

The intellectual property landscape around therapeutic antibodies in oncology is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. We are aware of certain third-party patents and third-party patent applications in this landscape that may, if issued as patents, be asserted to encompass current product candidates.

The field of therapeutic antibodies, including CD39, CCR8 and CD112R antibodies for use in oncology, is crowded, and no such products have reached the market. Due to the intense research and development undertaken by academic institutions and multiple companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain for the coming years. There may be significant intellectual property-related litigation and proceedings relating to our own and other third-party intellectual property and proprietary rights in the future.

In the future, we may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any product candidates we may develop, including interference proceedings, post-grant review, inter-partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office, or EPO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit.

We are aware of certain third-party patents and third-party patent applications in this landscape that may, if issued as patents, be asserted to encompass our current or future product candidates. For example, we are aware of third-party European patents and pending third-party European patent applications relating to CD39, CCR8 and CD112R antibody technology that, without invalidation of (in the case of an issued patent), a change in claim scope, or a license, could materially impair our ability to commercialize our product candidates.

In order to avoid infringing third-party patents, or patents that issue from these third-party patent applications, we may find it necessary or prudent to obtain licenses from such third-party intellectual property holders. We may be forced to obtain or maintain a license on commercially unreasonable terms to any third-party patents that cover our product candidates or activities, and such third parties could potentially assert infringement claims against us, which could have a material adverse effect on the conduct of our business.

If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing any product candidates we may develop and our technology. 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 a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. 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 a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

Our development and commercialization rights to our therapeutic antibodies, current and future product candidates and technology are subject, in part, to the terms and conditions of licenses granted to us by others.

We are reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the engineering and development of our therapeutic antibodies, and our current and future product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we choose to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

We engage in collaborations with scientists at academic and non-profit institutions to access technologies and materials that are not otherwise available to us. The agreements that govern these collaborations may include an option to negotiate an exclusive license to the institution's rights in any inventions that are created in the course of these collaborations, but we may not be able to come to a final agreement with an institution holding rights in an invention that is relevant to the development and commercialization of our technology.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. Additionally, we may be required to reimburse our licensors for all of their expenses related to the prosecution, maintenance, enforcement and defense of patents and patent applications that we in-license from them.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

Competitors may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. In addition, our patents or the patents of our licensing partners also are, and may become, involved in inventorship, priority, or validity disputes. To counter or defend against such claims can be expensive and time-consuming, and our licensors' adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. In an infringement proceeding, a court may decide that a patent owned or in-licensed by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. Accordingly, despite our or our licensors' efforts, we or our licensors may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own or control. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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 develop biosimilar or competing antibodies to any product candidates that we have or may develop, but that are not covered by the claims of the patents that we own or may own or license in the future.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors 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 any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees 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. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and 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. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we do not obtain patent term extension and data exclusivity for any of our current or future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, our intellectual property license agreements may not always include worldwide rights. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, 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. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is 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.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, 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, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may not be successful in obtaining necessary rights to our current and future product candidates through acquisitions and in-licenses.

We currently have rights to intellectual property, through licenses from third parties, to identify and develop product candidates. Many pharmaceutical companies, biotechnology companies, and academic institutions are competing with us in the field of therapeutic antibodies and filing patent applications potentially relevant to our business. For example, we are aware of third-party patents and patent applications that may be construed to cover uses of our CCR8 antibody product candidates.

In order to avoid infringing these third-party patents, or patents that issue from these third-party patent applications, we may find it necessary or prudent to obtain licenses from such third-party intellectual property holders. In addition, with respect to any patents we co-own with third parties, we may require licenses to such co-owners’ interest to such patents. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for product candidates we may develop. The licensing or acquisition of third-party intellectual property rights is a competitive area, and other companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all.

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

The U.S. government may exercise its march-in rights with regards to certain in-licensed patents.

Pursuant to the Bayh-Dole Act, the U.S. government has march-in rights with regards to government-funded technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail 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 inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations, and prospects.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements 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 both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Risks Related To Employee Matters, Managing Our Growth And Other Risks Related To Our Business

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are “at-will” employees. We currently do not have “key person” insurance on any of our employees. The loss of the services of one or more of our current employees might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of February 28, 2022, we had 67 employees, all full-time, including 45 employees engaged in research and development. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for any product candidate we develop, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

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

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of marketing approval, clinical management, and manufacturing. We cannot assure you that the services of independent 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 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 any current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our current product candidates and any future product candidates we develop and, accordingly, may not achieve our research, development and commercialization goals.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive 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. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, 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.

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

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not to our knowledge experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future product candidates could be delayed.

Our employees, independent contractors, vendors, principal investigators, CROs and consultants 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 that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and comparable foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or 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, but it is not always possible to identify and deter misconduct by employees and other third parties, 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. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Legal, political and economic uncertainty surrounding the planned exit of the United Kingdom from the European Union may be a source of instability in international markets, create significant currency fluctuations and pose additional risks to our business, revenue, financial condition, and results of operations.

On June 23, 2016, the United Kingdom, or UK, held a referendum in which a majority of the eligible members of the electorate voted for the UK to leave the European Union, or EU. The UK's withdrawal from the EU is commonly referred to as Brexit. Pursuant to Article 50 of the Treaty on European Union, the UK ceased being a member state of the EU on January 31, 2020. There was a transition period during which EU pharmaceutical laws continued to apply to the UK, which expired on December 31, 2020. However, the EU and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently broadly aligns with EU regulations, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. It remains to be seen how Brexit will impact regulatory requirements for medicinal products and devices in the UK in the long-term. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations may negatively impact foreign direct investment in the UK, increase costs, depress economic activity, and restrict access to capital. The uncertainty concerning the UK's legal, political and economic relationship with the EU after Brexit may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise) beyond the date of Brexit.

If other EU Member States pursue withdrawal, barrier-free access between the UK and other EU Member States or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on how the TCA, and any future agreements signed by the UK and the EU, take effect in practice.

Such a withdrawal from the EU is unprecedented, and it is unclear how the restrictions on the UK's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities (including, without limitation, clinical activities for our product candidates) in the long-term.

As a result of Brexit, the EMA, formerly situated in London, relocated to Amsterdam. Great Britain is also no longer covered by the centralized procedure for obtaining EEA-wide marketing authorization from the EMA, and a separate process for authorization of drug products, including our product candidates, will be required in Great Britain resulting in an authorization covering the UK or Great Britain only. For a period of two years from January 1, 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure in order to more quickly grant a UK marketing authorization. A separate application will, however, still be required. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK or the EU and limit our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. The UK will lose the benefits of global trade agreements negotiated by the EU on behalf of its members, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. Even prior to any change to the UK's relationship with the EU, the announcement of Brexit has created economic uncertainty surrounding the terms of Brexit and its consequences could adversely impact customer confidence resulting in customers reducing their spending budgets on our solutions, which could adversely affect our business, revenue, financial condition, results of operations and could adversely affect the market price of our common shares.

Risks Related To Our Business and Common Stock

The price of our common stock may be volatile and fluctuate substantially.

The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials and preclinical studies or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license product candidates or companion diagnostics;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

An active trading market for our common stock may not be sustainable, and you may not be able to resell your shares at or above the purchase price.

An active trading market for our shares may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

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

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

Our executive officers, directors and their affiliates continue to exercise significant influence over our company, which limits your ability to influence corporate matters and could delay or prevent a change in corporate control.

Our executive officers, directors and their affiliates beneficially own, in the aggregate, approximately 7% of our outstanding common stock. As a result, these stockholders, if they act together, are able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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

As a public company, and particularly after we are no longer an emerging growth company, as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global 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. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We are currently evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or SOX Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the Securities and Exchange Commission, or the SEC. 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. To achieve compliance with SOX 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. 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 SOX 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.

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock, and impair our ability to raise adequate capital through the sale of additional equity securities.

If securities analysts publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware or the United States District Court for the District of Massachusetts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us or any of our current or former directors, officers, employees or stockholders arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated bylaws further provide that the United States District Court for the District of Massachusetts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. We have chosen the United States District Court for the District of Massachusetts as the exclusive forum for such causes of action because our principal executive offices are located in Cambridge, Massachusetts. We recognize that the federal district court forum selection clause may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general additional litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the Commonwealth of Massachusetts. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Alternatively, if the federal district court forum selection provision is found inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have an adverse effect on our business, financial condition or results of operations. The United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. On December 19, 2018, the Court of Chancery of the State of Delaware issued a decision declaring that such federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are ineffective and invalid under Delaware law. On January 17, 2019, the decision was appealed to the Delaware Supreme Court. While the Delaware Supreme Court recently dismissed the appeal on jurisdictional grounds, we expect that the appeal will be re-filed after the Court of Chancery issues a final judgment. Unless and until the Court of Chancery's decision is reversed by the Delaware Supreme Court or otherwise abrogated, we do not intend to enforce our federal forum selection provision designating the District of Massachusetts as the exclusive forum for Securities Act claims. In the event that the Delaware Supreme Court affirms the Court of Chancery's decision or otherwise determines that federal forum selection provisions are invalid, the Company's Board of Directors intends to amend promptly our amended and restated bylaws to remove our federal forum selection bylaw provision. As a result of the Court of Chancery's decision or a decision by the Supreme Court of Delaware affirming the Court of Chancery's decision, we may incur additional costs associated with our federal forum selection bylaw provision, which could have an adverse effect on our business, financial condition or results of operations.

Our business may be adversely affected by the ongoing COVID-19 pandemic.

Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business activities and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. COVID-19 has spread rapidly throughout many countries, and, on March 11, 2020, the World Health Organization characterized COVID-19 as a global pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, Canada and China, have imposed unprecedented restrictions on travel, and there have been business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19.

As a result of the ongoing coronavirus pandemic, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- We believe that the COVID-19 pandemic could have an impact on various aspects of our clinical trials, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. For example, with respect to our immuno-oncology clinical trials, investigators may not want to take the risk of exposing cancer patients to COVID-19 since the dosing of patients is conducted within an in-patient setting. Other potential impacts of the COVID-19 pandemic on our various clinical trials include patient dosing and study monitoring, which may be paused or delayed due to changes in policies at various clinical sites, federal, state, local or foreign laws, rules and regulations, including quarantines or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trials, interruption or delays in the operations of the FDA or other reasons related to the COVID-19 pandemic. If the COVID-19 pandemic continues, other aspects of our clinical trials may be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, availability of clinical trial materials, and data analysis. Some patients and clinical investigators may not be able to comply with clinical trial protocols and patients may choose to withdraw from our studies or we may have to pause enrollment or we may choose to, or be required to, pause enrollment and/or patient dosing in our ongoing clinical trials in order to preserve health resources and protect trial participants. Additionally, healthcare resources could potentially be diverted away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials. It is unknown how long these pauses or disruptions could continue.
- We currently rely on third parties to, among other things, manufacture raw materials, manufacture our product candidates for our clinical trials, ship investigational product and clinical trial samples, perform quality testing and supply other goods and services to run our business. Three vaccines for COVID-19 have been granted Emergency Use Authorization by the FDA, and two of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the product candidates needed for our clinical trials. If any such third-party in our supply chain for materials are adversely impacted by restrictions resulting from the COVID-19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and conduct our research and development operations.
- We have closed our offices and requested that most of our personnel, including all of our administrative employees, work remotely, restricted on-site staff to only those personnel and contractors who must perform essential activities that must be completed on-site and limited the number of staff in any given research and development laboratory. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors.
- Our employees and contractors conducting research and development activities may not be able to access our laboratory for an extended period of time as a result of the closure of our offices and the possibility that governmental authorities further modify current restrictions. As a result, this could delay timely completion of preclinical activities, including completing Investigational New Drug-enabling studies or our ability to select future development candidates, and initiation of additional clinical trials for other of our development programs.

- Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced and review, inspection, and other timelines may be materially delayed. As of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee goals. On July 16, 2020, the FDA stated that it is continuing to expedite oncology product development with its staff teleworking full-time. However, the FDA may not be able to continue its current pace and approval timelines could be extended. It is unknown how long these disruptions could continue, were they to occur. Since March 2020, when foreign and domestic inspections of facilities by FDA have largely been on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Any delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. For example, regulatory authorities may require that we not distribute a product candidate lot until the relevant agency authorizes its release. Such release authorization may be delayed as a result of the COVID-19 pandemic and could result in delays to our clinical trials. Additionally, there may be 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, or to discontinue such clinical trials altogether.
- The trading prices for our common shares and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common shares or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common shares.

The COVID-19 pandemic continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the identification of the virus, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and the actions taken to contain coronavirus or address its impact in the short and long term, among others. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy. We will continue to monitor the situation closely.

General Risk Factors

Our ability to utilize our net operating loss carryforwards and certain other tax attributes has been limited by "ownership changes" and may be further limited.

We have incurred substantial losses during our history. As of December 31, 2021, we had federal and state net operating loss carryforwards of $92.7 million and $156.0 million, respectively. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire (other than federal and certain state net operating loss carryforwards generated in taxable years beginning after December 31, 2017, which are not subject to expiration). Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage points change (by value) in its equity ownership over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have in the past experienced, and we may in the future experience ownership changes, some of which are outside our control. Use of our federal and state net operating loss carryforwards has been limited and could be further limited if we experience additional ownership changes, which could have an adverse effect on our future results of operations.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ended December 31, 2019. When we lose our status as an "emerging growth company," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth 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 not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering in April 2018, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. 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 stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

Changes in tax law may adversely affect us or our investors.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. We urge investors to consult with their legal and tax advisers regarding the potential implications of changes in tax law on an investment in our common stock.

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These statements may be identified by such forward-looking terminology as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. Our forward-looking statements are based on a series of expectations, assumptions, estimates and projections about our company, are not guarantees of future results or performance and involve substantial risks and uncertainty. We may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Our business and our forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks and uncertainties inherent in our statements regarding:

- the timing, progress and results of preclinical studies and clinical trials for our current product candidates and other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the timing, scope or likelihood of regulatory filings and approvals, including timing of Investigational New Drug application and Biological Licensing Application filings for, and final U.S. Food and Drug Administration approval of our current product candidates and any other future product candidates;
- the timing, scope or likelihood of foreign regulatory filings and approvals;
- our ability to use our understanding of the tumor microenvironment to identify product candidates and to match immunotherapies to select patient subsets;
- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical studies;
- our ability to develop combination therapies, whether on our own or in collaboration with Novartis and other third parties;
- our manufacturing, commercialization and marketing capabilities and strategy;
- the pricing and reimbursement of our current product candidates and other product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of our current product candidates and other product candidates we may develop;
- the potential benefits of and our ability to maintain our collaboration with Novartis, and establish or maintain future collaborations or strategic relationships or obtain additional funding;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our current product candidates and other product candidates we may develop, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our competitive position, and developments and projections relating to our competitors and our industry;
- our expectations related to the use of our existing cash, cash equivalents and marketable securities and the proceeds from our initial public offering and the concurrent private placement;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- the impact of laws and regulations.

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We lease a facility containing our research and development, laboratory and office space, which consists of approximately 65,000 square feet located at 50 Hampshire Street, Cambridge, Massachusetts. We sublease 33,526 square feet of this facility to a third party pursuant to a sublease that expires in January 2023. Our lease expires on March 31, 2030. We believe that our facilities are adequate for our current needs and that suitable additional or substitute space would be available if needed.

Item 3. Legal Proceedings.

In October 2020, we filed an opposition in the European Patent Office, or EPO, opposing the grant of European Patent No. EP 3258951B1 to Compugen, Ltd., or the Compugen Patent. We are one of two parties opposing the grant of the Compugen Patent, which relates generally to PVRIG (an alternate name for CD112R) antibodies for use in treating cancer. In connection with the GSK Agreement, GSK has assumed responsibility for this opposition. The proprietor’s response to the statements of opposition was filed on March 22, 2021; the opponents are currently awaiting a summons to oral proceedings. Accordingly, final resolution of the opposition may be several years in the future.

In June 2021, we filed an opposition in the European Patent Office, or EPO, opposing the grant of European Patent No. EP 3153526B1 to INSERM (Institut National de la Santé et de la Recherche Médicale), or the INSERM Patent. We are one of four parties opposing the grant of the INSERM Patent, which relates generally to pharmaceutical compositions comprising anti-CD39 antibodies which inhibit activity of regulatory T cells (Treg) for use in the treatment or prevention of cancers. The proprietor’s response to the statements of opposition was filed on January 14, 2022; we are currently awaiting a summons to oral proceedings. Accordingly, final resolution of the opposition may be several years in the future.

From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

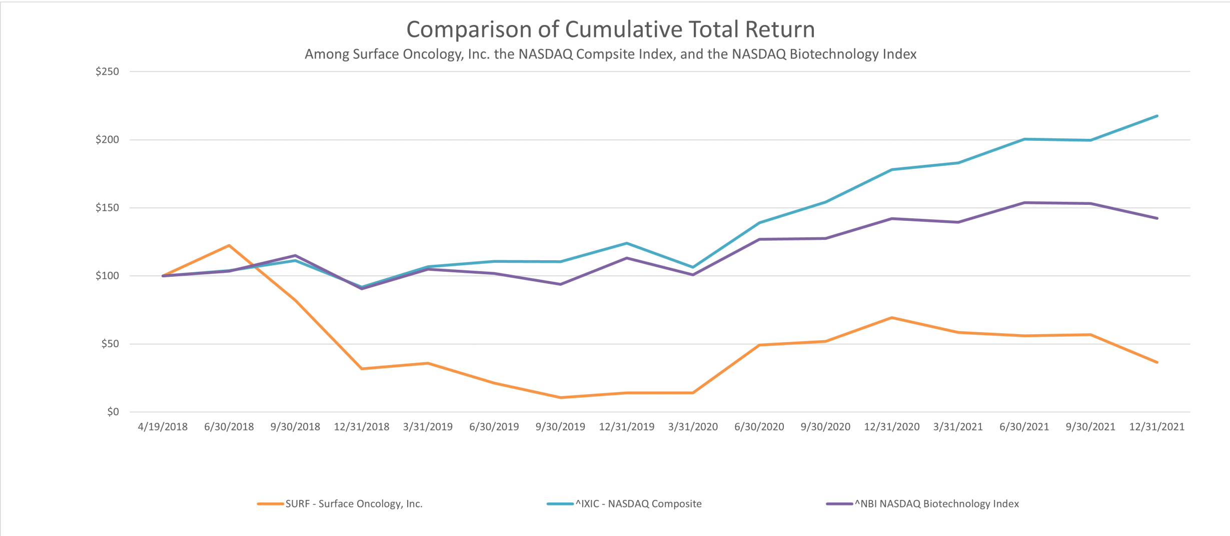
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been traded on The Nasdaq Global Market under the symbol “SURF” since April 19, 2018. Prior to this time, there was no public market for our common stock.

Stock Performance Graph

The graph set forth below compares the cumulative total stockholder return on our common stock between April 19, 2018 and December 31, 2021, with the cumulative total return of (a) the Nasdaq Composite Index and (b) the Nasdaq Biotechnology Index, over the same period. This graph assumes the investment of $100 on April 19, 2018 in our common stock, the Nasdaq Composite Index, and the Nasdaq Biotechnology Index and assumes the reinvestment of dividends, if any. The graph assumes our closing sales price on April 19, 2018 of $13.33 per share as the initial value of our common stock and not the initial offering price to the public of $15.00 per share.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.



Stockholders

As of February 28, 2022, there were approximately 9 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item relating to our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Unregistered Sales of Equity Securities

On February 3, 2021, K2 HealthVentures LLC elected to convert $1.5 million of our then outstanding term loan amount and all accrued and unpaid interest thereon into 961,538 shares of our common stock at a conversion price of $1.56 per share in accordance with our loan agreement with K2 HealthVentures LLC. The issuance of such shares of common stock was exempt from the registration requirements of the Securities Act, pursuant to Section 4(a)(2) of the Securities Act.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

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

Item 6. Reserved.

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

The following discussion and analysis of our financial condition and operating results should be read together with the section captioned "Selected Consolidated Financial Data" and our consolidated financial statements and the related notes included elsewhere in the Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section of the Annual Report on Form 10-K captioned "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a clinical-stage immuno-oncology company focused on using our specialized knowledge of the biological pathways critical to the immunosuppressive tumor microenvironment, or the TME, for the development of next-generation cancer therapies. While first-generation immuno-oncology therapies, such as checkpoint inhibitors, represented a remarkable therapeutic advancement, we believe most patients do not achieve durable clinical benefit primarily because these therapies focus on only one element of the complex and interconnected immunosuppressive TME. We believe there is a significant opportunity to more broadly engage both the innate and adaptive arms of the immune system in a multi-faceted, coordinated and patient-specific approach, to meaningfully improve cure rates for patients with a variety of cancers.

We were incorporated and commenced principal operations in 2014. We have devoted substantially all of our resources to developing our programs, including NZV930, SRF617, SRF388, GSK4381562, and SRF114, 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 with proceeds from public and private sales of our securities, payments received under our collaboration agreement with Novartis and license agreement with GSK and a debt financing. As of December 31, 2021, we had cash, cash equivalents and marketable securities of $154.1 million. Since our inception, we have incurred significant losses. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of the product candidates we develop. Our net loss was $78.5 million and $54.8 million for the years ended December 31, 2021 and 2019, respectively. Our net income was $59.3 million for the year ended December 31, 2020. As of December 31, 2021 and 2020 we had an accumulated deficit of $140.7 million and $62.3 million, respectively. We expect to continue to incur significant expenses and operating losses for at least the next several years, particularly as we:

- pursue the clinical development of product candidates;
- leverage our programs to advance product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control, and scientific personnel;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our clinical development, manufacturing, and commercialization efforts, and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio;
- establish a sales, marketing, medical affairs, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with a commercial partner; and
- acquire or in-license other product candidates and technologies.

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. We may be unable to raise additional funds or enter into other agreements or arrangements, when needed, on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates.

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.

We believe that our existing cash, cash equivalents and marketable securities, as of December 31, 2021 will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the second half of 2023, excluding any future milestone payments from Novartis or GSK. 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.

We are monitoring the ongoing global outbreak and spread of the novel coronavirus disease, or COVID-19, and have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address the COVID-19 pandemic. Although COVID-19 has not had a material adverse impact on our operations and our clinical and preclinical programs, the extent to which COVID-19 ultimately impacts the Company's business, results of operations or financial condition will depend on future developments which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken to contain the pandemic or mitigate its impact, among others. Given the fluidity of the COVID-19 pandemic, however, we do not yet know the full extent of the potential impact of COVID-19 on our business operations. We will continue to monitor the situation closely.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to do so in the near future. All of our revenue to date has been derived from our collaboration agreement with Novartis and our license agreement with GSK. If our development efforts for our programs are successful and result in regulatory approval or additional license or collaboration agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from additional collaboration or license agreements that we may enter into with third parties. We expect that our revenue for the next several years will be derived primarily from our collaboration agreement with Novartis and our license agreement with GSK, as well as any additional collaborations or licenses that we may enter into in the future.

Collaboration Agreement with Novartis

In January 2016, we entered into the Novartis Agreement to develop next-generation cancer therapies. Under the Novartis Agreement, as amended, we were responsible for performing research on antibodies that bind to CD73 and four other specified targets. We were responsible for all costs and expenses incurred by, or on behalf of, us in connection with the research.

Upon entering into the agreement, we received an upfront payment of $70.0 million from Novartis and granted Novartis a worldwide exclusive license to research, develop, manufacture and commercialize antibodies that target CD73. In addition, we initially granted Novartis the right to purchase exclusive option rights, each an Option, to up to four specified targets, including certain research, development, manufacturing and commercialization rights. Pursuant to the Novartis Agreement, Novartis initially had the right to exercise up to three purchased Options. In February 2019, Novartis notified us of its decision not to purchase its Option related to IL-27. In January 2020, Novartis did not purchase and exercise its single remaining Option under the Novartis Agreement and, as a result, the option purchase period expired. Accordingly, there are no Options remaining eligible for purchase and exercise by Novartis, and our performance obligations under the Novartis Agreement have ended. We are currently entitled to potential development milestones of $325.0 million and potential sales milestones of $200.0 million, as well as tiered royalties on annual net sales of NZV930 by Novartis ranging from high single-digit to mid-teens percentages. Such amount of potential milestone payments assumes the successful clinical development and achievement of all sales milestones for NZV930.

Under ASC 606 we accounted for (i) the license conveyed with respect to CD73 and (ii) our obligations to perform research on CD73 and other specified targets as a single performance obligation under the Novartis Agreement. We recognize revenue using the cost-to-cost method, which we believe best depicts the transfer of control to the customer. Under the cost-to-cost method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified performance obligation. Under this method, revenue is recorded as a percentage of the estimated transaction price based on the extent of progress towards completion.

Through December 31, 2021, we had received an aggregate of $150.0 million from Novartis in upfront payments, milestone payments, and option purchase payments. As of January 2020, we no longer had any performance obligations under the Novartis Agreement. We removed all costs associated with the remaining performance obligation for the single remaining Option from the cost-to-cost model in January 2020. This resulted in our recognizing the remaining deferred revenue of $38.6 million to collaboration revenue – related party in the first quarter of 2020. During the year ended December 31, 2021 we did not recognize any revenue related to the Novartis Agreement. During the years ended December 31, 2020, and 2019, we recognized revenue of $38.6 million and $15.4 million, respectively, related to the Novartis Agreement.

License Agreement with GSK

In December 2020, we entered into the GSK Agreement (as amended by the GSK Amendment (as defined below), under which we granted GSK a worldwide exclusive, sublicensable license to develop, manufacture and commercialize antibodies that target the antibody SRF813, targeting CD112R, also known as PVRIG, or the Licensed Antibodies. GSK will be responsible for the development, manufacturing and commercialization of the Licensed Antibodies and a joint development committee will be formed to facilitate information sharing between us and GSK. Under the terms of the GSK Agreement, GSK is obligated to use commercially reasonable efforts to develop and commercialize the Licensed Antibodies. In August 2021, we entered into the first amendment to the GSK License Agreement, or the GSK Amendment. Pursuant to the GSK Amendment, we provided additional transition and supply services related to the development and manufacturing of the Licensed Antibodies.

Under the terms of the agreement, GSK made a one-time upfront payment of $85.0 million and is required to make additional payments to us for supply services and transition services, initially estimated to be $4.3 million and $1.0 million, respectively. We are eligible to receive up to $90.0 million in clinical and $155.0 million in regulatory milestones. In addition, we may receive up to $485.0 million in sales milestone payments. We are also eligible to receive royalties on global net sales of any approved products based on the licensed antibodies, ranging in percentages from high single digits to mid-teens.

Under ASC 606 we account for (i) the delivery of the worldwide exclusive, sublicensable license to develop, manufacture and commercialize the Licensed Antibodies; (ii) supply of Licensed Antibodies until an investigational new drug application is accepted by a regulatory authority; and (iii) transition services until an investigational new drug application is accepted by a regulatory authority as separate and distinct performance obligations. We determined the transaction price under ASC 606 at the inception of the GSK Agreement to be $90.3 million, consisting of the upfront payment of $85.0 million plus $4.3 million for supply of the Licensed Antibodies and $1.0 million for the transition services. We recognized revenue for the license performance obligation at a point in time, that is upon transfer of the license to GSK. As control of the license was transferred on the effective date of December 16, 2020 and GSK could begin to use and benefit from the license, we recognized $85.0 million of license-related revenue during the year ended December 31, 2020 under the GSK Agreement. We recognized the portion of the transaction price allocated to supply services and transition services over time. We transfer control of these services over time and GSK receives and consumes the benefit over time as we perform the services. For the year ended December 31, 2021, we recognized $2.0 million of license-related revenue related to supply services and $0.7 million license-related revenue related to transition services. During the year ended December 31, 2020, we recognized $2.6 million of license-related revenue related to supply services and an immaterial amount of license-related revenue related to the transition services.

Through December 31, 2021, we have received $85.0 million from GSK in upfront payments and $4.5 million for the transition and supply services performed.

In November 2021, GSK received clearance from the FDA for GSK4381562 to proceed into a first-in-human clinical trial and as a result our performance obligations under the GSK Agreement have ended. No amount of the transaction price allocated to the performance obligations was partially unsatisfied, nor did we have a contract liability associated with the GSK Agreement as of December 31, 2021.

Operating Expenses

Research and Development Expenses

Research and development expenses are expensed as incurred and consist of costs incurred for our research activities, including our discovery efforts, and the development of our programs. These expenses include:

- salaries, benefits and other related costs, including stock-based compensation, for personnel engaged in research and development functions;
- expenses incurred in connection with the preclinical development of our programs and clinical trials of our product candidates, including under agreements with third parties, such as consultants, contractors, and contract research organizations, or CROs;
- the cost of manufacturing drug products for use in our preclinical studies and clinical trials, including under agreements with third parties, such as consultants, contractors, and contract manufacturing organizations, or CMOs;
- laboratory supplies;
- facilities, depreciation and other expenses, which include direct and allocated expenses for depreciation and amortization, rent and maintenance of facilities, insurance and supplies; and
- third-party license fees.

We do not track our internal research and development expenses on a program-by-program basis as they primarily relate to personnel, early research and consumable costs, which are deployed across multiple projects under development. These costs are included in unallocated research and development expenses in the table below. A portion of our research and development costs are external costs, which we do track on a program-by-program basis.

The following table summarizes our research and development expenses by program:

	Year ended December 31,		
	2021	2020	2021 vs 2020
	(in thousands)		
SRF388	13,834	5,350	8,484
SRF617	12,243	6,559	5,684
SRF114	4,241	328	3,913
GSK4381562 (formerly SRF813)	2,319	6,339	(4,020)
Other early-stage programs	507	950	(443)
Unallocated research and discovery expenses	20,428	21,492	(1,064)
Total research and development expenses	$ 53,572	$ 41,018	$ 12,554

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We anticipate that our research and development expenses will increase in the future as a result of increased clinical development costs as we advance our SRF388 and SRF617 clinical trials and progress our early-stage programs.

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of any of our product candidates that we develop from our programs. We are also unable to predict when, if ever, net cash inflows will commence from sales of product candidates we develop. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- successful completion of clinical trials and preclinical studies;
- sufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- acceptance of INDs for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of regulatory and marketing approvals from applicable regulatory authorities;

- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- successfully launching commercial sales of our product candidates, if and when approved;
- acceptance of our product candidates' benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of the product candidates following approval;
- effectively competing with other therapies; and
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors.

A change in the outcome of any of these variables with respect to the development of any of our programs or any product candidate we develop would significantly change the costs, timing, and viability associated with the development of such program or product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and personnel-related costs, including stock-based compensation, for our personnel in executive, legal, finance and accounting, human resources, and other administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees paid for accounting, auditing, consulting and tax services; insurance costs; travel expenses; and facility costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as a result of increased accounting, audit, legal, regulatory, compliance, and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Interest and Other Income (Expense), Net

Interest and other income consist primarily of interest earned on our cash, cash equivalents, and marketable securities as well interest paid on the Loan Agreement.

Income Taxes

During the years ended December 31, 2021 and 2019, we did not record any income tax benefits for the net losses incurred or for the research and development tax credits generated in each year, as we believed, based upon the weight of available evidence, that it was more likely than not that all of the net operating loss carryforwards and tax credits will not be realized. During the year ended December 31, 2020, we did not record any income tax expense or benefit for the net income incurred, or for the research and development tax credits generated during the year, due to the utilization of net operating loss carryforwards and the uncertainty of realizing a benefit from the credits.

Results of Operations

Comparison of Years Ended December 31, 2021, and 2020

The following table summarizes our results of operations for the years ended December 31, 2021, and 2020, along with the changes in those items:

	Year ended December 31, 2021	2020	2021 vs 2020
	(in thousands)		
Collaboration revenue - related party	$ —	$ 38,592	$ (38,592)
License-related revenue	2,687	87,570	(84,883)
Total revenue	2,687	126,162	(123,475)
Operating expenses:			
Research and development	53,572	41,018	12,554
General and administrative	25,128	23,558	1,570
Total operating expenses	78,700	64,576	14,124
Income (loss) from operations	(76,013)	61,586	(137,599)
Interest and other income (expense), net	(2,472)	(2,249)	(223)
Net income (loss)	$ (78,485)	$ 59,337	$ (137,822)

Collaboration Revenue – Related Party

We did not recognize any collaboration revenue - related party in the year ended December 31, 2021. Collaboration revenue – related party was $38.6 million for the year ended December 31, 2020, all of which was derived from the Novartis Agreement. The decrease in collaboration revenue - related party during the year ended December 31, 2021 was due to our performance obligations under the Collaboration Agreement ending in January 2020 and removing all future costs from the cost-to-cost model. This resulted in the recognition of the remaining deferred revenue of $38.6 million to collaboration revenue – related party in the first quarter of 2020.

License-Related Revenue

During the year ended December 31, 2021 and 2020, we recognized revenue of $2.7 million and $87.6 million, respectively, related to the GSK Agreement. The decrease in license-related revenue during the year ended December 31, 2021 was due to recognizing the $85.0 million upfront payment in December 2020 upon entering into the GSK Agreement.

Research and Development Expenses

	Year Ended December 31, 2021	2020	2021 vs 2020
		(in thousands)	
Direct research and development expenses by program:			
SRF388	13,834	5,350	8,484
SRF617	12,243	6,559	5,684
SRF114	4,241	328	3,913
GSK4381562 (formerly SRF813)	2,319	6,339	(4,020)
Other early-stage programs	507	950	(443)
Research and discovery and unallocated expenses:			
Personnel related (including stock-based compensation)	13,047	15,487	(2,440)
Facility related and other	7,381	6,005	1,376
Total research and development expenses	$ 53,572	$ 41,018	$ 12,554

Research and development expenses were $53.6 million for the year ended December 31, 2021, compared to $41.0 million for the year ended December 31, 2020. The increase of $12.6 million was primarily due to increases of $8.5 million in external costs for our SRF388 program, $5.7 million in external costs for our SRF617 program, $3.9 million in external costs for our SRF114 program, which were partially offset by a decrease of $4.0 million in external costs for the GSK4381562 program, a $0.4 million in external costs for our other early-stage programs, and $1.1 million for research and discovery and unallocated expenses.

The increase in research and development expenses for our SRF388 program was primarily due to continued enrollment in our Phase 1 dose escalation trial and advancement into the expansion stages of the ongoing trial in 2021.

The increase in research and development expenses for our SRF617 program was primarily due to continued enrollment in our Phase 1/1b dose escalation trial and advancement into combination cohorts of the ongoing trial in 2021.

The increase in research and development expenses for our SRF114 program was primarily due to the initiation of IND-enabling activities in 2021.

The decrease in research and development expenses for the GSK4381562 program was primarily due to the transfer of responsibility for development of this program to GSK as part of the GSK Agreement signed in December 2020.

The decrease in research and discovery and unallocated expenses was primarily due to the reduction in severance expense as a result of the strategic restructuring announced in January 2020.

General and Administrative Expenses

General and administrative expenses were $25.1 million for the year ended December 31, 2021, compared to $23.6 million for the year ended December 31, 2020. The increase of $1.6 million was primarily due to an increase of $0.8 million in personnel-related costs due to increased headcount in 2021, as well as increases in insurance.

Interest and Other Income (Expense), Net

Interest and other income (expense) was approximately $(2.5) million and $(2.2) million during the years ended December 31, 2021, and 2020, respectively, primarily due to interest expense related to our Loan Agreement with K2 HealthVentures LLC offset by interest income on invested balances of our cash, cash equivalents and marketable securities.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have generated limited revenue to date from our collaboration agreement with Novartis and license agreement with GSK. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. To date, we have financed our operations with proceeds from public and private sales of our securities, payments received under our collaboration agreement with Novartis and our license agreement with GSK, and a debt financing. Through December 31, 2021, we had received gross proceeds of $48.6 million from our sales of preferred stock, $108.0 million from sales of our common stock during our initial public offering, $11.5 million in a private placement, $60.1 million from sales of our common stock under the 2019, 2020, and 2021 ATM Facilities, $25.0 million from our loan and security agreement with K2 HealthVentures LLC, $150.0 million from the Novartis Agreement, and $89.5 million from the GSK Agreement.

In May 2019, we entered into a Capital on Demand™ Sales Agreement, or the 2019 Sales Agreement, with JonesTrading Institutional Services to issue and sell up to $30.0 million in shares of our common stock, from time to time. Through December 31, 2021, we sold 11,229,174 shares of common stock at-the-market under the 2019 ATM Facility for net proceeds of $29.1 million. As of May 2020, we had fully utilized and closed the 2019 ATM Facility.

In May 2020, we entered into a Capital on Demand™ Sales Agreement, or the 2020 Sales Agreement, with JonesTrading Institutional Services to issue and sell up to $50.0 million in shares of our common stock, from time to time. Through December 31, 2021, we have sold 2,303,545 shares of common stock at-the-market under the 2020 ATM Facility for net proceeds of $19.5 million. As of August 2021, we had closed the 2020 ATM Facility.

In August 2021, we entered into Amendment No. 1 to Capital on Demand™ Sales Agreement, or the Amended Sales Agreement, with JonesTrading, which amends the 2020 Sales Agreement to issue and sell up to $80.0 million in shares of our common stock from time to time. As of December 31, 2021, we have sold 1,433,627 shares of common stock at-the-market under the 2021 ATM Facility for net proceeds of $10.0 million.

As of December 31, 2021, we had cash, cash equivalents and marketable securities of $154.1 million.

Future Funding Requirements

We expect our expenses will increase in the future as we anticipate incurring increased clinical development costs as we advance our SRF617 and SRF388 Phase 1 clinical trials. Additionally, we expect to continue to incur additional costs associated with operating as a public company.

We believe that our existing cash, cash equivalents, and marketable securities, as of March 2, 2022, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the second half of 2023, excluding any future milestone payments from Novartis or GSK. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- completing clinical development of existing product candidates and programs, identifying new product candidates, and completing pre-clinical and clinical development of such product candidates;
- seeking and obtaining marketing approvals for any of product candidates that we develop;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving adequate coverage and reimbursement by hospitals, government and third-party payors for product candidates that we develop;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for product candidates that we develop, if approved;
- obtaining market acceptance of product candidates that we develop as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference or infringement claims, if any; and
- attracting, hiring and retaining qualified personnel.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

In addition to the variables described above, if and when any product candidate we develop successfully completes development, we will incur substantial additional costs associated with regulatory filings, marketing approval, post-marketing requirements, maintaining our intellectual property rights, and regulatory protection, in addition to other costs. We cannot reasonably estimate these costs at this time.

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity or debt financings and collaboration and license arrangements, including the Novartis Agreement and GSK Agreement. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of debt securities, these securities could contain covenants that would restrict our operations. We may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, or at all. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate development or future commercialization efforts.

Cash Flows

The following table summarizes information regarding our cash flows for each of the periods presented:

	Year Ended December 31, 2021	Year Ended December 31, 2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (62,344)	$ 29,997
Investing activities	(99,252)	58,307
Financing activities	42,500	40,082
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (119,096)	$ 128,386

Operating Activities

During the year ended December 31, 2021, net cash used in operating activities was $62.3 million, primarily due to our net loss of $78.5 million, which was partially offset by non-cash charges of $14.0 million and net cash provided by our operating assets and liabilities of $2.1 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2021 consisted primarily of a $2.3 million increase in accrued expenses and other current liabilities, a $0.5 million decrease in unbilled receivables, and a 2.2 million decrease in our lease liability, and a $1.7 million decrease in prepaid expenses and other current assets. The increase in accrued expenses and other current liabilities was primarily due to increases in R&D accruals associated with our clinical trials. The decrease in our lease liability is a result of rental payments made on our operating leases in 2021. The decrease in unbilled receivables is a result of the completion of our performance obligations under the GSK Agreement in December 2021.

During the year ended December 31, 2020, net cash provided by operating activities was $30.0 million, primarily due to our net income of $59.3 million and non-cash charges of $13.0 million, partially offset by net cash used in our operating assets and liabilities of $42.3 million. Net cash used in changes in our operating assets and liabilities for the year ended December 31, 2020 consisted primarily of a $2.4 million increase in accrued expenses and other current liabilities, a $2.6 million increase in unbilled receivables, a decrease of $38.6 million in deferred revenue related party, and a $2.7 million decrease in accounts payable. The increase in unbilled receivables is a result of amounts due from GSK for the reimbursement of supplying the licensed antibodies and transition services performed in December 2020 under the GSK Agreement. The decrease in deferred revenue was due to the removal of all future costs in the cost-to-cost model as a result of Novartis’ decision not to purchase and exercise the single remaining Option under the Novartis Agreement prior to it expiring in January 2020. The increase in accrued expenses and other current liabilities was primarily due to increases in payroll related accruals and R&D accruals associated with our clinical trials.

Investing Activities

During the year ended December 31, 2021, net cash used in investing activities was $99.3 million, primarily due to purchases of marketable securities of $111.6 million and purchases of property and equipment of 0.1 million. This was partially offset by $12.5 million in proceeds from sales or maturities of marketable securities.

During the year ended December 31, 2020, net cash provided by investing activities was $58.3 million, primarily due to $59.0 million in proceeds from sales or maturities of marketable securities. This was partially offset by purchases of marketable securities of $0.7 million.

Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities was $42.5 million, consisting of proceeds of $29.5 million received from issuance of our shares of common stock at-the-market under the 2020 and 2021 ATM Facilities, proceeds from the issuance of the first tranche of our amended convertible note payable of $10.7 million, proceeds from the exercise of common stock of $2.0 million, and proceeds from employee stock purchases of $0.3 million.

During the year ended December 31, 2020, net cash provided by financing activities was $40.1 million, consisting of proceeds of $29.1 million received from issuance of our shares of common stock at-the-market under the 2019 Sales Agreement, proceeds from the issuance of the second tranche of our convertible note payable of $10.0 million, proceeds from the exercise of common stock of $0.8 million, and proceeds from employee stock purchases of $0.2 million.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with the rules and regulations of the SEC, and generally accepted accounting principles in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as revenue and expenses during the reporting period. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are 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. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements, we believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue Recognition

We account for revenue in accordance with Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

In accordance with ASC Topic 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC Topic 606, we perform the following five steps:

i. identify the contract(s) with a customer;

ii. identify the performance obligations in the contract;

iii. determine the transaction price

iv. allocate the transaction price to the performance obligations within the contract; and

v. recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when we determine that it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in our arrangements typically consist of a license to our intellectual property and/or research and development services. We may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

We determine transaction price based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, we estimate the probability and extent of consideration we expect to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. We then consider any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

We then allocate the transaction price to each performance obligation based on the relative standalone selling price and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations which consist of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

We record amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded for deferred revenue.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in our balance sheet. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, non-current.

Our revenue arrangement includes the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes research and development milestone payments, we evaluate each milestone to determine when and how much of the milestone to include in the transaction price. We first estimate the amount of the milestone payment that we could receive using either the expected value or the most likely amount approach. We primarily use the most likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. Then, we consider whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty.) We update the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any revenue related to sales-based royalties or milestone payments based on the level of sales.

All of our revenues to date have been generated through our collaboration agreements with Novartis and GSK. See Note 8, “Collaboration and License Agreements” for additional details regarding our collaboration agreements.

Accrued Research and Development Expenses

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

There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Our cash, cash equivalents and marketable securities as of December 31, 2021 consisted of cash and a money market fund invested primarily in short-term U.S. Treasury obligations. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, we do not believe that we have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

a. *Evaluation of Disclosure Controls and Procedures* - Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

b. *Management's Annual Report on Internal Control Over Financial Reporting* - Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this assessment, it used the criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on such assessment, our management has concluded that our internal control over financial reporting was effective, as of December 31, 2021.

c. *Changes in Internal Controls* - There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the fourth quarter of our last fiscal year that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

On February 28, 2022, Geoffrey McDonough, M.D. provided the Company with notice of his resignation from the Board of Directors of the Company, including his positions as Chair of the Company's Compensation Committee and as a member of the Company's Audit Committee, effective immediately. Dr. McDonough's resignation was voluntary and not the result of any disagreement with the operations, policies or practices of the Company.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 11. Executive Compensation.

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

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

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

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

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 14. Principal Accounting Fees and Services.

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(1) Financial Statements

The following documents are included on pages F-1 through F-34 attached hereto and are filed as part of this Annual Report on Form 10-K.

(2) Financial Statement Schedules:

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

(3) Exhibits.

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

Exhibit Number	Description
1.1	Capital on Demand[TM] Sales Agreement, dated as of May 22, 2020, by and between the Company and JonesTrading Institutional Services LLC (filed as Exhibit 1.1 to the Company's Current Report on Form 8-K filed on May 22, 2020 (File No.001-38459) and incorporated herein by reference)
1.2	Amendment No. 1, dated as of August 5, 2021, to Capital on DemandTM Sales Agreement, dated as of May 22, 2020, by and between Surface Oncology, Inc. and JonesTrading Institutional Services LLC (filed as Exhibit 1.1 to the Company's Quarterly Report on Form 10-Q filed on August 5, 2021 (File No. 001-38459) and incorporated herein by reference)
3.1	Amended and Restated Certificate of Incorporation of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on April 23, 2018 (File No. 001-38459) and incorporated herein by reference)
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on April 23, 2018 (File No. 001-38459) and incorporated herein by reference)
4.1	Specimen Common Stock Certificate (filed as Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
4.2	Amended and Restated Investors' Rights Agreement among the Company and certain of its stockholders, dated November 6, 2014, as amended on January 9, 2016 (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
4.3	Description of the Registrant's Securities (filed as Exhibit 4.3 to the Company's Annual Report on Form 10-K filed on March 10, 2020 (File No. 001-38459) and incorporated herein by reference)
10.1#	2014 Stock Option and Grant Plan, as amended, and forms of award agreements thereunder (filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.2#	2018 Stock Option Plan (filed as Exhibit 10.2 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.3#	Form of Incentive Stock Option Agreement under the Company's 2018 Stock Option and Incentive Plan (filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.4#	Form of Non-Qualified Stock Option Agreement for Company Employees under the Company's 2018 Stock Option and Incentive Plan (filed as Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.5#	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Company's 2018 Stock Option and Incentive Plan (filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.6#	Form of Restricted Stock Award Agreement under the Company's 2018 Stock Option and Grant Plan (filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.7#	Form of Restricted Stock Unit Award Agreement for Company Employees under the Company's 2018 Stock Option and Incentive Plan (filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.8#	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under the Company's 2018 Stock Option and Incentive Plan (filed as Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.9#	2018 Employee Stock Purchase Plan (filed as Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.10#	Senior Executive Cash Incentive Bonus Plan (filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)

Exhibit Number	Description
10.11#*	2021 Inducement Plan and form of award agreement thereunder
10.12#	Employment Agreement between Vito J. Palombella, Ph.D. and the Company, dated April 23, 2018 (filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.13#	Employment Agreement between Robert W. Ross, M.D. and the Company, dated April 23, 2018 (filed as Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.14#	Employment Agreement between J. Jeffrey Goater and the Company, dated April 23, 2018 (filed as Exhibit 10.15 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.15	Lease by and between the Company and BMR-Hampshire LLC, dated May 13, 2016, as amended on February 28, 2017 (filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.16	Second Amendment to Lease, dated May 22, 2018, by and between BMR-Hampshire LLC and the Company (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 24, 2018 (File No.001-3845) and incorporated herein by reference)
10.17†	Collaboration Agreement between Novartis Institutes for BioMedical Research, Inc. and the Company, dated January 9, 2016, as amended on May 6, 2016, as further amended on July14, 2017, and as further amended on September 18, 2017 (filed as Exhibit 10.18 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.18†	Amendment No. 4 to the Collaboration Agreement between Novartis Institutes for BioMedical Research, Inc. and the Company, dated October 9, 2018 (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 13, 2018 (File No. 001-38459) and incorporated herein by reference)
10.19†	Exclusive License Agreement between Harbour Antibodies B.V. and the Company, dated September 23, 2015, as amended on January 4, 2016 (filed as Exhibit 10.19 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.20#	Form of Director Indemnification Agreement (filed as Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.21#	Form of Officer Indemnification Agreement (filed as Exhibit 10.22 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.22†	First Amended and Restated Development and Option Agreement between Adimab, LLC and the Company, dated October 3, 2018 (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 13, 2018 (File No. 001-38459) and incorporated herein by reference)
10.23	Sublease Agreement by and between the Company and EQRx, Inc., dated December 16, 2019 (filed as Exhibit 10.22 to the Company's Annual Report on Form 10-K filed on March 10, 2020 (File No. 001-38459) and incorporated herein by reference)
10.24†	Loan and Security Agreement, dated November 22, 2019, by and among Surface Oncology, Inc., K2 HealthVentures, LLC and Ankura Trust Company, LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 25, 2019 (File No. 001-38459) and incorporated herein by reference)
10.25†	First Amendment to Loan and Security Agreement, dated October 1, 2021, by and among the Company and, K2 HealthVentures LLC and Ankura Trust Company, LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 4, 2021 (File No. 001-38459) and incorporated herein by reference).
10.26#	Transition and CEO Support Agreement, dated February 9, 2021, by and between J. Jeffrey Goater and the Company (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 11, 2021 (File No. 001-38459) and incorporated herein by reference)

Exhibit Number	Description
10.27#	Amended and Restated Employment Agreement, dated February 9, 2021, by and between Robert Ross, M.D. and the Company (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on February 11, 2021 (File No. 001-38459) and incorporated herein by reference)
10.28#	Amended and Restated Employment Agreement, dated April 26, 2021, by and between Jessica Fees and the Company (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 27, 2021 (File No. 001-38495) and incorporated herein by reference)
10.29†	License Agreement, dated as of December 16, 2020, by and between the Company and GLAXOSMITHKLINE INTELLECTUAL PROPERTY (No. 4) LIMITED (filed as Exhibit 1.1 to the Company's Current Report on Form 8-K filed on December 17, 2020 (File No. 001-38459) and incorporated herein by reference)
10.30†	Amendment No. 1, dated as of August 11, 2021, to License Agreement, dated as of December 16, 2020, by and between the Company and GLAXOSMITHKLINE INTELLECTUAL PROPERTY (No. 4) LIMITED (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 4, 2021 (File No. 001-38459) and incorporated herein by reference)
10.31†	Exclusive Product License Agreement, dated March 23, 2021, by and between Vaccinex, Inc. and the Company (filed as Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed May 5, 2021 (File No. 001-38459) and incorporated herein by reference)
21.1	List of Subsidiaries of the Company (filed as Exhibit 21.1 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No.333-223877) and incorporated herein by reference)
23.1*	Consent of PricewaterhouseCoopers LLP
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1+	Certification of Principal Executive Officer a Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+	Certification of Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

\+ Furnished herewith.

† Confidential treatment obtained as to certain portions.

\# A management contract or compensatory plan or arrangement required to be filed as an exhibit pursuant to Item 15(a)(3) of Form 10-K

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**.**

		Company Name
Date: March 2, 2022	By:	/s/ Robert W. Ross, M.D.
		Robert W. Ross, M.D.
		Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned directors and officers of Surface Oncology, Inc. (the "Company"), hereby severally constitute and appoint Robert W. Ross, M.D. and Denice Torres, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, any and all amendments to this Annual Report on Form 10-K, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as each of us might or could do in person, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Robert W. Ross, M.D.	Chief Executive Officer *(Principal Executive Officer and Duly Authorized Officer)*	March 2, 2022
Robert W. Ross, M.D.		
/s/ Jessica Fees	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 2, 2022
Jessica Fees		
/s/ Denice Torres	Chair	March 2, 2022
Denice Torres		
/s/ J. Jeffrey Goater	Director	March 2, 2022
J. Jeffrey Goater		
/s/ David S. Grayzel, M.D.	Director	March 2, 2022
David S. Grayzel, M.D.		
/s/ Benjamin Hickey	Director	March 2, 2022
Benjamin Hickey		
/s/ Ramy Ibrahim M.D.	Director	March 2, 2022
Ramy Ibrahim M.D.		
/s/ Armen B. Shanafelt, Ph.D.	Director	March 2, 2022
Armen B. Shanafelt, Ph.D.		
/s/ Elliott Sigal, M.D., Ph.D.	Director	March 2, 2022
Elliott Sigal, M.D., Ph.D.		
/s/ Laurie D. Stelzer	Director	March 2, 2022
Laurie D. Stelzer		

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Surface Oncology, Inc. and its subsidiary (the “Company”) as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive income (loss), of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2021, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/PricewaterhouseCoopers LLP
Boston, Massachusetts
March 2, 2022

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

SURFACE ONCOLOGY, INC.
CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 56,045	$ 175,141
Marketable securities	98,104	—
Prepaid expenses and other current assets	3,197	5,368
Total current assets	157,346	180,509
Property and equipment, net	5,651	6,664
Operating lease right-of-use asset	25,870	27,911
Restricted cash	1,595	1,595
Other assets	385	459
Total assets	$ 190,847	$ 217,138
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,550	$ 1,674
Accrued expenses and other current liabilities	13,089	10,448
Operating lease liability	5,384	5,529
Total current liabilities	20,023	17,651
Operating lease liability, non-current	26,909	28,981
Convertible note payable, non-current	25,015	14,759
Total liabilities	71,947	61,391
Commitments and contingencies (Notes 13 and 16)		
Stockholders' equity:		
Preferred stock, $0.0001 par value per share; 5,000,000 shares authorized at December 31, 2021 and December 31, 2020; no shares issued and outstanding at December 31, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 150,000,000 authorized at December 31, 2021 and December 31, 2020; 46,958,776 and 40,707,047 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	5	4
Additional paid-in capital	259,859	218,001
Accumulated other comprehensive loss	(221)	—
Accumulated deficit	(140,743)	(62,258)
Total stockholders' equity	118,900	155,747
Total liabilities and stockholders' equity	$ 190,847	$ 217,138

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

SURFACE ONCOLOGY, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2021	2020	2019
Collaboration revenue - related party	$ —	$ 38,592	$ 15,360
License-related revenue	2,687	87,570	—
Total revenue	$ 2,687	$ 126,162	$ 15,360
Operating expenses:			
Research and development	53,572	41,018	52,118
General and administrative	25,128	23,558	20,608
Total operating expenses	78,700	64,576	72,726
Income (loss) from operations	(76,013)	61,586	(57,366)
Interest expense	(2,546)	(2,855)	(145)
Other income (expense), net	74	606	2,722
Net income (loss)	(78,485)	59,337	(54,789)
Net income (loss) per share—basic	$ (1.77)	$ 1.67	$ (1.97)
Weighted average common shares outstanding—basic	44,243,317	35,545,121	27,854,912
Net income (loss) per share—diluted	$ (1.77)	$ 1.57	$ (1.97)
Weighted average common shares outstanding—diluted	44,243,317	38,141,793	27,854,912
Comprehensive income (loss):			
Net income (loss)	$ (78,485)	$ 59,337	$ (54,789)
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities, net of tax	(221)	(103)	222
Comprehensive income (loss)	$ (78,706)	$ 59,234	$ (54,567)

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

SURFACE ONCOLOGY, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	**Amount**				
Balances at December 31, 2018	27,772,600	$ 3	$ 169,784	$ (119)	$ (66,806)	$ 102,862
Issuance of common stock upon exercise of stock options	110,156	—	255			255
Issuance of common stock upon public offering, net of issuance costs	10,581	—	24	—	—	24
Stock-based compensation expense	—	—	5,991	—	—	5,991
Portion of convertible note payable proceeds allocated to beneficial conversion feature	—	—	2,101	—	—	2,101
Unrealized gain on marketable securities	—	—	—	222	—	222
Net loss	—	—	—	—	(54,789)	(54,789)
Balances at December 31, 2019	27,893,337	3	178,155	103	(121,595)	56,666
Issuance of common stock upon exercise of stock options	223,895	—	802			802
Issuance of common stock under stock purchase plan	89,172	—	194	—	—	194
Issuance of common stock upon public offering, net of issuance costs	11,218,593	1	29,085	—	—	29,086
Issuance of common stock upon conversion of convertible note payable	1,282,050	—	2,000	—	—	2,000
Stock-based compensation expense	—	—	7,765	—	—	7,765
Unrealized loss on marketable securities	—	—	—	(103)	—	(103)
Net income	—	—	—	—	59,337	59,337
Balances at December 31, 2020	40,707,047	4	218,001	—	(62,258)	155,747
Issuance of common stock upon exercise of stock options	508,720	—	2,022	—	—	2,022
Issuance of common stock upon vesting of RSUs	997,400	—	—	—	—	—
Issuance of common stock under stock purchase plan	46,899	—	266	—	—	266
Issuance of common stock upon public offering, net of issuance costs	3,737,172	1	29,524	—	—	29,525
Issuance of common stock upon conversion of convertible note payable	961,538	—	1,500	—	—	1,500
Stock-based compensation expense	—	—	8,546	—	—	8,546
Unrealized loss on marketable securities	—	—	—	(221)	—	(221)
Net loss	—	—	—	—	(78,485)	(78,485)
Balances at December 31, 2021	46,958,776	$ 5	$ 259,859	$ (221)	$ (140,743)	$ 118,900

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

SURFACE ONCOLOGY, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands, except share amounts)

	Year Ended December 31, 2021	2020	2019
Cash flows from operating activities:			
Net income (loss)	$ (78,485)	$ 59,337	$ (54,789)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization expense	1,569	1,670	1,785
Stock-based compensation expense	8,546	7,765	5,991
Non-cash interest expense related to note payable	1,069	1,650	74
Net amortization of premiums and discounts on marketable securities	807	(47)	(764)
Loss on disposal of property and equipment	—	1	1
Non-cash operating lease cost	2,041	1,950	1,814
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	1,653	(32)	3,001
Unbilled receivable	518	(2,571)	—
Other assets	74	(431)	12
Accounts payable	(226)	(2,716)	583
Accrued expenses and other current liabilities	2,307	2,436	(710)
Operating lease liability	(2,217)	(423)	(1,778)
Deferred revenue - related party	—	(38,592)	(15,360)
Net cash provided by (used in) operating activities	(62,344)	29,997	(60,140)
Cash flows from investing activities:			
Purchases of property and equipment	(120)	(43)	(1,538)
Purchases of marketable securities	(111,632)	(650)	(118,347)
Proceeds from sales or maturities of marketable securities	12,500	59,000	136,850
Net cash provided by (used in) investing activities	(99,252)	58,307	16,965
Cash flows from financing activities:			
Proceeds from issuance of convertible note payable, net of issuance costs	10,687	10,000	7,217
Payments of debt issuance costs	—	—	(81)
Proceeds for issuance of common stock, net	29,525	29,086	24
Proceeds from employee stock purchases	266	194	—
Proceeds from exercise of stock options	2,022	802	255
Net cash provided by financing activities	42,500	40,082	7,415
Net increase (decrease) in cash and cash equivalents and restricted cash	(119,096)	128,386	(35,760)
Cash and cash equivalents and restricted cash at beginning of period	176,736	48,350	84,110
Cash and cash equivalents and restricted cash at end of period	$ 57,640	$ 176,736	$ 48,350
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 1,406	$ 1,052	$ —
Supplemental disclosure of non-cash investing and financing activities:			
Purchases of property and equipment included in accounts payable and accrued expenses	$ 436	$ 1,006	$ —
Additional right-of-use asset and related lease liability	$ —	$ 15,003	$ —
Conversion of note payable into shares of common stock	$ 1,500	$ 2,000	$ —

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

1. Nature of the Business

Surface Oncology, Inc. (the “Company” or “Surface”) is a clinical-stage immuno-oncology company focused on using its specialized knowledge of the biological pathways critical to the immunosuppressive tumor microenvironment (“TME”) for the development of next-generation cancer therapies. Surface was incorporated in April 2014 under the laws of the State of Delaware.

The Company is subject to risks common to early-stage companies in the biotechnology industry including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the ability to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities. Even if the Company’s development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

On May 1, 2019, the Company entered into a Capital on Demand™ Sales Agreement (the “2019 Sales Agreement”) with JonesTrading Institutional Services LLC (“JonesTrading”) to issue and sell shares of the Company’s common stock of up to $30,000 in gross proceeds, from time to time during the term of the a Sales Agreement, through an “at-the-market” equity offering program under which JonesTrading will act as the Company’s agent and/or principal (the “2019 ATM Facility”). The 2019 ATM Facility provides that JonesTrading will be entitled to compensation for its services in an amount of up to 3.0% of the gross proceeds of any shares sold under the 2019 ATM Facility. The Company has no obligation to sell any shares under the 2019 ATM Facility and may, at any time, suspend solicitation and offers under the 2019 Sales Agreement. As of December 31, 2021, the Company has sold 11,229,174 shares under the 2019 ATM Facility for net proceeds of $29,110. As of May 22, 2020, the Company had fully utilized and closed the 2019 ATM Facility.

On May 22, 2020, the Company entered into a Capital on Demand™ Sales Agreement (the “2020 Sales Agreement”) with JonesTrading to issue and sell shares of the Company’s common stock of up to $50,000 in gross proceeds, from time to time during the term of the 2020 Sales Agreement, through an “at-the-market” equity offering program under which JonesTrading will act as the Company’s agent and/or principal (the “2020 ATM Facility”). The 2020 ATM Facility provides that JonesTrading will be entitled to compensation for its services in an amount of up to 3.0% of the gross proceeds of any shares sold under the 2020 ATM Facility. The Company has no obligation to sell any shares under the 2020 ATM Facility and may, at any time, suspend solicitation and offers under the 2020 Sales Agreement. As of December 31, 2021, the Company has sold 2,303,545 shares of common stock at-the-market under the 2020 ATM Facility for net proceeds of $19,479. As of August 5, 2021, the Company had closed the 2020 ATM Facility.

On August 5, 2021, the Company entered into Amendment No. 1 to Capital on Demand™ Sales Agreement (the “Amended Sales Agreement”) with JonesTrading, which amends the 2020 Sales Agreement to allow the issuance and sale of up to $80,000 in gross proceeds, from time to time during the term of the Amended Sales Agreement, through an “at-the-market” equity offering program under which JonesTrading will act as the Company’s sales agent ("the 2021 ATM Facility"). The 2021 ATM Facility provides that JonesTrading will continue to be entitled to compensation for its services in an amount of up to 3.0% of the gross proceeds of any shares sold under the 2021 ATM Facility. The Company has no obligation to sell any shares under the Amended Sales Agreement and may, at any time, suspend solicitation and offers under the 2021 ATM Facility. As of December 31, 2021, the Company has sold 1,433,627 shares of common stock at-the-market under the 2021 ATM Facility for net proceeds of $10,046.

The Company's financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has primarily funded its operations with proceeds from private and public sales of its securities, proceeds from a collaboration agreement with Novartis, a license agreement with GSK, and issuance of a debt facility with K2 Health Ventures. The Company has incurred losses and negative cash flows from operations since its inception, including net losses of $78,485 and $54,789 for the years ended December 31, 2021 and 2019, respectively. The Company earned income of $59,337 for the year ended December 31, 2020, primarily related to revenue recognized under the GSK Agreement. As of December 31, 2021 and 2020, the Company had an accumulated deficit of $140,743 and $62,258, respectively. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. As of March 2, 2022, the issuance date of the consolidated financial statements for the year ended December 31, 2021, the Company expects that its cash and cash equivalents and marketable securities will be sufficient to fund its operating expenses, capital expenditure requirements and debt service obligations for at least the next 12 months. The future viability of the Company beyond that date is dependent on its ability to raise additional capital to finance its operations.

The Company will seek additional funding through public financings, debt financings, collaboration agreements, strategic alliances and licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect its business prospects.

Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The ongoing global outbreak of the novel coronavirus disease ("COVID-19") has resulted in significant governmental measures being implemented to control the spread of the virus and while the Company cannot predict their scope or the severity of the outbreak, these developments and measures could materially and adversely affect the Company's business, the Company's results of operations and financial condition. The Company is closely monitoring the impact of the COVID-19 pandemic on all aspects of its business and has taken steps to minimize its impact on the Company's business. Although COVID-19 has not had a material adverse impact on the Company's operations and its clinical and preclinical programs, the extent to which COVID-19 ultimately impacts the Company's business, results of operations or financial condition will depend on future developments which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken to contain the pandemic or mitigate its impact, among others. Certain of the Company's third-party service providers have experienced shutdowns or other business disruptions. As a result, the Company's ability to conduct its business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on the Company's business, results of operations and financial condition.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiary, Surface Securities Corporation, a Massachusetts corporation, after elimination of all intercompany accounts and transactions.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from the Company's estimates.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at the acquisition date to be cash equivalents. Cash equivalents, which consist of money market funds are stated at fair value.

Marketable Securities

Marketable securities consist of investments with original maturities greater than 90 days at their acquisition date. The Company has classified its investments with maturities beyond one year as current, based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations.

The Company classifies all of its marketable securities as available-for-sale securities. The Company's marketable securities are measured and reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale debt securities are reported as accumulated other comprehensive income (loss), which is a separate component of stockholders' equity. The cost of debt securities sold is determined on a specific identification basis, and realized gains and losses are included in interest and other income (expense), net in the consolidated statements of operations and comprehensive income (loss).

The Company evaluates its marketable securities with unrealized losses for other-than-temporary impairment. When assessing marketable securities for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other than temporary," the Company reduces the investment to fair value through a charge to the statement of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

Restricted Cash

At December 31, 2021 and 2020, restricted cash consisted of cash deposited in a separate bank account as collateral for the Company's facilities lease obligations. At December 31, 2021 and 2020, $1,595 of restricted cash was classified as non-current.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash, cash equivalents and marketable securities. The Company maintains its cash, cash equivalents, and marketable securities at two accredited financial institution in amounts that exceed federally insured limits. The Company does not believe that it is subject to 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 testing. These programs could be adversely affected by a significant interruption in the supply of such drug substance products.

Fair Value of Financial Instruments

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

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

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above. The carrying values of the Company's prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the useful life of the asset. Laboratory equipment is depreciated over five years. Computer equipment and furniture and office equipment are depreciated over three years. Leasehold improvements are amortized over the shorter of the lease term or 10 years. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation and amortization of assets disposed of are removed from the accounts, and any resulting gain or loss is included in income (loss) from operations.

Impairment of Long-Lived Assets

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

Revenue Recognition

We account for revenue in accordance with Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

In accordance with ASC Topic 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC Topic 606, it performs the following five steps:

i. identify the contract(s) with a customer;

ii. identify the performance obligations in the contract;

iii. determine the transaction price

iv. allocate the transaction price to the performance obligations within the contract; and

v. recognize revenue when (or as) the entity satisfies a performance obligation.

The Company only applies the five-step model to contracts when it determines that it is probable it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in the Company’s arrangements typically consist of a license to the Company’s intellectual property and/or research and development services. The Company may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

The Company determines transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company then allocates the transaction price to each performance obligation based on the relative standalone selling price and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded for deferred revenue.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in the Company’s balance sheet. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, non-current.

The Company’s revenue arrangements include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes research and development milestone payments, the Company evaluates each milestone to determine when and how much of the milestone to include in the transaction price. The Company first estimates the amount of the milestone payment that the Company could receive using either the expected value or the most likely amount approach. The Company primarily uses the most likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. Then, the Company considers whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty.) The Company updates the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any revenue related to sales-based royalties or milestone payments based on the level of sales.

The Company's revenues have been generated through our collaboration agreement with Novartis and license agreement with GSK. See Note 8, "Collaboration and License Agreements" for additional details regarding the Company's collaboration and license agreements.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include salaries, stock-based compensation and benefits of employees, third-party license fees and other operational costs related to the Company's research and development activities, including allocated facility-related expenses and external costs of outside vendors engaged to conduct both preclinical studies and clinical trials.

Research Contract Costs and Accruals

The Company has entered into various research and development contracts with research institutions and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Nonrefundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Patent Costs

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

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock options and restricted stock awards with only service-based vesting conditions and records the expense for these awards using the straight-line method.

Following the Company's adoption of ASU 2018-7, Compensation—Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-7"), on January 1, 2019, for stock-based awards issued to non-employees, the Company no longer revalues non-employee awards at each reporting date and instead calculates the fair value of the awards as of the grant date using the Black-Scholes option-pricing model. Compensation expense for these awards is recognized over the related service period.

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

The fair value of each stock option grant is estimated using the Black- Scholes option-pricing model. The Company has historically been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The Company elects to account for forfeitures as they occur rather than apply an estimated forfeiture rate to share based payment expense.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") asset, operating lease liability, and operating lease liability, non-current in the Company's consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Many lease agreements include the option to renew or extend the lease term. The exercise of lease renewal options or extensions is at the Company's sole discretion, and are only included in the calculation of the operating lease ROU asset and operating lease liability when it is reasonably certain that the Company would exercise such options. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate, which it calculates based on the credit quality of the Company, and by comparing interest rates available in the market for similar borrowings, and adjusting this amount based on the impact of collateral over the term of each lease.

The components of a lease are split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components. Although separation of lease and non-lease components is required, certain practical expedients are available to entities. Entities electing the practical expedient would not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company's facilities operating leases have lease and non-lease components to which the Company has elected to apply the practical expedient and account for each lease component and related non-lease component as one single component. The Company also elected the package of practical expedients, which, among other things, allows the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. The Company also made an accounting policy election not to recognize leases with an initial term of 12 months or less within its consolidated balance sheets and to recognize those lease payments on a straight-line basis in its consolidated statements of operations and comprehensive loss over the lease term.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making decisions. The Company's singular focus is using its specialized knowledge of the biological pathways critical to the TME for the development of next-generation cancer therapies. All of the Company's tangible assets are held in the United States, and all revenue is derived from the Company's two collaboration partners, both of which are in the United States.

Income Taxes

The Company accounts for income taxes under 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 financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years 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 and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by analyzing carryback capacity in periods with taxable income, reversal of existing taxable temporary differences and estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

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

Comprehensive Income (Loss)

Comprehensive income (loss) includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. The Company's only element of other comprehensive income (loss) in all periods presented was unrealized gains (losses) on marketable securities.

Net Income (Loss) per Share

The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities, including the assumed conversion of the Company's convertible note payable and outstanding options to purchase common stock, except where the results would be anti-dilutive. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effective of the conversion of the convertible note payable and outstanding options to purchase common stock. In the diluted net income (loss) per share calculation, net income (loss) would also be adjusted for the elimination of interest expense on the convertible note payable (which includes amortization of the discount created for the beneficial conversion feature), if the impact was not anti-dilutive. For purpose of this calculation, outstanding options to purchase common stock or redeemable convertible preferred stock are considered potential dilutive common shares.

(In thousands, except share and per share amounts)

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13")*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes may result in earlier recognition of credit losses. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*, which narrowed the scope and changed the effective date for non-public entities for ASU 2016-13. The FASB subsequently issued supplemental guidance within ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief ("ASU 2019-05")*. ASU 2019-05 provides an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. For public entities that are Securities and Exchange Commission filers, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, ASU 2016-13 is effective for annual periods beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. This standard will be effective for the Company on January 1, 2023. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

Other accounting standards that have been issued by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements upon adoption.

3. Marketable Securities

As of December 31, 2021, the fair value of available-for-sale marketable securities by type of security was as follows:

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable debt securities:				
U.S. Treasury notes	$ 77,550	$ —	$ (188)	$ 77,362
U.S. government agency bonds	20,775	—	(33)	$ 20,742
	$ 98,325	$ —	$ (221)	$ 98,104

The amortized cost and fair value of the Company's available-for-sale securities by contractual maturity are summarized as follows:

	December 31, 2021	
	Amortized Cost	Fair Value
Maturing in one year or less	$ 60,462	$ 60,406
Maturing in more than one year	37,863	$ 37,698
	$ 98,325	$ 98,104

As of December 31, 2020, there were no available-for-sale marketable debt securities.

The cost of securities sold is determined based on the specific identification method for purposes of recording realized gains and losses. During the year ended December 31, 2021, there were no realized losses on sales of marketable securities. During the years ended December 31, 2020 and 2019 realized gain on sales of marketable securities were $12 and $7, respectively. There were no marketable securities that required adjustment for other-than-temporary declines in fair value during the years ended December 31, 2021, 2020, and 2019.

(In thousands, except share and per share amounts)

There were 54 securities held by the Company in an unrealized loss position for less than twelve months as of December 31, 2021. The aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months as of December 31, 2021 was $98,104. There were no securities held by the Company in an unrealized loss position for less than twelve months as of December 31, 2020. There were no securities held in an unrealized loss position for more than twelve months as of December 31, 2021 and 2020. The Company determined that there was no material change in the credit risk of these investments. As a result, the Company determined it did not hold any investments with an other-than-temporary decline in fair value as of December 31, 2021 and 2020.

4. Fair Value of Financial Assets

The following tables present information about the Company's financial assets that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	Fair Value Measurements as of December 31, 2021 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 20,309	$ —	$ —	$ 20,309
Marketable securities:				
U.S. Treasury notes	—	77,362	—	77,362
U.S. government agency bonds	—	20,742	—	20,742
	$ 20,309	$ 98,104	$ —	$ 118,413

	Fair Value Measurements as of December 31, 2020 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 139,266	$ —	$ —	$ 139,266
	$ 139,266	$ —	$ —	$ 139,266

As of December 31, 2021 and 2020, the Company's cash equivalents were invested in money market funds and were valued based on Level 1 inputs. As of December 31, 2021, the Company's marketable securities consisted of U.S. Treasury notes and U.S. government agency bonds and were valued based on Level 2 inputs. In determining the fair value of its U.S. Treasury notes and U.S. government agency bonds, the Company relied on quoted prices for similar securities in active markets or other inputs that are observable or can be corroborated by observable market data. During the years ended December 31, 2021 and 2020, there were no transfers between Level 1, Level 2 and Level 3.

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	Year Ended December 31,	
	2021	2020
Laboratory equipment	$ 3,653	$ 3,601
Leasehold improvements	7,638	7,638
Computer equipment	702	535
Furniture and office equipment	1,074	1,074
Construction in process	337	—
	13,404	12,848
Less: Accumulated depreciation and amortization	(7,753)	(6,184)
	$ 5,651	$ 6,664

(In thousands, except share and per share amounts)

For the years ended December 31, 2021, 2020, and 2019 depreciation and amortization expense was $1,569, $1,670, and $1,785 respectively.

6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Prepaid expenses	$ 2,432	$ 2,797
Unbilled receivable	518	2,571
Interest receivable on marketable securities	247	—
	$ 3,197	$ 5,368

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Accrued external research and development costs	$ 5,316	$ 4,017
Accrued payroll and payroll-related costs	4,180	5,056
Accrued professional fees	355	327
Other	3,238	1,048
	$ 13,089	$ 10,448

8. Collaboration and License Agreements

Collaboration Agreement with Novartis

In January 2016, the Company entered into a collaboration agreement with Novartis (the “Novartis Agreement”), which was subsequently amended in May 2016, July 2017, September 2017, and October 2018. Pursuant to the Novartis Agreement, the Company granted Novartis a worldwide exclusive license to research, develop, manufacture and commercialize antibodies that target cluster of differentiation 73 ("CD73"). In addition, the Company initially granted Novartis the right to purchase exclusive option rights (each an “Option”) for up to four specified targets (each an “Option Target”) including certain development, manufacturing and commercialization rights. Novartis initially had the right to exercise up to three purchased Options. Under the Novartis Agreement, therefore, Novartis had the ability to exclusively license the development and manufacturing rights for up to four targets (inclusive of CD73). In January 2020, Novartis did not purchase and exercise its single remaining Option under the Novartis Agreement and, as a result, the option purchase period expired. Therefore, there are no Options remaining eligible for purchase, and potential exercise, and the Company’s performance obligations under the Novartis Agreement have ended. Under the Novartis Agreement, the Company is currently entitled to potential development milestones of $325,000 and sales milestones of $200,000, as well as tiered royalties on annual net sales by Novartis ranging from high single-digit to mid-teens percentages upon the successful commercialization of NZV930 (formerly SRF373).

Novartis is a related party because it is a greater than 5% stockholder of the Company. During the years ended December 31, 2021 and 2020, the Company made no cash payments to Novartis related to the Novartis Agreement.

(In thousands, except share and per share amounts)

Termination

Unless terminated earlier, the Novartis Agreement will continue in effect until neither the Company nor Novartis is researching, developing, manufacturing or commercializing NZV930. Novartis may terminate the Novartis Agreement for any reason upon prior notice to the Company within a specified time period. Either party may terminate the Novartis Agreement in full if an undisputed material breach is not cured within a certain period of time or upon notice of insolvency of the other party. To the extent Novartis terminates for convenience, or the Company terminates for Novartis' material breach, Novartis will grant the Company, on mutually agreeable financial terms, an exclusive, worldwide, irrevocable, perpetual and royalty-bearing license with respect to intellectual property controlled by Novartis that is reasonably necessary to research, develop, manufacture or commercialize NZV930.

Revenue Recognition - Collaboration Revenue – Related Party

In determining the appropriate amount of revenue to be recognized under ASC 606, the Company performed the following steps: (i) identified the promised goods or services in the contract; (ii) determined whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

Under ASC 606, the Company recognized revenue using the cost-to-cost method, which it believes best depicts the transfer of control to the customer. Under the cost-to-cost method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified performance obligation. Under this method, revenue will be recorded as a percentage of the estimated transaction price based on the extent of progress towards completion. Under ASC 606, the estimated transaction price will include variable consideration. The Company does not include variable consideration to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will occur when any uncertainty associated with the variable consideration is resolved. The estimate of the Company's measure of progress and estimate of variable consideration to be included in the transaction price will be updated at each reporting date as a change in estimate. The amount related to the unsatisfied portion will be recognized as that portion is satisfied over time.

Under ASC 606 the Company accounted for (i) the license it conveyed with respect to CD73; and (ii) its obligations to perform research on CD73 and other specified targets as a single performance obligation under the Novartis Agreement. Novartis' right to purchase exclusive options to obtain certain development, manufacturing and commercialization rights were accounted for separately as they do not represent material rights, based on the criteria of ASC 606. Upon the exercise of any purchased option by Novartis, the contract promises associated with an Option Target would have used a separate cost-to-cost model for purposes of revenue recognition under ASC 606.

In February 2019, Novartis notified the Company of its decision not to purchase the Option related to IL-27. Future costs associated with this target were removed from the estimated total costs in the cost-to-cost model.

In January 2020, Novartis did not purchase and exercise its single remaining Option under the Novartis Agreement and, as a result, the option purchase period expired. Future costs associated with this target were removed from the estimated total costs in the cost-to-cost model. This resulted in the Company recognizing the remaining deferred revenue of $38,592 to collaboration revenue - related party in January 2020.

For the years ended December 31, 2021, 2020, and 2019, the Company recognized the following totals of collaboration revenue – related party:

	Year Ended December 31,		
	2021	2020	2019
Collaboration revenue - related party	$ —	$ 38,592	$ 15,360

As there are no Options remaining eligible for purchase and exercise, the Company's performance obligations under the Novartis Agreement have ended.

License Agreement with GSK

In December 2020, the Company entered into a license agreement (as amended by the GSK Amendment (as defined below) the “GSK Agreement”) with GSK. Pursuant to the GSK Agreement, the Company granted GSK a worldwide exclusive, sublicensable license to develop, manufacture and commercialize antibodies that target the antibody GSK4381562 (formerly SRF813), targeting CD112R, also known as PVRIG (the “Licensed Antibodies”). GSK will be responsible for the development, manufacturing and commercialization of the Licensed Antibodies and a joint development committee will be formed to facilitate information sharing between the Company and GSK. Under the terms of the GSK Agreement, GSK is obligated to use commercially reasonable efforts to develop and commercialize the Licensed Antibodies. In August 2021, the Company entered into the first amendment to the GSK Agreement (the "GSK Amendment"). Pursuant to the GSK Amendment, the Company will provide additional transition and supply services related to the development and manufacturing of the Licensed Antibodies.

Development, Manufacturing and Commercialization of Licensed Antibodies

GSK has the sole right to develop, manufacturer and commercialize the Licensed Antibodies and corresponding licensed products worldwide. GSK is obligated to use commercially reasonable efforts to develop the Licensed Antibodies and corresponding licensed products. GSK is responsible for all costs and expenses of such development, manufacturing and commercialization and is obligated to provide the Company with updates on its development, manufacturing and commercialization activities through the joint development committee.

Exclusivity

During the term of the GSK Agreement, neither the Company, nor any affiliates, will research, develop, manufacture, or commercialize any alternative product.

Financial Terms

Under the terms of the agreement, GSK made a one-time upfront payment of $85,000 and is required to make additional payments to the Company for supply services and transition services initially estimated to be $4,314 and $950, respectively. The Company is eligible to receive up to $90,000 in clinical and $155,000 in regulatory milestones. In addition, the Company may receive up to $485,000 in sales milestone payments. The Company is also eligible to receive royalties on global net sales of any approved products based on the licensed antibodies, ranging in percentages from high single digits to mid-teens. Due to the uncertainty of pharmaceutical development and the historical failure rates generally associated with drug development, the Company may not receive any milestone payments or any royalty payments under the GSK Agreement.

Termination

Unless terminated earlier, the GSK Agreement expires on a licensed product-by-licensed product and country-by-country basis on the later of ten years from the date of first commercial sale or when there is no longer a valid patent claim or regulatory exclusivity covering such licensed product in such country. Either party may terminate the GSK Agreement for an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party. GSK may terminate the GSK Agreement for its convenience. The Company may terminate the GSK Agreement if GSK institutes certain actions related to the licensed patents or if GSK ceases development activities, other than for certain specified technical or safety reasons. In the event of termination, the Company would regain worldwide rights to the terminated program.

Revenue Recognition – License-Related Revenue

In determining the appropriate amount of revenue to be recognized under ASC 606, the Company performed the following steps: (i) identified the promised goods or services in the contract; (ii) determined whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company assessed the GSK Agreement in accordance with ASC 606 and concluded that GSK is a customer. The Company identified the following promises under the contract: (i) a worldwide exclusive, sublicensable license to develop, manufacture and commercialize the Licensed Antibodies; (ii) supplying Licensed Antibodies until an investigational new drug application is accepted by a regulatory authority (iii) transition services until an investigational new drug application is accepted by a regulatory authority; and (iv) participation on the joint development and joint patent committees. The Company assessed the above promises and determined that the worldwide exclusive, sublicensable license to develop, manufacture and commercialize the Licensed Antibodies is considered functional intellectual property and distinct from other promises under the contract. This functional license is distinct in the context of the GSK Agreement as GSK can benefit from the license on its own or together with other readily available resources. In addition, the supply and transition services are not complex or specialized, could be performed by another qualified third party, are not expected to significantly modify or customize the license to SRF813, and are expected to be performed only for a short period of time. The Company determined that the impact of participation on the joint development and joint patent committees was insignificant and had an immaterial impact on the accounting model. Based on these assessments, the Company identified three distinct performance obligations at the outset of the GSK Agreement.

The Company determined the transaction price under ASC 606 at the inception of the GSK Agreement to be $90,264, consisting of the upfront payment of $85,000 plus $4,314 for supply of the Licensed Antibodies and $950 for the transition services. The Company evaluated how much variable consideration related to clinical and regulatory milestones to include in the transaction price using the most likely amount approach and concluded that no amount should be included in the transaction price due to the high degree of uncertainty and risk associated with these potential payments. The Company also determined that royalties and sales milestones relate solely to the licenses of intellectual property and are therefore excluded from the transaction price under the sales- or usage-based royalty exception of ASC 606. Revenue related to these royalties and sales milestones will only be recognized when the associated sales occur, and relevant thresholds are met.

As noted above, the Company identified three performance obligations in the GSK Agreement: (i) the delivery of the worldwide exclusive, sublicensable license to develop, manufacture and commercialize the Licensed Antibodies; (ii) supply of Licensed Antibodies until an investigational new drug application is accepted by a regulatory authority; and (iii) transition services until an investigational new drug application is accepted by a regulatory authority. The selling price of each performance obligation in the GSK Agreement was determined based on the Company’s standalone selling price (“SSP”) with the objective of determining the price at which it would sell such an item if it were to be sold regularly on a standalone basis. The Company recognizes revenue for the license performance obligation at a point in time, that is upon transfer of the license to GSK. As control of the license was transferred on the effective date of December 16, 2020 and GSK could begin to use and benefit from the license, the Company recognized $85,000 of license-related revenue during the year ended December 31, 2020 under the GSK Agreement. The Company recognized the costs allocated to supply services and transition services over time. The Company transferred control of these services over time and GSK received and consumed the benefit over time as the Company performed the services. The Company re-evaluated the transaction price at the end of each reporting period and as uncertain events were resolved, or other changes in circumstances occur, adjusted its estimate of the transaction price as necessary.

For the year ended December 31, 2021, the Company recognized $1,954 of license-related revenue for supply services and $733 of license-related revenue related to the transition services. For the year ended December 31, 2020, the Company recognized $2,570 of license-related revenue for supply services, which represented the costs incurred associated with the portion of goods that were immediately transferred upon execution of the GSK Agreement. An immaterial amount of the transition services was performed in the year ended December 31, 2020.

In November 2021, GSK notified the Company it received clearance from the FDA for GSK4381562 to proceed into a first-in-human clinical trial and as a result the Company's performance obligations under the GSK Agreement have ended. No amount of the transaction price allocated to the performance obligations was partially unsatisfied, nor did the Company have a contract liability associated with the GSK Agreement as of December 31, 2021.

(In thousands, except share and per share amounts)

For the years ended December 31, 2021, 2020, and 2019, the Company recognized the following totals of license-related revenue:

	Year Ended December 31,		
	2021	2020	2019
License-related revenue	$ 2,687	$ 87,570	$ —

9. Stockholders' Equity

Common Stock

As of December 31, 2021 and 2020, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 150,000,000 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, if any, subject to the preferential dividend rights of any outstanding preferred stock. No dividends have been declared or paid by the Company through December 31, 2021.

As of December 31, 2021 and 2020, the Company had reserved 32,934,776 and 22,728,991 shares, respectively, of common stock for the exercise of outstanding stock options, the vesting of restricted stock units, shares to be issued under the 2021 and 2020 ATM Facilities, shares to be issued upon the conversion of the Loan Agreement, as amended (defined below), and the number of shares remaining available for future grant under the Company's 2018 Stock Option and Incentive Plan and 2018 Employee Stock Purchase Plan.

Reserved for future issuance

The Company has reserved for future issuance the following number of shares of common stock:

	As of December 31,	
	2021	2020
Options to purchase common stock	7,057,258	6,011,126
Shares available for future grant	783,873	664,544
RSU's issued and expecting to vest	—	1,043,300
2018 Employee Stock Purchase Plan	1,084,476	724,305
Shares available for conversion of note payable	832,677	1,282,052
Shares available for ATM offering	23,176,492	13,003,664
Total reserved	32,934,776	22,728,991

In August 2021, the Company entered into the Amended Sales Agreement with JonesTrading, which amends the 2020 Sales Agreement to issue and sell up to $80,000 in shares of the Company's common stock from time to time. As of December 31, 2021, the Company has sold 1,433,627 shares of common stock at-the-market under the 2021 ATM Facility for net proceeds of $10,046.

In May 2020, the Company entered into the 2020 Sales Agreement with JonesTrading to issue and sell shares up to $50,000 in shares of the Company's common stock from time to time. As of December 31, 2021, the Company has sold 2,303,545 shares of common stock at-the-market under the 2020 ATM Facility for net proceeds of $19,479. As of August 2021, the Company had closed the 2020 ATM Facility.

(In thousands, except share and per share amounts)

In May 2019, the Company entered into the 2019 Sales Agreement with JonesTrading to issue and sell shares up to $30,000 in shares of the Company's common stock from time to time. As of December 31, 2021, the Company has sold 11,229,174 shares under the 2019 ATM Facility for net proceeds of $29,110. As of May 2020, the Company had fully utilized and closed the 2019 ATM Facility.

10. Stock-Based Awards

2014 Stock Incentive Plan

The Company's 2014 Stock Incentive Plan (the "2014 Plan") provides for the Company to grant incentive stock options or nonqualified stock options, restricted stock awards, unrestricted stock awards or restricted stock units to employees, directors and consultants of the Company. The 2014 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of the stock options may not be less than 100% of the fair market value of a share of the Company's common stock on the date of grant and the term of the stock options may not be greater than ten years.

As of December 31, 2021 and 2020 all remaining shares available under the 2014 Plan were transferred to the 2018 Plan.

2018 Stock Option and Incentive Plan

On April 3, 2018, the Company's stockholders approved the 2018 Stock Option and Incentive Plan (the "2018 Plan"), which became effective on April 18, 2018, the date on which the registration statement for the Company's initial public offering was declared effective. The 2018 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, non-employee directors and other key persons (including consultants). The number of shares initially reserved for issuance under the 2018 Plan was 1,545,454, plus the shares of common stock remaining available for issuance under the 2014 Plan, which shall be cumulatively increased on each January 1 by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's board of directors or compensation committee of the board of directors. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Plan and the 2014 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan.

As of December 31, 2021 and 2020, 783,873 shares and 664,544 shares were available for future issuance under the 2018 Plan, respectively.

Stock options granted under the 2014 Plan and 2018 Plan to employees generally vest over four years and expire after ten years. The Company does not currently hold any treasury shares. Upon stock option exercise, the Company issues new shares and delivers them to the participant.

Stock Option Valuation

The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors were as follows, presented on a weighted average basis:

	Year Ended December 31,		
	2021	2020	2019
Risk-free interest rate	0.89 %	1.29 %	2.46 %
Expected term (in years)	5.96	5.99	6.12
Expected volatility	83.87 %	71.34 %	73.62 %
Expected dividend yield	0.0 %	0.0 %	0.0 %

(In thousands, except share and per share amounts)

Stock Options

The following table summarizes the Company's stock option activity for the year ended December 31, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
			(in years)	
Outstanding as of December 31, 2020	6,011,126	$ 5.55	7.28	$ 24,912
Granted	1,838,905	9.11		
Exercised	(508,720)	3.98		
Forfeited	(284,053)	5.56		
Outstanding as of December 31, 2021	7,057,258	$ 6.59	6.98	$ 4,678
Options exercisable at December 31, 2021	4,678,355	$ 6.22	6.13	$ 3,683
Vested and expected to vest at December 31, 2021	7,057,258	$ 6.59	6.98	$ 4,678

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2021 and 2020, was $6.41 and $2.11, respectively.

The aggregate fair value of stock options vested during the years ended December 31, 2021 and 2020, was $10,864 and $6,742, respectively.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2021, 2020, and 2019 was $1,887, $735, and $208 respectively.

As of December 31, 2021, and 2020, there were outstanding stock options held by non-employees for the purchase of 276,570 and 253,971 shares of common stock, respectively, with service-based vesting conditions.

Restricted Stock Units

The Company has granted restricted stock units ("RSUs") with service-based vesting conditions. RSUs represent the right to receive shares of common stock upon meeting specified vesting requirements. Unvested shares of restricted common stock may not be sold or transferred by the holder. These restrictions lapse according to the service-based vesting conditions of each award.

The table below summarizes the Company's restricted stock unit activity since December 31, 2020:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested restricted stock units as of December 31, 2020	1,043,300	$ 3.21
Granted	—	—
Vested	(997,400)	3.21
Forfeited	(45,900)	3.18
Unvested restricted stock units as of December 31, 2021	—	$ —

The expense related to RSUs granted to employees was $1,103 for the year ended December 31, 2021.

At December 31, 2021, there was no unrecognized compensation cost related to unvested restricted stock units.

(In thousands, except share and per share amounts)

2018 Employee Stock Purchase Plan

On April 3, 2018, the Company's stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"), which became effective on April 18, 2018, the date on which the registration statement for the Company's initial public offering was declared effective. A total of 256,818 shares of common stock were initially reserved for issuance under this plan. In addition, the number of shares of common stock that may be issued under the ESPP automatically increased on January 1, 2019, and shall increase each January 1 thereafter through January 1, 2028, by the lesser of (i) 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 and (ii) such lesser number of shares as determined by the administrator of the Company's ESPP. As of December 31, 2021, a total of 1,084,476 shares of common stock were reserved for issuance under this plan.

For the year ended December 31, 2021 and 2020, the Company issued 46,899 and 89,172 shares of common stock, respectively, under the ESPP.

Inducement Plan

In December 2021, the Company adopted the Company's 2021 Inducement Plan (the "Inducement Plan") pursuant to which the Company reserved 600,000 shares of common stock to be used exclusively for grants of equity-based awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Marketplace Rules of the Nasdaq Stock Market, Inc. The Inducement Plan provides for the grant of equity-based awards in the form of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, unrestricted stock awards, and dividend equivalent rights. The Inducement Plan was adopted by the Company without stockholder approval pursuant to Rule 5635(c)(4) of the Marketplace Rules of the Nasdaq Stock Market, Inc. To date, there have been no grants made pursuant to the Inducement Plan.

Stock-Based Compensation

The Company recorded stock-based compensation expense related to stock options, restricted stock awards, and the ESPP in the following expense categories of its statements of operations and comprehensive loss:

	Year Ended December 31,		
	2021	2020	2019
Research and development expenses	$ 2,431	$ 2,826	$ 2,350
General and administrative expenses	6,115	4,939	3,641
	$ 8,546	$ 7,765	$ 5,991

As of December 31, 2021, the Company had an aggregate of $11,075 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.36 years.

11. Debt

On November 22, 2019, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with K2 HealthVentures LLC (the "Lender"). The Lender agreed to make available to the Company term loans in an aggregate principal amount of up to $25,000 under the Loan Agreement. On October 1, 2021, the Company entered into a First Amendment to Loan and Security Agreement (the "Loan Amendment") with the Lender, which amends the existing Loan Agreement. The Company plans to use the proceeds of the term loans to support clinical development as well as for working capital and general corporate purposes. The Loan Agreement provided a term loan commitment of $25,000 in three potential tranches: (i) a $7,500 term loan facility funded on November 22, 2019 (the "First Tranche Term Loan"), (ii) a $10,000 term loan facility funded on June 5, 2020 (the "Second Tranche Term Loan"), and (iii) a $7,500 term loan facility (the "Third Tranche Term Loan"). All three of these term loans had a maturity date of December 1, 2023.

The Company was obligated to pay a final fee equal to 4.45% of the aggregate amount of the term loans funded, such payment to occur upon the earliest of (i) the maturity date, (ii) the acceleration of the term loans, and (iii) the prepayment of the term loans.

The Lender had, at its option, the ability to convert any portion of no more than $4,000 of the then outstanding term loan amount and all accrued and unpaid interest thereon into shares of the Company’s common stock at a conversion price of $1.56 per share. The Company determined that the embedded conversion option was not required to be separated from the term loan. The embedded conversion option met the derivative accounting scope exception since the embedded conversion option is indexed to the Company’s own common stock and qualifies for classification within stockholders’ equity. The Company recognized a beneficial conversion feature of $2,101, which represents the difference between the commitment date stock price of $2.33 per share and the conversion price of $1.56 per share. The beneficial conversion feature was recorded as a discount on the term loan and is accreted to interest expense using the effective interest method over the term of the loan.

In June 2020, the Company drew down the Second Tranche Term Loan and received an additional $10,000 in proceeds. The Company was permitted to make interest-only payments on the First Tranche Term Loan and the Second Tranche Term Loan until January 2022 in accordance with the terms of the Loan Agreement.

In August 2020, the Lender elected to convert $2,000 of the outstanding term loan amount into 1,282,050 shares of the Company's common stock, in accordance with the Loan Agreement. In February 2021, the Lender elected to convert $1,500 of the outstanding term loan agreement into 961,538 shares of the Company's common stock, in accordance with the Loan Agreement. After the conversion, the outstanding principal balance was $14,000.

In October 2021, the Loan and Security Agreement was amended. Under the Loan Amendment, the Lender made available to the Company term loans in an aggregate principal amount of up to $50,000, in three potential tranches: (i) a $25,000 term loan facility (including refinancing of the Company’s outstanding amounts under the Existing Loan Agreement) funded on October 1, 2021 (the "First Tranche Refinancing Term Loan"), (ii) up to a $15,000 term loan facility (the "Second Tranche Refinancing Term Loan"), and (iii) an up to $10,000 term loan facility (the "Third Tranche Refinancing Term Loan") (together the "Refinancing Term Loans"). All three of these tranches have a maturity date of October 1, 2025.

Borrowings under all three tranches of the term loan facility bear interest at a floating per annum rate equal to the greater of (i) 8.50% and (ii) the sum of (A) the greater of (x) the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) or (y) 3.25%, plus (B) 5.25%. The Company is permitted to make interest-only payments on the outstanding principal balance of the term loan for approximately nineteen months following the funding date. The interest-only period can be extended by an additional nine months, subject to the Company raising net cash proceeds from financing activities (including without limitation sales of the Company's securities and up-front or milestone payments pursuant to existing or new strategic partnerships), in an aggregate amount of at least $100,000. The term of the loan facility is 48 months, with repayment in monthly installments commencing at the end of the resulting interest-only period as outlined above through the end of the 48-month term.

The Company is obligated to pay a final fees equal to (i) 4.25% of the aggregate amount of the term loans funded, such payment to occur upon the earliest of (a) the maturity date, (b) the acceleration of the term loans, and (c) the prepayment of the term loans and (ii) $779 on the earlier of December 1, 2023 or the prepayment of the term loans. The Company has the option to prepay all, but not less than all, of the outstanding principal balance of the term loans under the Loan Amendment. If the Company prepays all of the term loans prior to the maturity date, it will pay the Lender a prepayment penalty fee based on a percentage of the outstanding principal balance, equal to 5% if the payment occurs on or before 24 months after the initial funding date, 3% if the prepayment occurs more than 24 months after, but on or before 36 months after the initial funding date, or 1% if the prepayment occurs more than 36 months after the initial funding date.

The Lender may, at its option, elect to convert any portion of no more than $4,500 of the then outstanding term loan amount and all accrued and unpaid interest thereon into shares of the Company’s common stock at a conversion price of (i) with respect to the first $500 converted, $1.56 per share and (ii) with respect to any additional amounts converted in excess of $500, $7.81 per share.

The Company’s obligations under the Loan Amendment are secured by a first priority security interest in substantially all of its assets. The Loan Amendment contains customary representations, warranties and also includes customary events of default, including payment defaults, breaches of covenants, change of control and a material adverse effect clause.

Upon the occurrence of an event of default, a default interest rate of an additional 5.00% per annum may be applied to the outstanding loan balances, and the Lender may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the Loan Amendment and under applicable law.

The Loan Amendment has been accounted for as a debt modification; as such, the financing costs of $313 has been reflected as additional debt discount and is amortized as an adjustment to interest expense over the term of the Loan Amendment. The Company recorded interest expense related to the loan facility of $2,546, $2,745, and $147 for the years ended December 31, 2021, 2020 and 2019, respectively. The fair value of the loan at December 31, 2021 approximates its face amount due to the floating interest rate.

Future principal debt payments on the loan payable are as follows (in thousands):

	December 31, 2021
2022	$ —
2023	6,676
2024	9,604
2025	8,720
Total principal payments	25,000
Final fee due in 2023	779
Final fee due at maturity in 2025	1,063
Total principal payments and final fee	26,842
Unamortized debt discount and final fee	1,827
Note payable	$ 25,015

12. Net Income (Loss) per Share

Basic and diluted net income (loss) per share attributable to common stockholders was calculated as follows:

	Year Ended December 31,		
	2021	2020	2019
Basic net income (loss) per share:			
Numerator:			
Net income (loss)	$ (78,485)	$ 59,337	$ (54,789)
Denominator:			
Weighted average commons shares outstanding—basic	44,243,317	35,545,121	27,854,912
Net income (loss) per share—basic	$ (1.77)	$ 1.67	$ (1.97)
Diluted net income (loss) per share:			
Numerator:			
Net income (loss) - basic	$ (78,485)	$ 59,337	$ (54,789)
Interest expense on convertible note payable	—	395	—
Net income (loss) - diluted	$ (78,485)	$ 59,732	$ (54,789)
Denominator:			
Weighted average commons shares outstanding—basic	44,243,317	35,545,121	27,854,912
Shares issuable upon conversion of convertible notes, as if converted	—	1,282,052	—
Dilutive effect of restricted stock units	—	557,402	—
Dilutive effect of common stock equivalents	—	757,218	—
Weighted average commons shares outstanding—diluted	44,243,317	38,141,793	27,854,912
Net income (loss) per share—diluted	$ (1.77)	$ 1.57	$ (1.97)

(In thousands, except share and per share amounts)

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share for the year ended December 31, 2021, as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated above because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2021	2020
Stock Options to purchase common stock	7,057,258	3,146,458
Shares to be issued under the ESPP	1,084,476	—
RSUs issued and expected to vest	—	2,400
Shares available from conversion of note payable	832,677	—

13. License Agreements

Adimab Development and Option Agreement

In October 2018, the Company and Adimab LLC ("Adimab"), entered into an amended and restated development and option agreement, ("the A&R Adimab Agreement"), which amended and restated the development and option agreement with Adimab dated July 2014, as amended, ("the Original Adimab Agreement"), for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the A&R Adimab Agreement, the Company will select biological targets against which Adimab will use its proprietary platform technology to research and develop antibody proteins using a mutually agreed upon research plan. The A&R Adimab Agreement, among other things, extended the discovery term of the Original Adimab Agreement, provided access to additional antibodies, and expanded the Company's right to evaluate and use antibodies that were modified or derived using Adimab technology for diagnostic purposes.

Upon the Company's selection of a target, the Company and Adimab will initiate a research plan and the discovery term begins. During the discovery term, Adimab will grant the Company a non-exclusive, non-sublicenseable license under its technology with respect to the target, to research, design and preclinically develop and use antibodies that were modified or derived using Adimab technology, solely to evaluate such antibodies, perform the Company's responsibilities under the research plan, and use such antibodies for certain diagnostic purposes. The Company also will grant to Adimab a non-exclusive, nontransferable license with respect to the target under the Company's technology that covers or relates to such target, solely to perform its responsibilities under the research plan during the discovery period. The Company is required to pay Adimab at an agreed upon rate for its full-time employees during the discovery period while Adimab performs research on each target under the applicable research plan.

Adimab granted the Company an exclusive option to obtain a non-exclusive, worldwide, fully paid-up, sublicensable license under Adimab's platform patents and other Adimab technology solely to research up to ten antibodies, chosen by the Company against a specific biological target for a specified period of time (the "Research Option"). In addition, Adimab granted the Company an exclusive option to obtain a worldwide, royalty-bearing, sublicensable license under Adimab platform patents and other Adimab technology to exploit, including commercially, 20 or more antibodies against specific biological targets (the "Commercialization Option"). Upon the exercise of a Commercialization Option, and payment of the applicable option fee to Adimab, Adimab will assign the Company the patents that cover the antibodies selected by such Commercialization Option. The Company will be required to use commercially reasonable efforts to develop, seek market approval of, and commercialize at least one antibody against the target covered by the Commercialization Option in specified markets upon the exercise of a Commercialization Option.

Under the agreement, the Company is obligated to make milestone payments and to pay specified fees upon the exercise of the Research or Commercialization Options. During the discovery term, the Company may be obligated to pay Adimab up to 250 for technical milestones achieved against each biological target. Upon exercise of a Research Option, the Company is obligated to pay a nominal research maintenance fee on each of the next four anniversaries of the exercise. Upon the exercise of each Commercialization Option, the Company will be required to pay an option exercise fee of a low seven-digit dollar amount, and the Company may be responsible for milestone payments of up to an aggregate of $13,000 for each licensed product that receives marketing approval. For any licensed product that is commercialized, the Company is obligated to pay Adimab tiered royalties of a low to mid single-digit percentage on worldwide net sales of such product. The Company may also partially exercise a Commercialization Option with respect to ten antibodies against a biological target by paying 65% of the option fee and later either (i) paying the balance and choosing additional antibodies for commercialization, up to the maximum number under the Commercialization Option, or (ii) foregoing the Commercialization Option entirely. For any Adimab diagnostic product that is used with or in connection with any compound or product other than a licensed antibody or licensed product, the Company is obligated to pay Adimab up to a low seven digits in regulatory milestone payments and low single-digit royalties on net sales. No additional payment is due with respect to any companion diagnostic or any diagnostic product that does not contain any licensed antibody. Any payments payable to Adimab as a result of any product candidates being developed pursuant to the GSK Agreement, will be payable to Adimab directly by GSK.

The A&R Adimab Agreement will remain in effect until (a) the earlier of (i) the expiration of the Research and Commercialization Options (if they expire without exercise) and (ii) 12 months from the effective date without the Company providing materials that pass Adimab’s quality control; or (b) if a Research Option is exercised but the Commercialization Option is not, then upon the expiration of the last to expire research license term; or (c) upon commercialization of a product, until the end of the royalty term, which will vary on a product-by-product and country-by-country basis, ending on the later of (y) the expiration of the last valid claim covering the licensed product in such country as the product is manufactured or sold, or (z) ten after the first commercial sale of the licensed product in such country.

Either party may terminate the A&R Adimab Agreement for material breach if such breach remains uncured for a specified period of time, however, if a Research Option or Commercialization Option has been exercised and the breach only applies to the applicable target of such Research Option or Commercialization Option, then the termination right will only apply to such target. The Company may also terminate the A&R Adimab Agreement for any reason with prior notice to Adimab. If Adimab is bankrupt, the Company will be entitled to a complete duplicate of, or complete access to, all rights and licenses granted under or pursuant to the A&R Adimab Agreement.

During the years ended December 31, 2021, 2020, and 2019, the Company recognized research and development expense under the agreement of $3,000, $3,092, and $1,175, respectively.

Memorial Sloan Kettering Cancer Center License Agreement

In November 2020, the Company and Memorial Sloan Kettering Cancer Center ("MSK") entered into a license agreement (the "MSK Agreement"). Under the agreement, MSK granted the Company a non-exclusive license to certain U.S. patent rights relating to methods of treating cancer with CCR8 antibodies to research, develop, make, use, sell, offer for sale, and import CCR8 antibodies intended to treat cancer.

Under the terms of the MSK Agreement the upfront license execution fee due to MSK was $100. Half of the execution fee was due to MSK upon signature of the agreement, with the remaining portion due on the first anniversary. Under the MSK Agreement, each of these CCR8 antibodies is a licensed product and the Company is obligated to make milestone payments of up to an aggregate of $7,500 for each licensed product, as well as reimburse MSK for a portion of past and future patent-related expenses. For any licensed product that is commercialized, the Company is obligated to pay MSK a low single-digit percentage royalty on net U.S. sales of such product.

The MSK License will remain in effect on a licensed product-by-licensed product basis until the later of when there is no longer a valid patent claim covering the composition, manufacture or use of such licensed product or 10 years from the date of first commercial sale of such licensed product in the U.S. The Company may terminate the MSK License for any reason with thirty days prior written notice to MSK. MSK may terminate the MSK License immediately upon written notice if the Company is convicted of a felony relating to the manufacture, use or sale of a licensed product anywhere we may manufacture, use or sell the licensed product, or, with a specified notice period, in the event of the Company's insolvency, bankruptcy, or cessation of business operations. MSK may also terminate the MSK License for nonpayment of any fees, milestones or royalties if such payment(s) remain past due for a specified period of time, and for an uncured material breach.

(In thousands, except share and per share amounts)

During the years ended December 31, 2021 and 2020, the Company recognized research and development expense under the agreement of $50 and $50.

Vaccinex Exclusive Product License Agreement

In March 2021, the Company and Vaccinex entered into an exclusive product license agreement (the "Vaccinex License Agreement"), to exclusively license certain antibodies, including SRF114. Pursuant to the terms of the Vaccinex License Agreement, the Company has a worldwide, exclusive, sublicensable license to make, have made, use, sell, offer to sell, have sold, import, and otherwise exploit licensed products that incorporate certain Vaccinex intellectual property which covers certain antibodies, including the antibody SRF114 targeting CCR8, each a “Licensed Product.”

Under the Vaccinex License Agreement, the Company is obligated to use commercially reasonable efforts to develop, clinically test, achieve regulatory approval, manufacture, market and commercialize at least one Licensed Product and have the sole right to develop, manufacture and commercialize the licensed products worldwide. The Company is responsible for all costs and expenses of such development, manufacturing and commercialization. Pursuant to the Vaccinex License Agreement, the Company paid Vaccinex a one-time fee of $850,000. Vaccinex is eligible to receive up to an aggregate of $3,500 based on achievement of certain clinical milestones and up to an aggregate of $11,500 based on achievement of certain regulatory milestones per Licensed Product. The Company also owes low single digit royalties on global net sales of any approved Licensed Products. Commencing on the third anniversary of the date of the Vaccinex License Agreement and continuing until the first dosing of a Licensed Product in a clinical trial, the Company will be required to pay Vaccinex a nominal yearly maintenance fee.

The Company may terminate the Vaccinex License Agreement for convenience upon the notice period specified in the Vaccinex License Agreement. Either party may terminate the Vaccinex License Agreement for an uncured material breach by the other party. Vaccinex may terminate the Vaccinex License Agreement if the Company defaults on any payments owed to Vaccinex under the agreement, if the Company is in material breach of, and fail to cure, its development obligations, or institute certain actions related to the licensed patents. In the event of termination, all rights in the licensed intellectual property would revert to Vaccinex.

During the years ended December 31, 2021, the Company recognized research and development expense under the Vaccinex License Agreement of $850.

14. Income Taxes

	Year Ended December 31,		
	2021	**2020**	**2019**
Income (loss) before taxes:			
Domestic	$ (78,485)	$ 59,346	$ (54,789)
Foreign	—	—	—
Total income (loss) before income taxes	$ (78,485)	$ 59,346	$ (54,789)

Income Taxes

During the years ended December 31, 2021 and 2019, the Company recorded no income tax benefits for the net losses incurred or for the research and development tax credits generated in each year due to its uncertainty of realizing a benefit from those items. During the year ended December 31, 2020, the Company recorded no income tax expense or benefit for the net income incurred or for the research and development tax credits generated during the year due to the utilization of net operating loss carryforwards and the uncertainty of realizing a benefit from the credits.

SURFACE ONCOLOGY, INC.
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(In thousands, except share and per share amounts)

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

	Year Ended December 31,		
	2021	2020	2019
Federal statutory income tax rate	(21.0)%	21.0 %	(21.0)%
State taxes, net of federal benefit	(12.5)%	6.3 %	(6.2)%
Stock-based compensation	0.2 %	0.5 %	1.0 %
Research and development tax credits	(5.0)%	(3.2)%	(7.9)%
Change in deferred tax asset valuation allowance	38.1 %	(24.5)%	33.7 %
Other	0.2 %	(0.1)%	0.4 %
Effective income tax rate	— %	— %	— %

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2021 and 2020 are as follows:

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 30,313	$ 8,635
Research and development tax credit carryforwards	12,230	8,344
Intangible assets	1,812	1,235
Accrued expenses	1,422	—
Stock-based compensation	5,237	3,911
Lease liability	8,808	9,428
Interest expense	269	—
Other	180	—
Total deferred tax assets	60,271	31,553
Valuation allowance	(51,957)	(21,961)
Deferred tax assets	8,314	9,592
Deferred tax liabilities:		
Right-of-use asset	(7,056)	(7,625)
Depreciation	(1,150)	(1,478)
Beneficial conversion feature on convertible note payable	(32)	(397)
Other	(76)	(92)
Total deferred tax liabilities	(8,314)	(9,592)
Net deferred tax assets	$ —	$ —

As of December 31, 2021 and 2020, the Company had federal net operating loss carryforwards of $92,735 and $31,394, respectively, and state net operating loss carryforwards of $155,989 and $32,312, respectively, available to reduce future income tax liabilities. As of December 31, 2021 and 2020, the Company also had federal research and development tax credit carryforwards of $9,747 and $6,259, respectively, and state research and development tax credit carryforwards of $3,067 and $2,545, respectively, available to reduce future income tax liabilities. The federal net operating loss carryforwards do not expire and the state net operating loss carryforwards begin to expire in 2039. The federal and state research and development tax credit carryforwards begin to expire in 2034 and 2032, respectively.

(In thousands, except share and per share amounts)

Utilization of the Company's net operating loss ("NOL") carryforwards and research and development ("R&D") credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 ("Section 382") as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock on several occasions. These financings, combined with the purchasing shareholders' subsequent disposition of those shares, could result in a change of control as defined by Section 382. The Company conducted an analysis under Section 382 to determine if historical changes in ownership through December 31, 2020 would limit or otherwise restrict its ability to utilize its NOL and R&D credit carryforwards. As a result of this analysis, the Company does not believe there are any significant limitations on its ability to utilize these carryforwards. However, future changes in ownership occurring after December 31, 2020 could affect the limitation in future years, and any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization.

As required by the provisions of ASC 740, management considers whether it is more likely than not that some portion or all of the net deferred tax assets will not be realized. Based upon the level of historical U.S. losses, management has determined that it is “more-likely-than-not” that the Company will not utilize the benefits of federal and state deferred tax assets for financial reporting purposes and, as a result, a full valuation allowance has been established at December 31, 2021 and 2020. The valuation allowance increase primarily relates to the Company's revenue recognition for tax purposes, and were as follows:

	Year Ended December 31,		
	2021	2020	2019
Valuation allowance at beginning of year	$ (21,961)	$ (36,535)	$ (18,602)
Increases recorded to income tax provision	(30,616)	(11,675)	(17,933)
Decreases recorded as a benefit to income tax provision	620	26,249	—
Valuation allowance at end of year	$ (51,957)	$ (21,961)	$ (36,535)

The Company had no unrecognized tax benefits or related interest and penalties accrued for the years ended December 31, 2021 and 2020. The Company will recognize interest and penalties related to uncertain tax positions in income tax expense.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company's tax years are still open under statute from 2018 to present. All years may be examined to the extent the tax credit or net operating loss carryforwards are used in future periods. There are currently no federal or state audits.

15. Leases

The Company leases real estate, primarily its corporate headquarters in Cambridge, Massachusetts. The Company’s leases have remaining terms ranging from 1 year to 8 years. Certain leases include options to renew, exercised at the Company’s sole discretion, with renewal terms that can extend the lease five years. The Company evaluated the renewal options in its leases to determine if it was reasonably certain that the renewal option would be exercised, and therefore should be included in the calculation of the operating lease assets and operating lease liabilities. Given the Company’s current business structure, uncertainty of future growth, and the associated impact to real estate, the Company concluded that it is not reasonably certain that the renewal option related to its corporate headquarters would be exercised. However, for leases it determined the renewal option was probable to be exercised, the Company included the renewal period in the calculation of the operating lease right-of-use assets and operating lease liabilities. All of the Company’s leases qualify as operating leases. With the adoption of the new leasing standard, the Company has recorded a right-of-use asset and corresponding lease liability, by calculating the present value of future lease payments, discounted at either 9.5% or 10.5%, the Company’s incremental borrowing rates, over the expected term. The right-of-use asset is reduced by any lease incentives received and the legacy deferred rent balance.

(In thousands, except share and per share amounts)

In May 2016, the Company entered into an operating lease agreement for its corporate headquarters in Cambridge, Massachusetts, with a ten-year term that expires in February 2027 (“Initial Space”). Rental payments related to the lease commenced in April 2017. In connection with this lease, the Company was entitled to cash incentives from the landlord to be used for the construction of leasehold improvements within the facility. As of January 1, 2019, the Company was entitled to $4,803 of such incentives, which were recorded as a reduction to the right-of-use asset and included as a straight-line reduction to lease expense over the lease term.

In May 2018, the Company executed an amendment to lease an additional 33,526 square feet at 50 Hampshire Street in Cambridge, Massachusetts, with a 10-year term (“Expansion Space”). This additional space became available for occupancy on January 1, 2020 and rental payments related to the lease commenced in April 2020. In connection with this lease amendment, the Company is entitled to a landlord-provided tenant improvement allowance of up to $1,005 to be applied to the cost of the construction of leasehold improvements. The Company determined that it owns the leasehold improvements and, as such, reflected the $1,005 lease incentive as a reduction of the rental payments used to measure the operating lease liability, and, in turn, the operating lease right-of-use asset as of the lease commencement date.

The components of the Company’s lease expense are as follows:

Lease Costs	Classification	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Operating lease cost	R&D Expense	$ 2,000	$ 2,111	$ 2,312
	G&A Expense	3,353	3,292	899
Variable lease costs [(1)]	R&D Expense	641	585	707
	G&A Expense	1,112	1,169	276
Total lease cost		$ 7,106	$ 7,157	$ 4,194
Weighted-average remaining lease term (in months)		98.73	109.84	119.6
Weighted-average discount rate		10.5 %	10.5 %	10.5 %

(1) Variable lease costs include certain additional charges for operating costs, including insurance, maintenance, taxes, utilities, and other costs incurred, which are billed based on both usage and as a percentage of the Company’s share of total square footage. Short term lease costs are immaterial.

Cash paid for amounts included in the measurement of the Company’s operating lease liabilities was $7,916 and $6,608 for the years ended December 31, 2021 and 2020.

As of December 31, 2021, the maturities of the Company’s operating lease liabilities were as follows:

Year Ending December 31,	
2022	$ 5,385
2023	5,413
2024	5,533
2025	5,656
2026	5,782
Thereafter	20,083
Total future lease payments	47,852
Less: Interest	(15,559)
Present value of future lease payments (lease liability)	$ 32,293

(In thousands, except share and per share amounts)

Future minimum lease payments for the Company’s operating leases as of December 31, 2020 were as follows:

Year Ending December 31,		
2021	$	5,529
2022		5,385
2023		5,413
2024		5,533
2025		5,656
Thereafter		25,865
	$	53,381

Sublease Agreement with EQRx, Inc.

In December 2019, the Company entered into a sublease agreement with EQRx, Inc. to sublease the entire Expansion Space. The term of the sublease agreement commenced in January 2020 and ends on the last day of the 36th calendar month following rent commencement, with no option to extend. The annual rent for the subleased premises is greater than the annual rent owed by the Company to the landlord for the leased premises. The sublessee is obligated to pay all real estate taxes and costs related to the subleased premises, including cost of operations, maintenance, repair, replacement and property management. The Company concluded that the sublease is an operating lease. Consistent with the Company’s policy election for lessor operating leases, each lease component and its associated non-lease components is accounted for as a single lease component.

As of December 31, 2021, future undiscounted cash inflows under the sublease are as follows:

Year Ending December 31,		
2022	$	2,884
2023		241
	$	3,125

In the years ended December 31, 2021 and 2020, the Company recognized sublease income of $3,371 and $3,169, respectively.

16. Commitments and Contingencies

Lease Agreements

The Company has entered into lease agreements under which it is obligated to make rental payments (see Note 15).

Manufacturing and Research Agreements

The Company has entered into agreements with external contract manufacturing organizations and contract research organizations engaged to manufacture clinical trial materials as well as to conduct discovery research and preclinical development activities.

License Agreements

The Company has entered into license agreements with various parties under which it is obligated to make contingent and non-contingent payments (see Note 13).

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that would have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of December 31, 2021.

Legal Proceedings

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

17. Related Party Transactions

Novartis Institutes for BioMedical Research, Inc.

Novartis is a related party because it is a greater than 5% stockholder of the Company. In January 2016, the Company entered into the Novartis Agreement and sold 2,000,000 shares of its Series A-1 preferred stock to Novartis for gross proceeds of $13,500. In addition, concurrent with the Company's initial public offering of common stock, the Company issued Novartis 766,666 shares of its common stock at $15.00 per share for proceeds of $11,500 in a private placement. During the year ended December 31, 2021, the Company did not receive any cash payments from Novartis. As of December 31, 2021 and 2020, no amounts were due from Novartis.

During the years ended December 31, 2021, 2020 and 2019, the Company made no cash payments to Novartis related to the Novartis Agreement.

Research Agreement with Vaccinex, Inc.

On November 30, 2017, the Company entered into a research agreement (the "Vaccinex Research Agreement") with Vaccinex, whereby Vaccinex will use its technology to assist the Company with identifying and selecting experimental human monoclonal antibodies against targets selected by the Company. On March 23, 2021, the Company exercised its option under the Vaccinex Research Agreement to enter into the Vaccinex License Agreement to exclusively license certain antibodies generated under the Vaccinex Research Agreement. The Company's former Chief Executive Officer and current member of its board of directors is a member of the board of directors of Vaccinex.

During the years ended December 31, 2021, 2020, and 2019, the Company paid Vaccinex an aggregate of $50, $50 and $606, respectively, relating to the Vaccinex Research Agreement. During the year ended December 31, 2021, the Company paid Vaccinex $850 relating to the Vaccinex License Agreement. The payments under the Vaccinex Research Agreement and the Vaccinex License Agreements were recognized as research and development expense during the years ended December 31, 2021, 2020, and 2019. No amounts were due by the Company to Vaccinex as of December 31, 2021 and 2020.

18. 401(k) Savings Plan

The Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements. The Company matches 100% of employees' contributions to the 401(k) Plan up to 3% of compensation and 50% of employees' contributions to the 401(k) Plan for salary deferrals between 3% and 5% of compensation. The Company's contributions made under the 401(k) Savings Plan for the years ended December 31, 2021, 2020, and 2019 totaled $403, $370, and $399, respectively.

Exhibit 10.11

SURFACE ONCOLOGY, INC.
2021 INDUCEMENT PLAN

SECTION 1. GENERAL PURPOSE OF THE PLAN; DEFINITIONS

The name of the plan is the Surface Oncology, Inc. 2021 Inducement Plan (the "Plan"). The purpose of the Plan is to encourage and enable Surface Oncology, Inc. (the "Company") to grant equity awards to induce highly-qualified prospective officers and employees to accept employment and provide them with a proprietary interest in the Company. It is anticipated that providing such persons with a direct stake in the Company's welfare will assure a closer identification of their interests with those of the Company and its stockholders, thereby stimulating their efforts on the Company's behalf and strengthening their desire to remain with the Company. The Company intends that the Plan be reserved for persons to whom the Company may issue securities without stockholder approval as an inducement pursuant to Rule 5635(c)(4) of the Marketplace Rules of the NASDAQ Stock Market, Inc.

The following terms shall be defined as set forth below:

"*Act*" means the Securities Act of 1933, as amended, and the rules and regulations thereunder.

"*Administrator*" means either the Board or the compensation committee of the Board or a similar committee performing the functions of the compensation committee and which is comprised of not less than two Non-Employee Directors who are independent.

"*Award*" or "*Awards*," except where referring to a particular category of grant under the Plan, shall include Non-Qualified Stock Options, Stock Appreciation Rights, Restricted Stock Units, Restricted Stock Awards, Unrestricted Stock Awards, and Dividend Equivalent Rights.

"*Award Certificate*" means a written or electronic document setting forth the terms and provisions applicable to an Award granted under the Plan. Each Award Certificate is subject to the terms and conditions of the Plan.

"*Board*" means the Board of Directors of the Company.

"*Code*" means the Internal Revenue Code of 1986, as amended, and any successor Code, and related rules, regulations and interpretations.

"*Consultant*" means any natural person that provides bona fide services to the Company, and such services are not in connection with the offer or sale of securities in a capital-raising transaction and do not directly or indirectly promote or maintain a market for the Company's securities.

"*Dividend Equivalent Right*" means an Award entitling the grantee to receive credits based on cash dividends that would have been paid on the shares of Stock specified in the Dividend Equivalent Right (or other award to which it relates) if such shares had been issued to and held by the grantee.

"*Effective Date*" means the date on which the Plan is approved by the Board as set forth in Section 19.

"*Exchange Act*" means the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder.

"*Fair Market Value*" of the Stock on any given date means the fair market value of the Stock determined in good faith by the Administrator; provided, however, that if the Stock is admitted to quotation on the National Association of Securities Dealers Automated Quotation System ("NASDAQ"), NASDAQ Global Market or another national securities exchange, the determination shall be made by reference to market quotations. If there are no market quotations for such date, the determination shall be made by reference to the last date preceding such date for which there are market quotations.

"*Non-Employee Director*" means a member of the Board who is not also an employee of the Company or any Subsidiary.

"*Non-Qualified Stock Option*" means any Stock Option that is not an "incentive stock option" under Section 422 of the Code.

"*Option*" or "*Stock Option*" means any option to purchase shares of Stock granted pursuant to Section 5.

"*Restricted Shares*" means the shares of Stock underlying a Restricted Stock Award that remain subject to a risk of forfeiture or the Company's right of repurchase.

"*Restricted Stock Award*" means an Award of Restricted Shares subject to such restrictions and conditions as the Administrator may determine at the time of grant.

"*Restricted Stock Units*" means an Award of stock units subject to such restrictions and conditions as the Administrator may determine at the time of grant.

"*Sale Event*" shall mean (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power and outstanding stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction, (iii) the sale of all of the Stock of the Company to an unrelated person, entity or group thereof acting in concert, or (iv) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company.

"*Sale Price*" means the value as determined by the Administrator of the consideration payable, or otherwise to be received by stockholders, per share of Stock pursuant to a Sale Event.

"*Section 409A*" means Section 409A of the Code and the regulations and other guidance promulgated thereunder.

"*Service Relationship*" means any relationship as a full-time employee, part-time employee, director or other key person (including Consultants) of the Company or any Subsidiary or any successor entity (e.g., a Service Relationship shall be deemed to continue without interruption in the event an individual's status changes from full-time employee to part-time employee or Consultant).

"*Stock*" means the Common Stock, par value $0.0001 per share, of the Company, subject to adjustments pursuant to Section 3.

"*Stock Appreciation Right*" means an Award entitling the recipient to receive shares of Stock (or cash, to the extent explicitly provided for in the applicable Award Certificate) having a value equal to the excess of the Fair Market Value of the Stock on the date of exercise over the exercise price of the Stock Appreciation Right multiplied by the number of shares of Stock with respect to which the Stock Appreciation Right shall have been exercised.

"*Subsidiary*" means any corporation or other entity (other than the Company) in which the Company has at least a 50 percent interest, either directly or indirectly.

"*Unrestricted Stock Award*" means an Award of shares of Stock free of any restrictions.

SECTION 2. <u>ADMINISTRATION OF PLAN; ADMINISTRATOR AUTHORITY TO SELECT GRANTEES AND DETERMINE AWARDS</u>

(a) <u>Administration of Plan</u>. The Plan shall be administered by the Administrator.

(b) Powers of Ad<u>ministrator</u>. The Administrator shall have the power and authority to grant Awards consistent with the terms of the Plan, including the power and authority:

(i) to select the individuals to whom Awards may from time to time be granted;

(ii) to determine the time or times of grant, and the extent, if any, of Non-Qualified Stock Options, Stock Appreciation Rights, Restricted Stock Awards, Restricted Stock Units, Unrestricted Stock Awards, Dividend Equivalent Rights, or any combination of the foregoing, granted to any one or more grantees;

(iii) to determine the number of shares of Stock to be covered by any Award;

(iv) to determine and modify from time to time the terms and conditions, including restrictions, not inconsistent with the terms of the Plan, of any Award, which terms and conditions may differ among individual Awards and grantees, and to approve the forms of Award Certificates;

(v) to accelerate at any time the exercisability or vesting of all or any portion of any Award in circumstances involving the grantee's death or disability;

(vi) subject to the provisions of Section 5(c), to extend at any time the period in which Stock Options may be exercised; and

(vii) at any time to adopt, alter and repeal such rules, guidelines and practices for administration of the Plan and for its own acts and proceedings as it shall deem advisable; to interpret the terms and provisions of the Plan and any Award (including related written instruments); to make all determinations it deems advisable for the administration of the Plan; to decide all disputes arising in connection with the Plan; and to otherwise supervise the administration of the Plan.

All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and Plan grantees.

(c) Reserved.

(d) Award Certificate. Awards under the Plan shall be evidenced by Award Certificates that set forth the terms, conditions and limitations for each Award which may include, without limitation, the term of an Award and the provisions applicable in the event employment or service terminates.

(e) Indemnification. Neither the Board nor the Administrator, nor any member of either or any delegate thereof, shall be liable for any act, omission, interpretation, construction or determination made in good faith in connection with the Plan, and the members of the Board and the Administrator (and any delegate thereof) shall be entitled in all cases to indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including, without limitation, reasonable attorneys' fees) arising or resulting therefrom to the fullest extent permitted by law and/or under the Company's articles or bylaws or any directors' and officers' liability insurance coverage which may be in effect from time to time and/or any indemnification agreement between such individual and the Company.

(f) Foreign Award Recipients. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws in other countries in which the Company and its Subsidiaries operate or have employees or other individuals eligible for Awards, the Administrator, in its sole discretion, shall have the power and authority to: (i) determine which Subsidiaries shall be covered by the Plan; (ii) determine which individuals outside the United States are eligible to participate in the Plan; (iii) modify the terms and conditions of any Award granted to individuals outside the United States to comply with applicable foreign laws; (iv) establish subplans and modify exercise procedures and other terms and procedures, to the extent the Administrator determines such actions to be necessary or advisable (and such subplans and/or modifications shall be attached to this Plan as appendices); provided, however, that no such subplans and/or modifications shall increase the share limitations contained in Section 3(a) hereof; and (v) take any action, before or after an Award is made, that the Administrator determines to be necessary or advisable to obtain approval or comply with any local governmental regulatory exemptions or approvals. Notwithstanding the foregoing, the Administrator may not take any actions hereunder, and no Awards shall be granted, that would violate the Exchange Act or any other applicable United States securities law, the Code, or any other applicable United States governing statute or law.

SECTION 3. STOCK ISSUABLE UNDER THE PLAN; MERGERS; SUBSTITUTION

(a) Stock Issuable. The maximum number of shares of Stock reserved and available for issuance under the Plan shall be 600,000 shares, subject to adjustment as provided in Section 3(c). For purposes of this limitation, the shares of Stock underlying any Awards that are forfeited, canceled, held back upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of Stock or otherwise terminated (other than by exercise) under the Plan shall be added back to the shares of Stock available for issuance under the Plan. In the event the Company repurchases shares of Stock on the open market, such shares shall not be added to the shares of Stock available for issuance under the Plan. The shares available for issuance under the Plan may be authorized but unissued shares of Stock or shares of Stock reacquired by the Company.

(b) Reserved.

(c) Changes in Stock. Subject to Section 3(d) hereof, if, as a result of any reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock, the outstanding shares of Stock are increased or decreased or are exchanged for a different number or kind of shares or other securities of the Company, or additional shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such shares of Stock or other securities, or, if, as a result of any merger or consolidation, sale of all or substantially all of the assets of the Company, the outstanding shares of Stock are converted into or exchanged for securities of the Company or any successor entity (or a parent or subsidiary thereof), the Administrator shall make an appropriate or proportionate adjustment in (i) the maximum number of shares reserved for issuance under the Plan, (ii) the number of shares or other securities subject to any then outstanding Awards under the Plan, (iii) the repurchase price, if any, per share subject to each outstanding Restricted Stock Award, and (iv) the exercise price for each share subject to any then outstanding Stock Options and Stock Appreciation Rights under the Plan, without changing the aggregate exercise price (i.e., the exercise price multiplied by the number of Stock Options and Stock Appreciation Rights) as to which such Stock Options and Stock Appreciation Rights remain exercisable. The Administrator shall also make equitable or proportionate adjustments in the number of shares subject to outstanding Awards and the exercise price and the terms of outstanding Awards to take into consideration cash dividends paid other than in the ordinary course or any other extraordinary corporate event. The adjustment by the Administrator shall be final, binding and conclusive. No fractional shares of Stock shall be issued under the Plan resulting from any such adjustment, but the Administrator in its discretion may make a cash payment in lieu of fractional shares.

(d) Mergers and Other Transactions. In the case of and subject to the consummation of a Sale Event, the parties thereto may cause the assumption or continuation of Awards theretofore granted by the successor entity, or the substitution of such Awards with new Awards of the successor entity or parent thereof, with appropriate adjustment as to the number and kind of shares and, if appropriate, the per share exercise prices, as such parties shall agree. To the extent the parties to such Sale Event do not provide for the assumption, continuation or substitution of Awards, upon the effective time of the Sale Event, the Plan and all outstanding Awards granted hereunder shall terminate. In such case, except as may be otherwise provided in the relevant Award Certificate, all Options and Stock Appreciation Rights that are not exercisable immediately prior to the effective time of the Sale Event shall become fully exercisable as of the effective time of the Sale Event, all other Awards with time-based vesting, conditions or restrictions shall become fully vested and nonforfeitable as of the effective time of the Sale Event, and all Awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with a Sale Event in the Administrator's discretion or to the extent specified in the relevant Award Certificate. In the event of such termination, (i) the Company shall have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the grantees holding Options and Stock Appreciation Rights, in exchange for the cancellation thereof, in an amount equal to the difference between (A) the Sale Price multiplied by the number of shares of Stock subject to outstanding Options and Stock Appreciation Rights (to the extent then exercisable at prices not in excess of the Sale Price) and (B) the aggregate exercise price of all such outstanding Options and Stock Appreciation Rights (provided that, in the case of an Option or Stock Appreciation Right with an exercise price equal to or greater than the Sale Price, such Option or Stock Appreciation Right shall be cancelled for no consideration); or (ii) each grantee shall be permitted, within a specified period of time prior to the consummation of the Sale Event as determined by the Administrator, to exercise all outstanding Options and Stock Appreciation Rights (to the extent then exercisable) held by such grantee. The Company shall also have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the grantees holding other Awards in an amount equal to the Sale Price multiplied by the number of vested shares of Stock under such Awards.

SECTION 4. ELIGIBILITY

Grantees under the Plan will be such individuals to whom the Company may issue securities without stockholder approval in accordance with Rule 5635(c)(4) of the Marketplace Rules of the NASDAQ Stock Market, Inc. and related guidance thereunder, as are selected from time to time by the Administrator in its sole discretion.

SECTION 5. STOCK OPTIONS

(a) Award of Stock Options. The Administrator may grant Stock Options under the Plan. Any Stock Option granted under the Plan shall be a Non-Qualified Stock Option and shall be in such form as the Administrator may from time to time approve.

Stock Options granted pursuant to this Section 5 shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Administrator shall deem desirable.

(b) Exercise Price. The exercise price per share for the Stock covered by a Stock Option granted pursuant to this Section 5 shall be determined by the Administrator at the time of grant but shall not be less than 100 percent of the Fair Market Value on the date of grant.

(c) Option Term. The term of each Stock Option shall be fixed by the Administrator, but no Stock Option shall be exercisable more than ten years after the date the Stock Option is granted.

(d) Exercisability; Rights of a Stockholder. Stock Options shall become exercisable at such time or times, whether or not in installments, as shall be determined by the Administrator at or after the grant date. Subject to Section 2(b)(v), the Administrator may at any time accelerate the exercisability of all or any portion of any Stock Option. An optionee shall have the rights of a stockholder only as to shares acquired upon the exercise of a Stock Option and not as to unexercised Stock Options.

(e) Method of Exercise. Stock Options may be exercised in whole or in part, by giving written or electronic notice of exercise to the Company, specifying the number of shares to be purchased. Payment of the purchase price may be made by one or more of the following methods except to the extent otherwise provided in the Option Award Certificate:

(i) In cash, by certified or bank check or other instrument acceptable to the Administrator;

(ii) Through the delivery (or attestation to the ownership following such procedures as the Company may prescribe) of shares of Stock that are not then subject to restrictions under any Company plan. Such surrendered shares shall be valued at Fair Market Value on the exercise date;

(iii) By the optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company for the purchase price; provided that in the event the optionee chooses to pay the purchase price as so provided, the optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Company shall prescribe as a condition of such payment procedure; or

(iv) By a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price.

Payment instruments will be received subject to collection. The transfer to the optionee on the records of the Company or of the transfer agent of the shares of Stock to be purchased pursuant to the exercise of a Stock Option will be contingent upon receipt from the optionee (or a purchaser acting in his stead in accordance with the provisions of the Stock Option) by the Company of the full purchase price for such shares and the fulfillment of any other requirements contained in the Option Award Certificate or applicable provisions of laws (including the satisfaction of any withholding taxes that the Company is obligated to withhold with respect to the optionee). In the event an optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the optionee upon the exercise of the Stock Option shall be net of the number of attested shares. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the exercise of Stock Options, such as a system using an internet website or interactive voice response, then the paperless exercise of Stock Options may be permitted through the use of such an automated system.

SECTION 6. STOCK APPRECIATION RIGHTS

(a) Award of Stock Appreciation Rights. The Administrator may grant Stock Appreciation Rights under the Plan. A Stock Appreciation Right is an Award entitling the recipient to receive shares of Stock (or cash, to the extent explicitly provided for in the applicable Award Certificate) having a value equal to the excess of the Fair Market Value of a share of Stock on the date of exercise over the exercise price of the Stock Appreciation Right multiplied by the number of shares of Stock with respect to which the Stock Appreciation Right shall have been exercised.

(b) Exercise Price of Stock Appreciation Rights. The exercise price of a Stock Appreciation Right shall not be less than 100 percent of the Fair Market Value of the Stock on the date of grant.

(c) Grant and Exercise of Stock Appreciation Rights. Stock Appreciation Rights may be granted by the Administrator independently of any Stock Option granted pursuant to Section 5 of the Plan.

(d) Terms and Conditions of Stock Appreciation Rights. Stock Appreciation Rights shall be subject to such terms and conditions as shall be determined on the date of grant by the Administrator. The term of a Stock

Appreciation Right may not exceed ten years. The terms and conditions of each such Award shall be determined by the Administrator, and such terms and conditions may differ among individual Awards and grantees.

SECTION 7. RESTRICTED STOCK AWARDS

(a) Nature of Restricted Stock Awards. The Administrator may grant Restricted Stock Awards under the Plan. A Restricted Stock Award is any Award of Restricted Shares subject to such restrictions and conditions as the Administrator may determine at the time of grant. Conditions may be based on continuing employment (or other Service Relationship) and/or achievement of pre-established performance goals and objectives.

(b) Rights as a Stockholder. Upon the grant of the Restricted Stock Award and payment of any applicable purchase price, a grantee shall have the rights of a stockholder with respect to the voting of the Restricted Shares and receipt of dividends; provided that if the lapse of restrictions with respect to the Restricted Stock Award is tied to the attainment of performance goals, any dividends paid by the Company during the performance period shall accrue and shall not be paid to the grantee until and to the extent the performance goals are met with respect to the Restricted Stock Award. Unless the Administrator shall otherwise determine, (i) uncertificated Restricted Shares shall be accompanied by a notation on the records of the Company or the transfer agent to the effect that they are subject to forfeiture until such Restricted Shares are vested as provided in Section 7(d) below, and (ii) certificated Restricted Shares shall remain in the possession of the Company until such Restricted Shares are vested as provided in Section 7(d) below, and the grantee shall be required, as a condition of the grant, to deliver to the Company such instruments of transfer as the Administrator may prescribe.

(c) Restrictions. Restricted Shares may not be sold, assigned, transferred, pledged or otherwise encumbered or disposed of except as specifically provided herein or in the Restricted Stock Award Certificate. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 16 below, in writing after the Award is issued, if a grantee's employment (or other Service Relationship) with the Company and its Subsidiaries terminates for any reason, any Restricted Shares that have not vested at the time of termination shall automatically and without any requirement of notice to such grantee from or other action by or on behalf of, the Company be deemed to have been reacquired by the Company at its original purchase price (if any) from such grantee or such grantee's legal representative simultaneously with such termination of employment (or other Service Relationship), and thereafter shall cease to represent any ownership of the Company by the grantee or rights of the grantee as a stockholder. Following such deemed reacquisition of Restricted Shares that are represented by physical certificates, a grantee shall surrender such certificates to the Company upon request without consideration.

(d) Vesting of Restricted Shares. The Administrator at the time of grant shall specify the date or dates and/or the attainment of pre-established performance goals, objectives and other conditions on which the non-transferability of the Restricted Shares and the Company's right of repurchase or forfeiture shall lapse. Subsequent to such date or dates and/or the attainment of such pre-established performance goals, objectives and other conditions, the shares on which all restrictions have lapsed shall no longer be Restricted Shares and shall be deemed "vested."

SECTION 8. RESTRICTED STOCK UNITS

(a) Nature of Restricted Stock Units. The Administrator may grant Restricted Stock Units under the Plan. A Restricted Stock Unit is an Award of stock units that may be settled in shares of Stock (or cash, to the extent explicitly provided for in the applicable Award Certificate) upon the satisfaction of such restrictions and conditions at the time of grant. Conditions may be based on continuing employment (or other Service Relationship) and/or achievement of pre-established performance goals and objectives. The terms and conditions of each such Award shall be determined by the Administrator, and such terms and conditions may differ among individual Awards and grantees. Except in the case of Restricted Stock Units with a deferred settlement date that complies with Section 409A, at the end of the vesting period, the Restricted Stock Units, to the extent vested, shall be settled in the form of shares of Stock. Restricted Stock Units with deferred settlement dates are subject to Section 409A and shall contain such additional terms and conditions as the Administrator shall determine in its sole discretion in order to comply with the requirements of Section 409A.

(b) Rights as a Stockholder. A grantee shall have the rights as a stockholder only as to shares of Stock acquired by the grantee upon settlement of Restricted Stock Units; provided, however, that the grantee may be credited with Dividend Equivalent Rights with respect to the stock units underlying his Restricted Stock Units, subject to the provisions of Section 11 and such terms and conditions as the Administrator may determine.

(c) Termination. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 16 below, in writing after the Award is issued, a grantee's right in all Restricted Stock Units that have not vested shall automatically terminate upon the grantee's termination of employment (or cessation of Service Relationship) with the Company and its Subsidiaries for any reason.

SECTION 9. UNRESTRICTED STOCK AWARDS

Grant or Sale of Unrestricted Stock. The Administrator may grant (or sell at par value or such higher purchase price determined by the Administrator) an Unrestricted Stock Award under the Plan. An Unrestricted Stock Award is an Award pursuant to which the grantee may receive shares of Stock free of any restrictions under the Plan. Unrestricted Stock Awards may be granted in respect of past services or other valid consideration, or in lieu of cash compensation due to such grantee.

SECTION 10. RESERVED

SECTION 11. DIVIDEND EQUIVALENT RIGHTS

(a) Dividend Equivalent Rights. The Administrator may grant Dividend Equivalent Rights under the Plan. A Dividend Equivalent Right is an Award entitling the grantee to receive credits based on cash dividends that would have been paid on the shares of Stock specified in the Dividend Equivalent Right (or other Award to which it relates) if such shares had been issued to the grantee. A Dividend Equivalent Right may be granted hereunder to any grantee as a component of an award of Restricted Stock Units or as a freestanding award. The terms and conditions of Dividend Equivalent Rights shall be specified in the Award Certificate. Dividend equivalents credited to the holder of a Dividend Equivalent Right may be paid currently or may be deemed to be reinvested in additional shares of Stock, which may thereafter accrue additional equivalents. Any such reinvestment shall be at Fair Market Value on the date of reinvestment or such other price as may then apply under a dividend reinvestment plan sponsored by the Company, if any. Dividend Equivalent Rights may be settled in cash or shares of Stock or a combination thereof, in a single installment or installments. A Dividend Equivalent Right granted as a component of an Award of Restricted Stock Units shall provide that such Dividend Equivalent Right shall be settled only upon settlement or payment of, or lapse of restrictions on, such other Award, and that such Dividend Equivalent Right shall expire or be forfeited or annulled under the same conditions as such other Award.

(b) Termination. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 16 below, in writing after the Award is issued, a grantee's rights in all Dividend Equivalent Rights shall automatically terminate upon the grantee's termination of employment (or cessation of Service Relationship) with the Company and its Subsidiaries for any reason.

SECTION 12. TRANSFERABILITY OF AWARDS

(a) Transferability. Except as provided in Section 14(b) below, during a grantee's lifetime, his or her Awards shall be exercisable only by the grantee, or by the grantee's legal representative or guardian in the event of the grantee's incapacity. No Awards shall be sold, assigned, transferred or otherwise encumbered or disposed of by a grantee other than by will or by the laws of descent and distribution or pursuant to a domestic relations order. No Awards shall be subject, in whole or in part, to attachment, execution, or levy of any kind, and any purported transfer in violation hereof shall be null and void.

(b) Administrator Action. Notwithstanding Section 14(a), the Administrator, in its discretion, may provide either in the Award Certificate regarding a given Award or by subsequent written approval that the grantee (who is an employee or director) may transfer his or her Non-Qualified Stock Options to his or her immediate family members, to trusts for the benefit of such family members, or to partnerships in which such family members are the only partners, provided that the transferee agrees in writing with the Company to be bound by all of the terms and conditions of this Plan and the applicable Award. In no event may an Award be transferred by a grantee for value.

(c) Family Member. For purposes of Section 14(b), "family member" shall mean a grantee's child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, any person sharing the grantee's household (other than a tenant of the grantee), a trust in which these persons (or the grantee) have more than 50 percent of the beneficial interest, a foundation in which these persons (or the grantee) control the management of assets, and any other entity in which these persons (or the grantee) own more than 50 percent of the voting interests.

(d) Designation of Beneficiary. To the extent permitted by the Company, each grantee to whom an Award has been made under the Plan may designate a beneficiary or beneficiaries to exercise any Award or receive any payment under any Award payable on or after the grantee's death. Any such designation shall be on a form provided for that purpose by the Administrator and shall not be effective until received by the Administrator. If no beneficiary has been designated by a deceased grantee, or if the designated beneficiaries have predeceased the grantee, the beneficiary shall be the grantee's estate.

SECTION 13. TAX WITHHOLDING

(a) Payment by Grantee. Each grantee shall, no later than the date as of which the value of an Award or of any Stock or other amounts received thereunder first becomes includable in the gross income of the grantee for Federal income tax purposes, pay to the Company, or make arrangements satisfactory to the Administrator regarding payment of, any Federal, state, or local taxes of any kind required by law to be withheld by the Company with respect to such income. The Company and its Subsidiaries shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the grantee. The Company's obligation to deliver evidence of book entry (or stock certificates) to any grantee is subject to and conditioned on tax withholding obligations being satisfied by the grantee.

(b) Payment in Stock. Subject to approval by the Administrator, a grantee may elect to have the Company's required tax withholding obligation satisfied, in whole or in part, by authorizing the Company to withhold from shares of Stock to be issued pursuant to any Award a number of shares with an aggregate Fair Market Value (as of the date the withholding is effected) that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid liability accounting treatment. The Administrator may also require Awards to be subject to mandatory share withholding up to the required withholding amount. For purposes of share withholding, the Fair Market Value of withheld shares shall be determined in the same manner as the value of Stock includible in income of the Participants. The required tax withholding obligation may also be satisfied, in whole or in part, by an arrangement whereby a certain number of shares of Stock issued pursuant to any Award are immediately sold and proceeds from such sale are remitted to the Company in an amount that would satisfy the withholding amount due..

SECTION 14. SECTION 409A AWARDS

To the extent that any Award is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A (a "409A Award"), the Award shall be subject to such additional rules and requirements as specified by the Administrator from time to time in order to comply with Section 409A. In this regard, if any amount under a 409A Award is payable upon a "separation from service" (within the meaning of Section 409A) to a grantee who is then considered a "specified employee" (within the meaning of Section 409A), then no such payment shall be made prior to the date that is the earlier of (i) six months and one day after the grantee's separation from service, or (ii) the grantee's death, but only to the extent such delay is necessary to prevent such payment from being subject to interest, penalties and/or additional tax imposed pursuant to Section 409A. Further, the settlement of any 409A Award may not be accelerated except to the extent permitted by Section 409A.

SECTION 15. TERMINATION OF SERVICE RELATIONSHIP, TRANSFER, LEAVE OF ABSENCE, ETC.

(a) Termination of Service Relationship. If the grantee's Service Relationship is with a Subsidiary and such Subsidiary ceases to be a Subsidiary, the grantee shall be deemed to have terminated his or her Service Relationship for purposes of the Plan.

(b) For purposes of the Plan, the following events shall not be deemed a termination of Service Relationship:

(i) a transfer to the Service Relationship of the Company from a Subsidiary or from the Company to a Subsidiary, or from one Subsidiary to another; or

(ii) an approved leave of absence for military service or sickness, or for any other purpose approved by the Company, if the employee's right to re-employment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise so provides in writing.

SECTION 16. AMENDMENTS AND TERMINATION

The Board may, at any time, amend or discontinue the Plan and the Administrator may, at any time, amend or cancel any outstanding Award for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall adversely affect rights under any outstanding Award without the holder's consent. Except as provided in Section 3(c) or 3(d), without prior stockholder approval, in no event may the Administrator exercise its discretion to reduce the exercise price of outstanding Stock Options or Stock Appreciation Rights or effect repricing through cancellation and re-grants or cancellation of Stock Options or Stock Appreciation Rights in exchange for cash or other Awards. Nothing in this Section 16 shall limit the Administrator's authority to take any action permitted pursuant to Section 3(c) or 3(d).

SECTION 17. STATUS OF PLAN

With respect to the portion of any Award that has not been exercised and any payments in cash, Stock or other consideration not received by a grantee, a grantee shall have no rights greater than those of a general creditor of the Company unless the Administrator shall otherwise expressly determine in connection with any Award or Awards. In its sole discretion, the Administrator may authorize the creation of trusts or other arrangements to meet the Company's obligations to deliver Stock or make payments with respect to Awards hereunder, provided that the existence of such trusts or other arrangements is consistent with the foregoing sentence.

SECTION 18. GENERAL PROVISIONS

(a) No Distribution. The Administrator may require each person acquiring Stock pursuant to an Award to represent to and agree with the Company in writing that such person is acquiring the shares without a view to distribution thereof.

(b) Issuance of Stock Certificates. To the extent certificated, stock certificates to grantees under this Plan shall be deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have mailed such certificates in the United States mail, addressed to the grantee, at the grantee's last known address on file with the Company. Uncertificated Stock shall be deemed delivered for all purposes when the Company or a Stock transfer agent of the Company shall have given to the grantee by electronic mail (with proof of receipt) or by United States mail, addressed to the grantee, at the grantee's last known address on file with the Company, notice of issuance and recorded the issuance in its records (which may include electronic "book entry" records). Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any evidence of book entry or certificates evidencing shares of Stock pursuant to the exercise of any Award, unless and until the Administrator has determined, with advice of counsel (to the extent the Administrator deems such advice necessary or advisable), that the issuance and delivery is in compliance with all applicable laws, regulations of governmental authorities and, if applicable, the requirements of any exchange on which the shares of Stock are listed, quoted or traded. Any Stock issued pursuant to the Plan shall be subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with federal, state or foreign jurisdiction, securities or other laws, rules and quotation system on which the Stock is listed, quoted or traded. The Administrator may place legends on any Stock certificate or notation on any book entry to reference restrictions applicable to the Stock. In addition to the terms and conditions provided herein, the Administrator may require that an individual make such reasonable covenants, agreements, and representations as the Administrator, in its discretion, deems necessary or advisable in order to comply with any such laws, regulations, or requirements. The Administrator shall have the right to require any individual to comply with any timing or other restrictions with respect to the settlement or exercise of any Award, including a window-period limitation, as may be imposed in the discretion of the Administrator.

(c) Stockholder Rights. Until Stock is deemed delivered in accordance with Section 20(b), no right to vote or receive dividends or any other rights of a stockholder will exist with respect to shares of Stock to be issued in connection with an Award, notwithstanding the exercise of a Stock Option or any other action by the grantee with respect to an Award.

(d) Other Compensation Arrangements; No Employment Rights. Nothing contained in this Plan shall prevent the Board from adopting other or additional compensation arrangements, including trusts, and such arrangements may be either generally applicable or applicable only in specific cases. The adoption of this Plan and the grant of Awards do not confer upon any employee any right to continued employment with the Company or any Subsidiary.

(e) Trading Policy Restrictions. Option exercises and other Awards under the Plan shall be subject to the Company's insider trading policies and procedures, as in effect from time to time.

(f) Clawback Policy. Awards under the Plan shall be subject to the Company's clawback policy, as in effect from time to time.

SECTION 19. EFFECTIVE DATE OF PLAN

This Plan shall become effective upon approval by the Board.

SECTION 20. GOVERNING LAW

This Plan and all Awards and actions taken thereunder shall be governed by, and construed in accordance with, the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by and construed in accordance with the internal laws of the State of Delaware, applied without regard to conflict of law principles.

NON-QUALIFIED STOCK OPTION AGREEMENT
FOR COMPANY EMPLOYEES
UNDER THE SURFACE ONCOLOGY, INC.
2021 INDUCEMENT PLAN

Name of Optionee:	___________________________
No. of Option Shares:	_______________
Option Exercise Price per Share:	$ _______________
Grant Date:	_______________
Expiration Date:	_______________

Pursuant to the Surface Oncology, Inc. 2021 Inducement Plan as amended through the date hereof (the "Plan"), Surface Oncology, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.0001 per share (the "Stock") of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan. This Stock Option has been granted as an inducement pursuant to Rule 5635(c)(4) of the Marketplace Rules of NASDAQ Stock Market, Inc. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated so long as Optionee remains an employee of the Company or a Subsidiary on such dates:

Incremental Number of Option Shares Exercisable	Exercisability Date
__________ (___%)	__________
__________ (___%)	__________
__________ (___%)	__________
__________ (___%)	__________
__________ (___%)	__________

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; (iv) by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; or (v) a combination of (i), (ii), (iii) and (iv) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company’s receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee’s name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

3. Termination of Employment. If the Optionee’s employment by the Company or a Subsidiary (as defined in the Plan) is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death. If the Optionee’s employment terminates by reason of the Optionee’s death, any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of death, may thereafter be exercised by the Optionee’s legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of death shall terminate immediately and be of no further force or effect.

(b) Termination Due to Disability. If the Optionee’s employment terminates by reason of the Optionee’s disability (as determined by the Administrator), any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of such termination of employment, may thereafter be exercised by the Optionee for a period of 12 months from the date of disability or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of disability shall terminate immediately and be of no further force or effect.

(c) Termination for Cause. If the Optionee’s employment terminates for Cause, any portion of this Stock Option outstanding on such date shall terminate immediately and be of no further force and effect. For purposes hereof, “Cause” shall mean, unless otherwise provided in an employment agreement between the Company and the Optionee, a determination by the Administrator that the Optionee shall be dismissed as a result of (i) any material breach by the Optionee of any agreement between the Optionee and the Company; (ii) the conviction of, indictment for or plea of nolo contendere by the Optionee to a felony or a crime involving moral turpitude; or (iii) any material misconduct or willful and deliberate non-performance (other than by reason of disability) by the Optionee of the Optionee’s duties to the Company.

(d) Other Termination. If the Optionee's employment terminates for any reason other than the Optionee's death, the Optionee's disability or Cause, and unless otherwise determined by the Administrator, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of termination shall terminate immediately and be of no further force or effect.

The Administrator's determination of the reason for termination of the Optionee's employment shall be conclusive and binding on the Optionee and his or her representatives or legatees.

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

6. Tax Withholding. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the minimum required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Optionee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the minimum withholding amount due.

7. No Obligation to Continue Employment. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Optionee in employment and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the employment of the Optionee at any time.

8. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

9. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

10. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

SURFACE ONCOLOGY, INC.

By:______________________
Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable.

Dated: ______________________________

____

Optionee's Signature

Optionee's name and address:

____

____

____

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8 (No. 333-254023, 333-237044, 333-230129 and 333-224403) and Form S-3 (No. 333-258518 and 333-231144) of Surface Oncology, Inc. of our report dated March 2, 2022 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 2, 2022

Exhibit 31.1

CERTIFICATION 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

I, Robert W. Ross, M.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Surface Oncology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e))and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Date: March 2, 2022

By: /s/ Robert W. Ross, M.D.
Robert W. Ross M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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

I, Jessica Fees, certify that:

1. I have reviewed this Annual Report on Form 10-K of Surface Oncology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles
   (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2022

By: /s/ Jessica Fees
Jessica Fees
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Surface Oncology, Inc. (the “Company”) on Form 10-K for the period ending December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 2, 2022

By: /s/ Robert W. Ross, M.D.
Robert W. Ross, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Surface Oncology, Inc. (the "Company") on Form 10-K for the period ending December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 2, 2022

By: /s/ Jessica Fees

Jessica Fees
Chief Financial Officer
(Principal Financial and Accounting Officer)