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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

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:

Common Stock, $0.0001	**The Nasdaq Global Market**
(Title of each class)	**(Name of each exchange on which registered)**

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 ☒

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

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 29, 2018, was $320,135,371. 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 March 4, 2019 was 27,829,570.

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 5, 2019, are incorporated by reference into Part III of this Report.

Table of Contents

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, are 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, including metabolites, cytokines and macrophages.

NZV930 (formerly SRF373) and SRF617 are antibodies inhibiting 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. Elevated adenosine levels in the TME are associated with a poor prognosis in patients with certain types of cancer. 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, a proinflammatory molecule and key driver of the maturation and activation of immune cells. In June 2018, a Phase 1 trial of NZV930 was initiated by our partner, Novartis Institutes for Biomedical Research, Inc., or Novartis, and we expect to file an investigational new drug application, or IND, for SRF617 in the fourth quarter of 2019.

SRF388 is an antibody targeting interleukin 27, or IL-27, an immunosuppressive cytokine, or protein secreted by cells, in the TME that is overexpressed in certain cancers. 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 expect to file an IND for SRF388 in the fourth quarter of 2019.

SRF231 is an antibody targeting CD47, which is a protein expressed on many cells, but often overexpressed on tumor cells. By targeting CD47, we believe we can promote macrophage activation to attack such tumors. We initiated a Phase 1 clinical trial of SRF231 in February 2018. In December 2018, we announced the deprioritization of SRF231 as a result of toxicities seen during the dose escalation portion of the ongoing Phase 1 trial and the evolving competitive landscape. We are continuing dose exploration in the Phase 1 trial and expect to provide additional data regarding SRF231 in the second half of 2019.

We also have several earlier stage programs that target other critical components of the TME, including regulatory T cells and natural killer, or NK, cells. 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 2016, we entered into a strategic collaboration agreement, or the Collaboration Agreement, with Novartis to develop next-generation cancer therapies. Importantly, this collaboration enables us to leverage the expertise and resources of Novartis to accelerate the development of our collaboration programs. We received an upfront payment of $70.0 million from Novartis upon entering into the agreement. Under the Collaboration Agreement, we are currently entitled to potential option purchase, option exercise and milestone payments upon the achievement of specified development and sales milestones, as well as tiered royalties on annual net sales by Novartis ranging from high single-digit to mid-teens percentages upon successful commercialization of any products. We have granted Novartis a worldwide exclusive license to develop and commercialize NZV930. In February 2019, Novartis notified us of its decision not to exercise its purchased option related to SRF388. Accordingly, Novartis currently has one option remaining eligible for purchase and potential exercise. As a result, the maximum aggregate amount of potential option purchase, option exercise, and milestone payments that we may be entitled to receive under the Collaboration Agreement is $750 million.

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 collaboration with Novartis, 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, the breadth and durability of clinical benefit achieved has been limited to a 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.

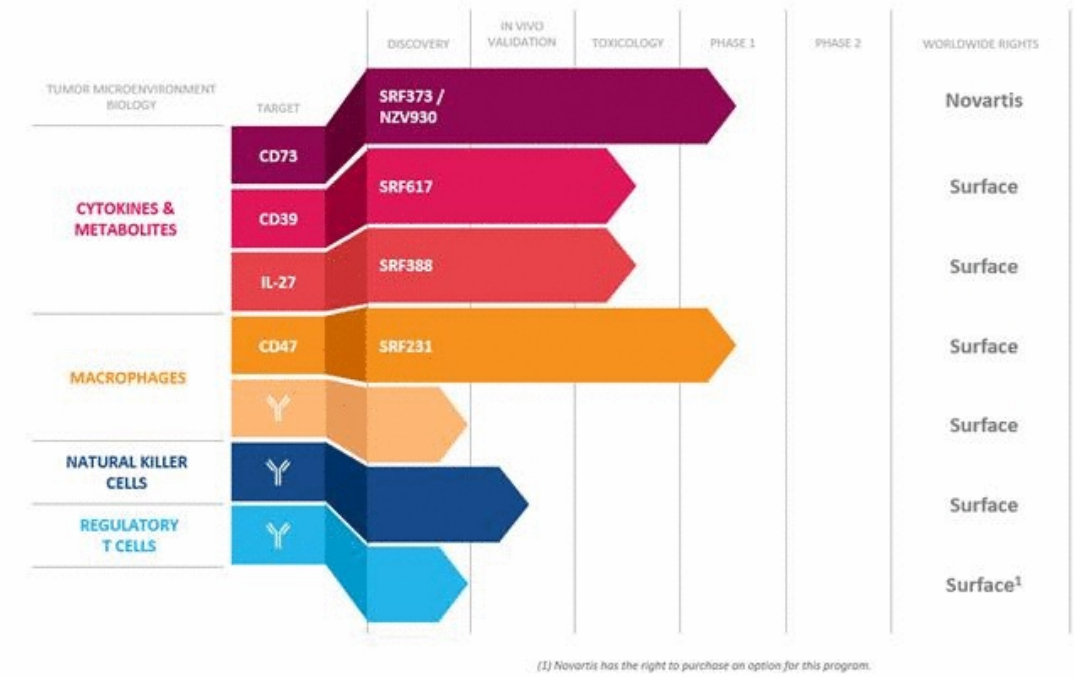
Adenosine is a key metabolite within the TME that accumulates and inhibits the function of important immune cells, including T cells and NK cells, leading to an environment conducive to tumor growth. CD39 and CD73, two of the enzymes involved in the production of extracellular adenosine, are both attractive 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 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.

Macrophages are a type of immune cell that can recognize and engulf, or phagocytose, other cells that need to be destroyed, including cancer cells. These immune cells are a key component of the immune system that provides a rapid, non-specific response to pathogens. Cells expressing CD47 on their surface are not phagocytosed by macrophages, causing CD47 to be termed a "don't eat me signal." Therefore, many tumor cells overexpress CD47, which suppresses macrophage activation and allows tumor cells to evade phagocytosis. Targeting CD47 is an attractive therapeutic strategy for restoring macrophage activity so that they can effectively recognize and phagocytose tumor cells.

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 in order to reduce the immunosuppressive effects of adenosine in the TME.

NZV930 (formerly SRF373) inhibits 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.

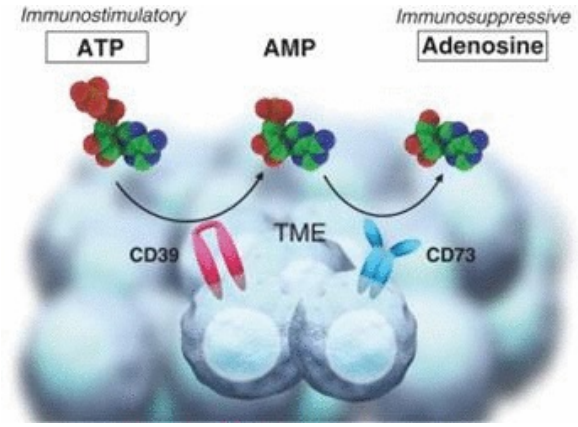
SRF617 inhibits CD39, an enzyme critical both to the production of adenosine and the breakdown of ATP. We believe targeting CD39 will not only reduce extracellular adenosine, but will also maintain extracellular levels of immunostimulatory ATP, both of which have been observed to promote anti-tumor immunity. CD39 overexpression also counteracts the effects of chemotherapy, which we believe further supports its importance as a therapeutic target. In preclinical studies, SRF617 exhibited potent CD39 enzymatic inhibition. We wholly own SRF617 and it is not part of the Novartis collaboration. We expect to file an IND for SRF617 in the fourth quarter of 2019.

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.

Role of Adenosine 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. 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 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 as a monotherapy and more potently in combination with a PD-1 inhibitor.

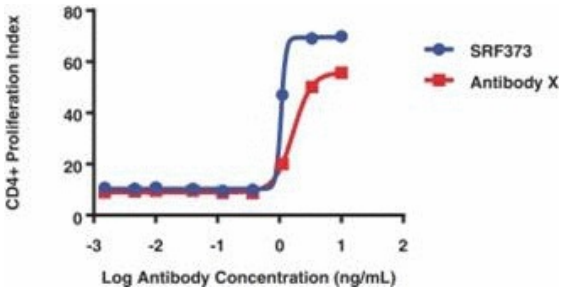
Our Preclinical Studies

We have conducted numerous preclinical studies across a variety of preclinical models to assess the activity of NZV930. We examined the ability of NZV930 to inhibit CD73 enzymatic activity in an ovarian cancer cell line expressing CD73 and observed that NZV930's inhibitory activity increased in a concentration-dependent manner. To compare the enzymatic inhibitory activity of NZV930 against potential competitor antibodies, we engineered an antibody, Antibody X, that we believe to have the same properties as another CD73 antibody in clinical development. We based our construction of this antibody on publicly available patent filings. Notably, the peak CD73 enzymatic inhibition achieved using NZV930 was observed to be substantially greater than Antibody X.

Further, NZV930 was observed to meaningfully reduce adenosine production from cells, and NZV930 treatment in a mouse tumor xenograft model was observed to reduce levels of plasma adenosine.

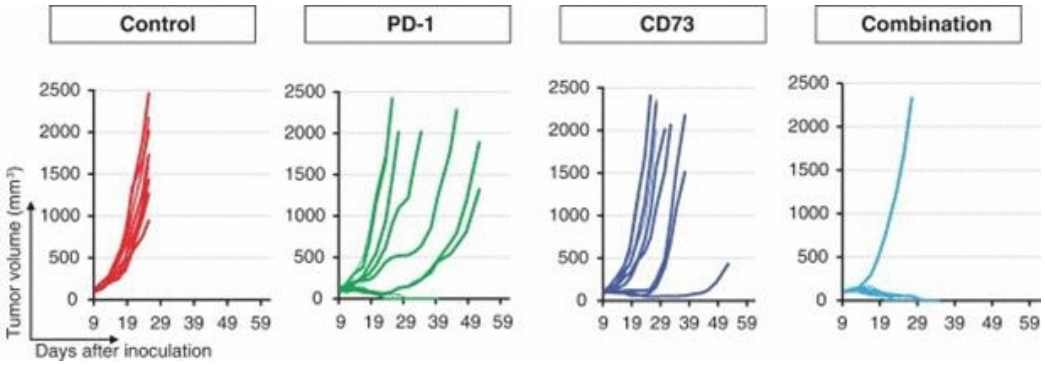
$CD4^+$ T cell proliferation is inhibited by adenosine, and high levels of adenosine in the TME enable the tumor to evade these important immune cells. By reducing the production of adenosine, NZV930 has the potential to increase the proliferation of $CD4^+$ T cells. As depicted in the figure below, in our preclinical studies, we observed that NZV930 treatment mitigated the immunosuppressive effects of adenosine produced by CD73 and subsequently increased the proliferation of T cell receptor-stimulated $CD4^+$ T cells in a concentration-dependent fashion. Further, the level of T cell proliferation achieved using NZV930 was greater than the levels achieved using Antibody X. We have observed similar results in additional studies conducted by us. We believe the increased T cell proliferation seen with NZV930 is a result of greater enzymatic inhibition of CD73.

NZV930 Effect on $CD4^+$ T Cell Proliferation



Additionally, we have seen compelling preclinical anti-tumor activity when combining a CD73 inhibitor with a PD-1 inhibitor. We developed a CD73 antibody closely related to NZV930 that cross reacts with murine CD73. In our preclinical studies, we observed that CD73 demonstrated anti-tumor activity as a monotherapy as well as in combination with a PD-1 inhibitor. Notably, combining the CD73 antibody and the PD-1 inhibitor was observed to result in synergistic anti-tumor effects. Further, when the same tumor cells were reintroduced into mice treated in the combination group, the anti-tumor effects were maintained in the absence of additional antibody treatment, demonstrating the potential to establish durable anti-tumor immunity. We have observed similar results in an additional study conducted by us.

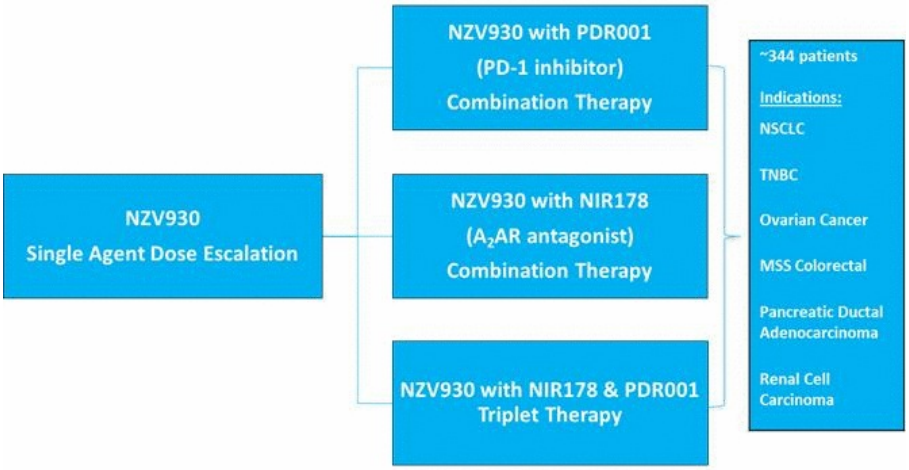
Effect of Targeting CD73 and PD-1 in Combination



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 of 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

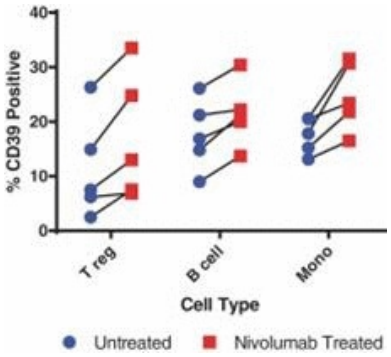
SRF617 is a fully human IgG4 monoclonal antibody that is a potent inhibitor of CD39 enzymatic activity. We selected SRF617 for clinical development based on the following key attributes observed in preclinical development:

- 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

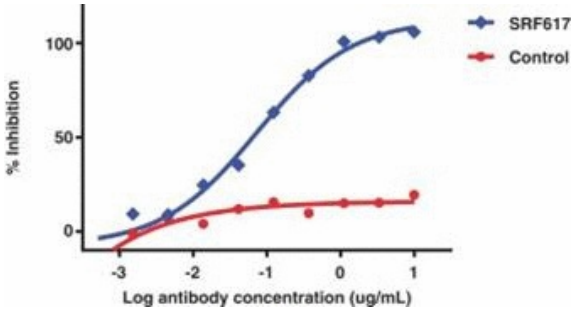
In preclinical studies, we observed increased expression of CD39 following treatment with nivolumab, a PD-1 inhibitor. Specifically, peripheral blood mononuclear cells from five human donors were either treated, or not, with nivolumab. As shown in the figure below, increased CD39 expression was observed in three cell types, specifically, $CD4^+$ T regulatory cells, or Treg; $CD19^+$ B cells, or B cell; and $CD14^+$ monocytes, or Mono. In clinical trials, others have shown increased CD39 expression in tumor biopsies from patients with renal cell carcinoma and non-small cell lung cancer that were resistant to treatment with atezolizumab, a PD-L1 inhibitor. These studies suggest that CD39 expression may contribute to PD-1/PD-L1 resistance and an immunosuppressive TME.

Effect of Nivolumab on CD39 Expression



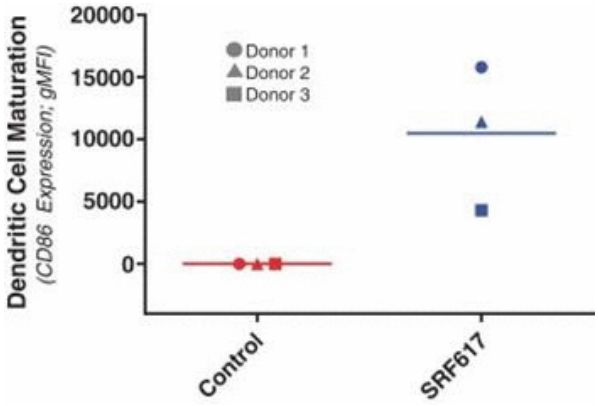
As shown in the figure below, we observed that SRF617 inhibited CD39 enzymatic activity in a concentration-dependent fashion in a multiple myeloma cell line expressing CD39 when compared to a control antibody. We have observed similar results in additional studies conducted by us.

SRF617 Effect on CD39 Enzymatic Activity



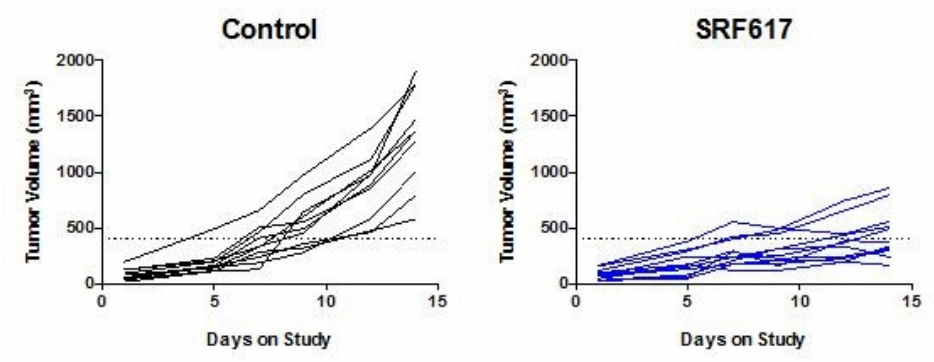
Further, we have observed the immunostimulatory effects of SRF617 in a preclinical model. Specifically, in three donor samples as shown below, SRF617 was observed to enhance the immunostimulatory effects of ATP, resulting in increased maturation of dendritic cells when compared to a control antibody. Dendritic cell maturation was determined by measuring levels of CD86, a known marker of dendritic cell maturation, following treatment with SRF617, or a control antibody, and ATP. In the figure below, CD86 expression levels shown for the control and SRF617 treated groups were normalized to pre-treatment levels of CD86. We have observed similar results in additional studies conducted by us.

SRF617 Effect on Dendritic Cell Maturation



Additionally, we have seen preclinical anti-tumor activity with SRF617. In the study shown below, we observed that SRF617 was associated with significantly inhibited tumor growth, as compared to a control antibody.

Effect of SRF617 on Tumor Growth



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

Overview of SRF388

SRF388 is a fully human IgG1 monoclonal antibody that binds to IL-27 and inhibits its activity. 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:

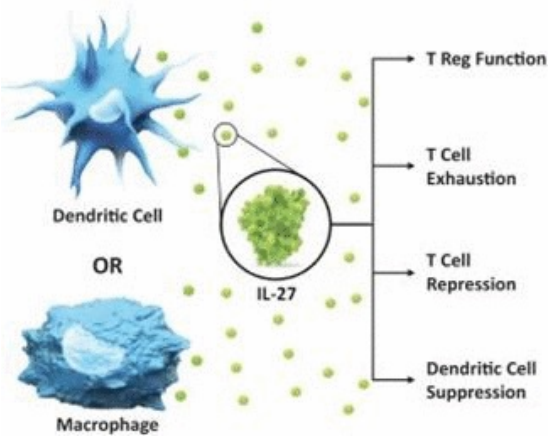
- Potent reduction of IL-27 driven immune cell suppression;
- Potential for combination therapy including checkpoint inhibitors; and
- Strong translational rationale for targeting IL-27 in certain types of cancer.

We expect to file an IND for SRF388 in the fourth quarter of 2019. We wholly own SRF388, as the program is no longer part of the Collaboration Agreement.

IL-27 Background

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 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.

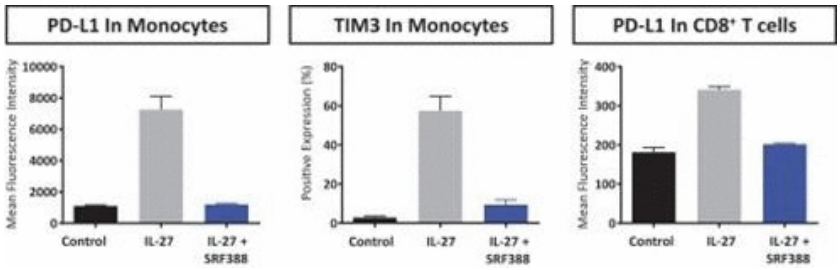
IL-27 Role in Immunosuppression



Our Preclinical Studies

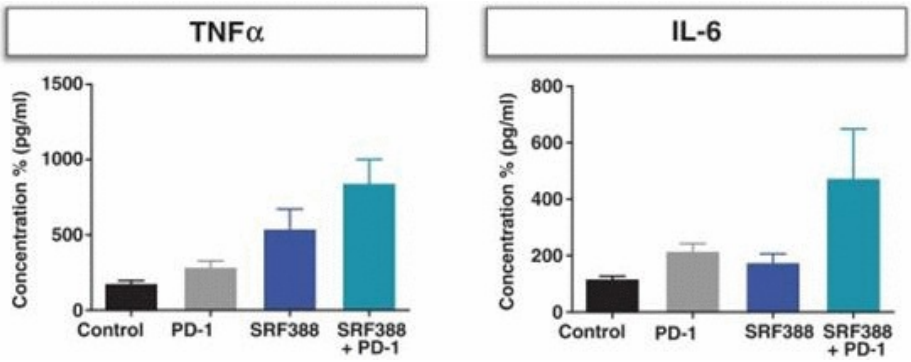
In several preclinical studies conducted by us, we observed that the treatment of human T cells and monocytes with IL-27 resulted in the induction of an immunosuppressive phenotype, including increased expression of the checkpoint proteins PD-L1 and TIM3. We observed that treatment with SRF388 blocked IL-27 signaling and prevented the induction of this phenotype, as shown in the figure below.

SRF388 Effect on IL-27 Induced Immunosuppressive Phenotype



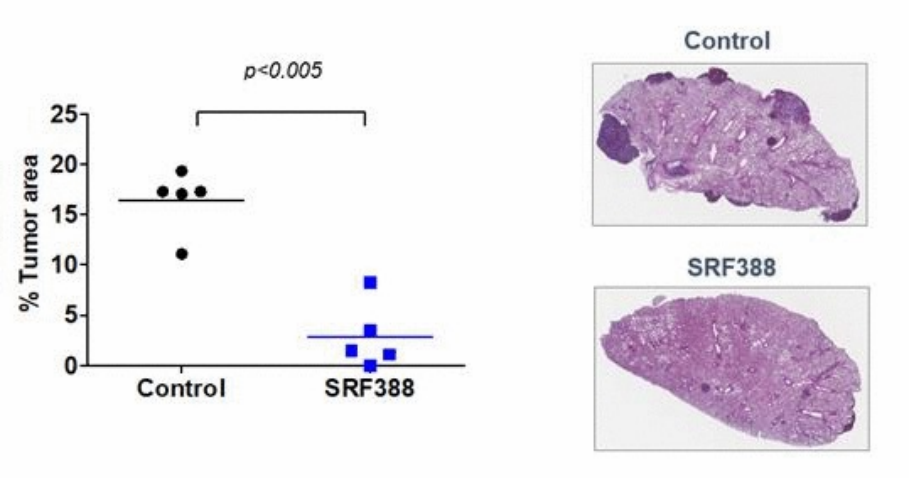
In several preclinical studies conducted by us, we observed that blocking IL-27 with SRF388 in cancer patient-derived human peripheral blood mononuclear cells, after T cell receptor activation, increased key inflammatory cytokines, TNFα and IL-6, which are indicative of an activated immune state, as shown in the figure below. Additionally, we conducted several preclinical studies and observed that by combining SRF388 with a PD-1 inhibitor, expression of these inflammatory cytokines was further increased, also shown in the figure below. Based upon our preclinical studies, we believe that blocking both PD-1 and IL-27 in certain clinical settings could help to promote tumor-specific immunity.

SRF388 Plus PD-1 Inhibitor Effect on Inflammatory Cytokine Production



We have seen compelling monotherapy anti-tumor activity following treatment with SRF388 in our preclinical studies. In the study below, SRF388 treatment resulted in a significant reduction in overall lung tumor metastasis, as compared to a control antibody.

Effect of SRF388 on Tumor Growth



We expect to file an IND for SRF388 in the fourth quarter of 2019. We wholly own SRF388, as the program is no longer part of the Collaboration Agreement.

Driving Macrophage Activation and Tumor Infiltration with SRF231, a CD47 Inhibitor

Overview of SRF231

SRF231 is a fully human IgG4 monoclonal antibody that is a potent inhibitor of CD47. We selected SRF231 for clinical development based on the following key attributes observed in preclinical development:

- Potent inhibition of CD47:SIRPα binding to drive macrophage activation, infiltration and phagocytosis;
- Potent activity against multiple hematologic and solid tumors, both as a monotherapy and in combination with other approved cancer therapies; and
- Well tolerated without resulting in hemagglutination.

We initiated a Phase 1 clinical trial of SRF231 in February 2018. We have exclusive, worldwide rights to SRF231.

CD47 Background

CD47 is a protein found on the surface of cells and is involved in physiological functions such as cell migration, cell adhesion, T cell function and macrophage activation. CD47 is a well-validated target in macrophage biology as overexpression of CD47 has been observed in various types of tumors, and there is a growing body of third-party clinical evidence that suggests blocking CD47 results in anti-tumor effects. Tumor cell expression of CD47 has been shown to prevent macrophages from recognizing and phagocytosing, or attacking and engulfing, tumor cells. SIRPα, an inhibitory protein expressed on macrophages, is a primary binding partner of CD47, and when the CD47:SIRPα interaction is blocked, the "don't eat me signal" is inhibited, which then enables the macrophage to kill the tumor cells.

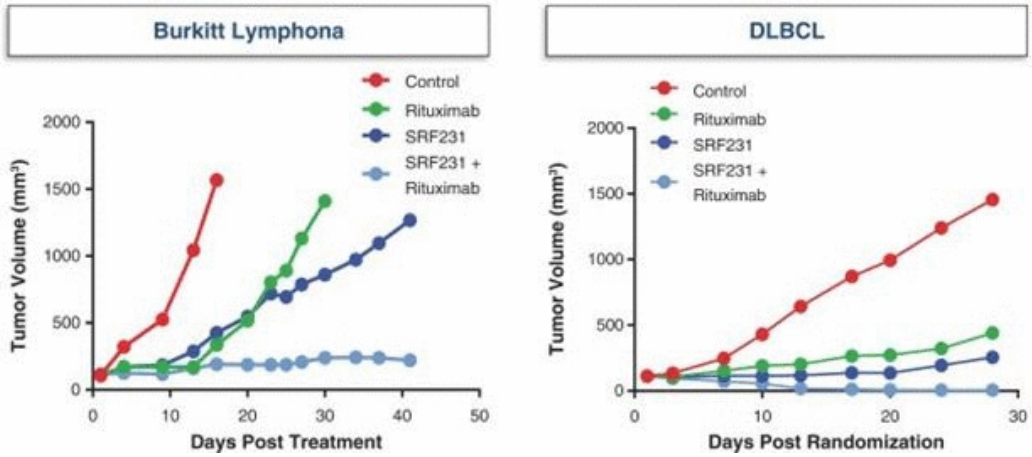
Our Preclinical Studies

Summary of Preclinical Activity Studies

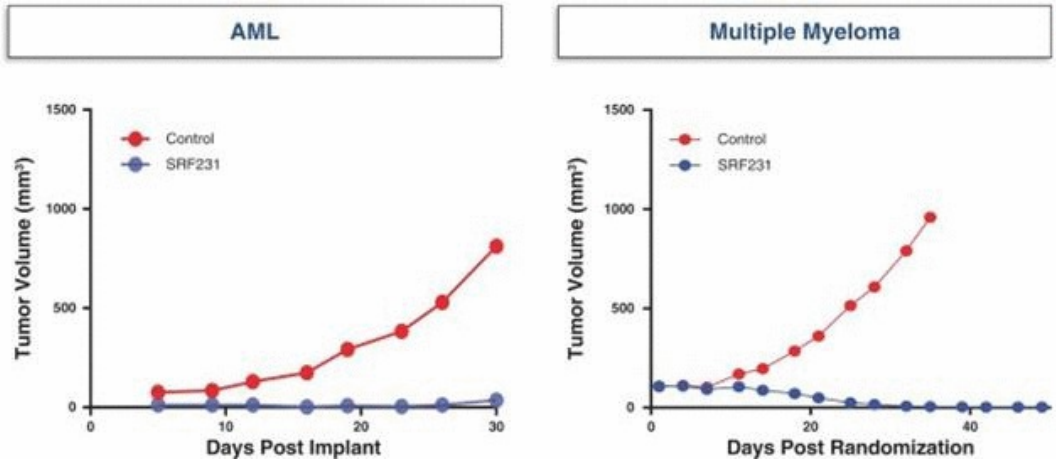
We initially assessed the ability of SRF231 to block the binding of CD47 to SIRPα and SRF231 was observed to be a potent blocker of the CD47:SIRPα interaction. Furthermore, we observed that SRF231 meaningfully increased phagocytosis of tumor cells by macrophages and macrophage infiltration into the tumor. We have also conducted numerous preclinical studies to assess the activity of SRF231 across a variety of models of solid and hematologic tumors, as both a monotherapy and in combination with other cancer therapeutics.

Data from our preclinical studies supports the use of SRF231 in combination with other cancer therapies. For example, when combined with rituximab, a CD20 antibody and current standard of care for the treatment of many hematologic malignancies, SRF231 was observed to meaningfully reduce tumor growth in murine models of Burkitt lymphoma and diffuse large B cell lymphoma, or DLBCL, when compared to treatment with either SRF231 or rituximab alone.

SRF231 Combination Anti-Tumor Activity in Hematologic Tumors



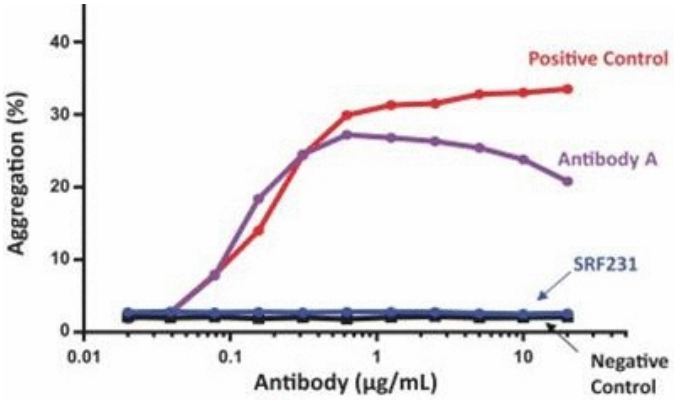
Further, SRF231 administered in combination with rituximab was observed to increase tumor cell phagocytosis in a concentration-dependent fashion when compared to treatment with SRF231 alone.



Preclinical Safety Studies

We have tested SRF231 in multiple preclinical studies, including incubation of SRF231 at concentrations of up to 1 mg/mL with human whole blood, and we have not observed hemagglutination. As shown in the figure below, blood samples treated with SRF231 did not agglutinate at any concentration tested. To examine the safety profile of SRF231 against potential competitor antibodies, we engineered an antibody that we believe to have the same properties as another CD47 antibody in clinical development. We based our construction of this antibody on information from a scientific publication. As depicted in the figure below, this analog of a competitor antibody, labeled as Antibody A, was observed to cause hemagglutination over a broad range of concentrations. Similar results were observed in additional studies conducted by us.

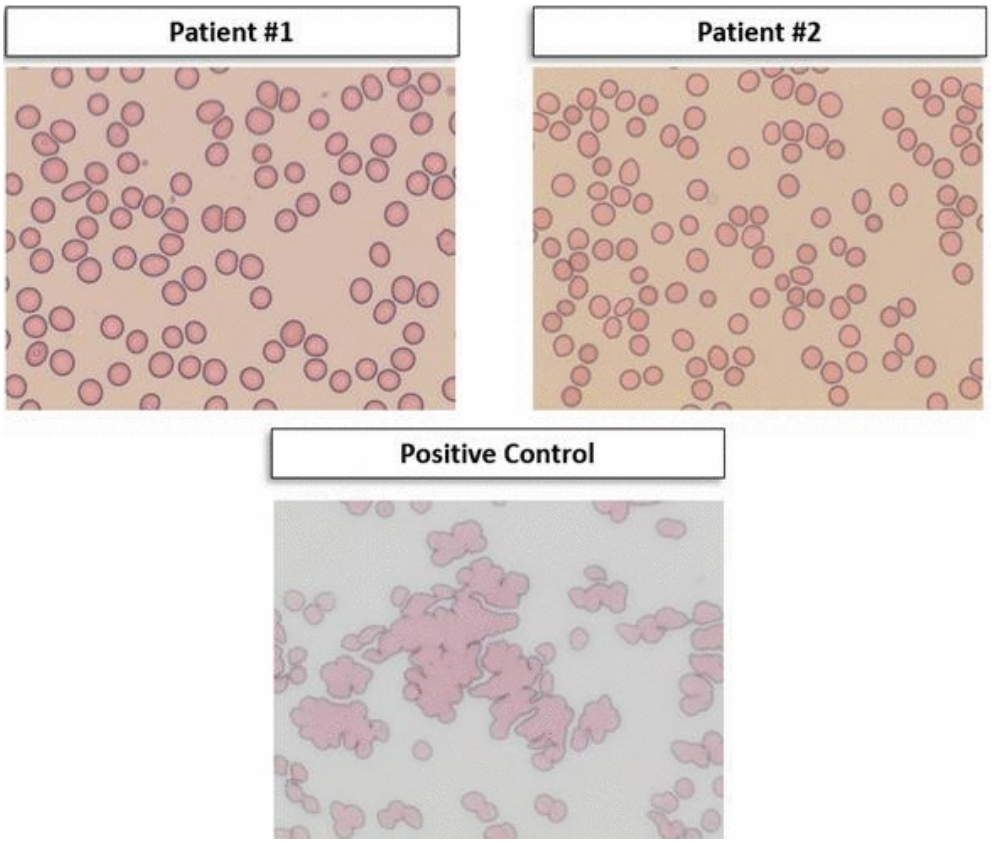
SRF231 Effect on Hemagglutination



Our Phase 1 Clinical Trial

We initiated our first Phase 1 clinical trial of SRF231 in February 2018 and this trial is being conducted at multiple sites in the United States and Canada pursuant to an IND that was filed and sponsored by us. In December 2018, we announced the deprioritization of SRF231 as a result of hematologic toxicities seen during the dose escalation portion of the ongoing Phase 1 trial and the evolving competitive landscape. To date, we have seen no evidence of hemagglutination in the ongoing Phase 1 trial, as shown in the figure below, which contains representative peripheral blood smears taken two hours after two separate patients were treated with SRF231 at a dose of 12 mg/kg. We are continuing dose exploration in the Phase 1 trial and expect to provide additional data regarding SRF231 in the second half of 2019.

SRF231 Effect on Hemagglutination from Phase 1 Trial



Other Research Programs

We also have several earlier stage programs that target other critical components of the TME, including regulatory T cells and NK cells. 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 Collaboration Agreement was subsequently amended in May 2016, July 2017, September 2017 and October 2018. Pursuant to the Collaboration Agreement, we granted Novartis a worldwide exclusive license to research, develop, manufacture and commercialize antibodies that target CD73, along with the right to purchase exclusive option rights, each an Option, for up to four specified targets, each an Option Target, to obtain certain development, manufacturing and commercialization rights. Prior to filing an IND for each Option Target, we are obligated to provide Novartis with a data package with respect to such Option Target, and Novartis may purchase the Option by paying the option purchase fee. If Novartis purchases an Option, following receipt of IND acceptance of a candidate with respect to the applicable Option Target, Novartis will be entitled to exercise the Option for such Option Target. The Collaboration Agreement initially granted Novartis the right to exercise up to three purchased Options. Each Option is designated as either a regional option or a global option in accordance with a selection mechanism in the Collaboration Agreement, as further described below. The Collaboration Agreement granted Novartis the right to exclusively license the development, commercialization and manufacturing rights for up to two targets (inclusive of CD73) worldwide. In addition, Novartis was granted the right to exclusively license the development and manufacturing rights and ex-U.S. commercial rights for up to two additional targets, for which we will retain the U.S. commercial rights, which we refer to as regional targets. We received an upfront payment of $70.0 million from Novartis upon entering into the agreement. Under the Collaboration Agreement, Novartis currently has one Option remaining eligible for purchase and potential exercise. As a result, we are entitled to potential option purchase, option exercise and milestone payments upon the achievement of specified development and sales milestones, which could amount to $750 million, as well as tiered royalties on annual net sales by Novartis ranging from high single-digit to mid-teens percentages. Such amount of potential option purchase, option exercise and milestone payments assumes that Novartis purchases, and exercises, the remaining Option available to it pursuant to the Collaboration Agreement as well as the successful clinical development of and achievement of all sales milestones for all targets covered by the Collaboration Agreement. For any regional target for which we retain U.S. commercial rights, we will pay Novartis tiered royalties ranging from a high single-digit to a mid-teens percentage on our annual net sales of regional licensed products in the United States. Through December 31, 2018, we had received an aggregate of $80.0 million in option purchase and milestone payments from Novartis. In January 2016 and April 2018, we also received equity investments of $13.5 million and $11.5 million, respectively, from Novartis.

Research on Targets

Under the Collaboration Agreement, we are responsible for performing preclinical research through the first IND acceptance on antibodies that bind to each Option Target, pursuant to a research plan directed toward each target. We are responsible for all costs and expenses incurred by or on behalf of us in connection with such research.

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 steering committee, joint development committee and joint commercialization committee.

Option Targets

Prior to the filing of an IND for an Option Target, Novartis may purchase the Option to obtain certain development, manufacturing and commercialization rights for antibodies that bind to up to four Option Targets. To the extent Novartis does not elect to purchase an Option to an Option Target, the Option for such Option Target will expire and all of Novartis' rights to such Option Target under the Collaboration Agreement will terminate. The Collaboration Agreement initially granted Novartis the right to exercise up to three purchased Options. Each exercised Option will be designated as either a regional option or global option, with each such designation determining the development and commercialization rights between the parties with respect to such Option Target, corresponding antibody candidates and licensed products, as summarized below. Following Novartis' exercise of an Option with respect to an Option Target, we will grant to Novartis licenses that are necessary to effectuate the development, manufacturing or commercialization rights associated with a regional or global option, as described below.

In December 2016, Novartis purchased an Option right for antibodies that bind to CD47 for $5.0 million. This was the first Option under the Collaboration Agreement, which gave us the ability to designate it as a regional or global option. In January 2018, we notified Novartis of our decision to designate the Option related to SRF231, our CD47 product candidate, as a regional option in order to retain U.S. rights. In March 2018, Novartis notified us of its decision to not exercise its previously purchased Option for SRF231. In March 2018, we and Novartis also mutually agreed to cease development of one of the undisclosed programs subject to the Collaboration Agreement. In February 2019, Novartis notified us of its decision not to purchase the Option for SRF388, resulting in the Company retaining full rights to the program. As a result, Novartis has one Option remaining eligible for purchase and potential exercise. Novartis has the ability to designate the geographical scope of the remaining Option. Pursuant to the terms of the Collaboration Agreement, if Novartis does not purchase this Option prior to January 9, 2020, the Option will expire.

Development and Commercialization of Regional Licensed Products

To the extent an exercised Option is designated as a regional target, we are primarily responsible for the early clinical development of each corresponding regional antibody candidate and regional licensed product at our own cost. Unless we choose to opt out of our development rights, we will collaborate with Novartis on the further clinical development of regional antibody candidates and regional licensed products. Pursuant to a regional development plan for each regional licensed product, we will be responsible for development activities related to obtaining regulatory approval in the United States, with Novartis responsible for development activities related to obtaining regulatory approval elsewhere in the world. The development costs of such later clinical development activities will be shared evenly between the parties. Thereafter, we are responsible for the commercialization of regional licensed products in the United States, and Novartis is responsible for the commercialization of regional licensed products outside of the United States, each pursuant to a commercialization plan. Each party must use commercially reasonable efforts to commercialize such products within their respective territories. We will work with Novartis to agree to a global commercialization strategy with respect to the regional licensed products prior to commercialization.

Development and Commercialization of Global Licensed Products

To the extent an exercised Option is designated as a global target, we are primarily responsible for the early clinical development of each global antibody candidate and global licensed product at our own cost, and Novartis is responsible for later worldwide clinical development of global antibody candidates and global licensed products, pursuant to a development plan for such global licensed product, at its own cost. Novartis is solely responsible for the worldwide commercialization of global licensed products and must use commercially reasonable efforts to commercialize such products, pursuant to a commercialization plan, at its own cost. Novartis agrees to provide us with development and commercialization updates regarding global licensed products through the joint steering committee, joint development committee and joint commercialization committee.

Exclusivity

Neither party may, alone or with any affiliate or third party, (i) research or develop any antibody that specifically binds to an Option Target for a specified period of time outside of the Collaboration Agreement or (ii) develop or commercialize any antibody that specifically binds to CD73 or any Option Target that subsequently becomes a licensed target for a specified period of time outside the Collaboration Agreement. The October 2018 Amendment clarified that Novartis is permitted to research, develop, manufacture or commercialize any diagnostic product that specifically binds to a licensed target, subject to Novartis' compliance with its rights and obligations under the Collaboration 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.

Financial Terms

In addition to the upfront fee, under the Collaboration Agreement, Novartis is obligated to pay us a fee to the extent it desires to purchase an Option for each Option Target and another fee to exercise such purchased Option. As of December 31, 2018, we had received $5.0 million in option purchase payments and we are entitled to an aggregate of up to $67.5 million of potential option purchase and option exercise payments. As a result of Novartis' decision not to purchase the Option relating to SRF-388 in February 2019, the maximum aggregate amount of potential option purchase and option exercise payments that we are entitled to receive under the Collaboration Agreement was reduced to $20.0 million. We are also eligible to receive payments on a target-by-target basis upon the achievement of specified development and sales milestones and tiered

royalties on annual net sales by Novartis of licensed products ranging from high single-digit to mid-teens percentages. We are required to pay Novartis tiered royalties of a high single-digit to mid-teens percentage on our annual net sales of regional licensed products in the United States. The royalty payments are subject to reduction under specified conditions set forth in the Collaboration Agreement. In January 2016 and April 2018, we also received equity investments of $13.5 million and $11.5 million, respectively, from Novartis.

Termination

Unless terminated earlier, the Collaboration Agreement will continue in effect until neither we nor Novartis is researching, developing, manufacturing or commercializing any antibody candidates or licensed products under the Collaboration Agreement. Novartis may terminate the Collaboration Agreement on a target-by-target basis for any reason upon prior notice to us within a specified time period. However, Novartis cannot terminate the Collaboration Agreement with respect to CD73 for a certain period of time following the effective date. Either party may terminate the Collaboration Agreement on a target-by-target basis 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 for our material breach or insolvency, 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 certain products.

Other Collaborations and License Agreements

H2L2 License Agreement

In April 2014, we entered into a license agreement, or the H2L2 License Agreement, with Harbour Antibodies H2L2 BV, or H2L2. Pursuant to the H2L2 License Agreement, H2L2 granted us a worldwide, non-exclusive license under H2L2's technology to (i) make, use, manufacture, import and export (but not sell) H2L2 mice, which are capable of generating fully human antibodies, for research, development, clinical and manufacturing purposes and (ii) make, use, sell, offer for sale, import and export antibodies discovered or generated using H2L2 technology, and products incorporating such antibodies. Such licenses are sublicensable only to our affiliates or third-party contractors, other than in the case of the license to sell antibody products, which we may license to any third party. Under the H2L2 License Agreement, we are obligated to pay H2L2 a low five-digit dollar amount as an upfront license fee for each antibody program that we initiate using the H2L2 mice. We may be obligated to pay up to an aggregate of $1.04 million in milestone payments to H2L2 for each antibody cell line we develop through Phase 3 clinical trials and regulatory approval. We are required to pay H2L2 a one-time sales performance payment of a low seven-digit dollar amount for each antibody product that is commercialized and achieves worldwide gross sales in excess of a low eight-digit dollar amount. If we enter an agreement with a third party to further research or commercialize an antibody product developed under the H2L2 License Agreement, then we are obligated to pay H2L2 a one-time payment of the lesser of (i) a low double-digit percentage of the upfront fee paid to us by the third party or (ii) a low six-digit dollar amount.

We own all results and inventions that we generate while exercising our rights under the licenses.

Unless earlier terminated, the H2L2 License Agreement will expire in April 2019. Either party may terminate the H2L2 License Agreement upon an uncured material breach by the other party. We may also terminate the H2L2 License Agreement at will upon providing prior written notice to H2L2.

Harbour License Agreement

In September 2015, we entered into an exclusive license agreement, or the Harbour License Agreement, with Harbour Antibodies B.V., or Harbour, to receive an exclusive license to Harbour's materials and patent rights directed to CD47. Pursuant to the Harbour License Agreement, Harbour granted us a worldwide, royalty-bearing exclusive license, with the right to sublicense, to exploit products that incorporate Harbour's materials or that would infringe Harbour's patent rights. We are obligated to use commercially reasonable efforts to develop and commercialize such licensed products.

In consideration, we paid Harbour a one-time license upfront payment of $125,000 and are required to pay a nominal annual maintenance fee during the term. We are obligated to pay up to an aggregate of $4.75 million in developmental and commercial milestones on each licensed product. In March 2018, we paid Harbour a $200,000 milestone payment due upon the dosing of the first patient in our SRF231 Phase 1 trial. We are also obligated to pay Harbour royalties of a low single-digit percentage on the worldwide net sales of any licensed product on a country-by-country basis until the expiration of the royalty term, which is the later of (i) expiration or termination of the last to expire of a valid claim within the patent rights that cover such licensed product in a country or (ii) ten years from the date of first commercial sale of the licensed product within a country.

The Harbour License Agreement will expire on the last to expire royalty term on a licensed product-by-licensed product basis, unless terminated earlier by the parties. We may terminate the agreement for any reason with proper prior notice to Harbour. Harbour may terminate if we fail to pay an amount due after Harbour provides us written notice or upon our uncured material breach, subject to completion of a dispute resolution process and subsequent cure.

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-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 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.

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 SRF231 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., Innate Pharma, S.A., iTeos, Palobiofarma SL, Tizona, and TRACON Pharmaceuticals, Inc.
- Programs in development targeting CD47 or SIRPα, including those by Aduro Biotech, Inc., ALX Oncology., Arch Oncology, Aurigene, Inc., Blink Biomedical, Inc., Celgene, Inc., Forty Seven, Inc., Innovent, Novimmune, S.A., OSE Immunotherapeutics S.A., Sorrento, Inc., Synthon Holding B.V. and Trillium Therapeutics, Inc.;
- 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 March 7, 2019, we co-own and have exclusively licensed to Novartis our rights in three U.S. provisional patent applications and one U.S. non-provisional patent application that cover compositions of matter and methods of use for our CD73 therapeutic antibody candidate, NZV930. Additionally, we co-own nine foreign patent applications. Any patents issuing from these applications would be expected to expire in 2038 or 2039, absent any applicable patent term adjustment or extension.

As of March 7, 2019, we co-own three U.S. provisional patent application that covers compositions of matter and methods of use for our CD39 therapeutic antibody candidates, including SRF617, and have the right to obtain exclusive ownership of these applications. Any patents issuing from these applications would be expected to expire in 2039 and 2040, absent any applicable patent term adjustment or extension. We do not yet own any non-provisional applications or issued patents for this program.

With respect to our IL-27 therapeutic antibody program, as of March 7, 2019, we own three U.S. provisional patent applications that cover compositions of matter and methods of use for various antibodies. Any patents issuing from these applications would be expected to expire in 2039, absent any applicable patent term adjustment or extension. We do not own any non-provisional applications or issued patents for this program.

As of March 7, 2019, we co-own U.S. Patent Nos. 9,803,016 and 9,650,441, which cover composition of matter and the treatment of cancer using our therapeutic CD47 antibody, SRF231. These patent rights are expected to expire in 2036, absent any applicable patent term adjustment or extension. Also, with respect to SRF231, we co-own two pending U.S. non-provisional applications and eleven pending foreign applications, and we own one pending PCT patent application, one U.S. non-provisional patent application and three pending provisional U.S. patent applications, within five patent families. Collectively, these patent applications cover compositions of matter and methods of using SRF231 in combination with certain other therapeutic agents. Any patent issuing from these applications would be expected to expire in 2036, 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;
- 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, 2018, the user fee for an application requiring clinical data, such as an NDA or BLA, is $2,421,495. The sponsor of an approved NDA or BLA is also subject to an annual prescription drug program fee, which for fiscal year 2018 is $304,162. 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 considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug 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. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

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. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product.

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.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, 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 Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FDCA to require 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.

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. 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 (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;
- 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; imposed a new federal excise tax on the sale of certain medical devices; 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, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, Congressional, and Executive challenges. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the "individual mandate." However, the current presidential administration has indicated that enacting changes to the ACA is a legislative priority and has discussed repealing and replacing or amending the ACA. While Congress has not passed repeal legislation to date, the 2017 Tax Reform Act includes a provision repealing the individual mandate, which became effective January 1, 2019. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement could have on our business.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give 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. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments that third-party payors argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions to Medicare payments to providers of 2% per fiscal year through 2027. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Individual states in the United States have also become increasingly active in enacting legislation and implementing 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.

The CMS has recently proposed regulations that would give 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 November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the

proposed rule changes would allow Medicare Advantage plans to use pre authorization (PA) and step therapy (ST) for six protected classes of drugs, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs; and change the definition of "negotiated prices" while a definition of "price concession" in the regulations. It is unclear whether these proposed changes we be accepted, and if so, what effect such changes will have on our business.

Moreover, 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 I 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 drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy. We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

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 under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of 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.

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.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. However, on December 27, 2018, the District Court for the District of Columbia invalidated a recent reimbursement formula change instituted by CMS under the 340B program. For the 2018 and 2019 fiscal years, CMS altered the reimbursement formula from Average Sale Price (ASP) plus 6% to ASP minus 22.5% on specified covered outpatient drugs ("SCODs"). The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make, but was instead a fundamental change in the reimbursement calculation, and such a dramatic change was beyond the scope of the Secretary's authority. The court has not determined whether reimbursement rates should be retroactively returned to the ASP plus 6% rate and the difference in such reimbursement made to the covered facilities, or if some other remedy is more appropriate. 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.

In recent years, additional laws have resulted in direct or indirect reimbursement reductions for certain Medicare providers, including:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken.
- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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.

Available Information

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.

Since inception, we have incurred significant net losses. Our net losses were $6.6 million for the year ended December 31, 2018 and $45.4 million for the year ended December 31, 2017. As of December 31, 2018, we had an accumulated deficit of $66.8 million. We have funded our operations to date primarily with proceeds from the sale of preferred stock and upfront fees received in connection with our collaboration with Novartis Institutes for Biomedical Research, Inc., or Novartis. 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 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', 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 and SRF388, 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 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 collaboration with Novartis;
- whether Novartis exercises its remaining licensing and co-development option under its collaboration agreement with us, which would trigger additional payments to us;
- 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 and capital expenditure requirements for at least the next 24 months.

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 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, 2018, we had federal and state net operating loss carryforwards of $19.1 million and $19.4 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. 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.

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. Two of our product candidates, SRF231 and NZV930 (formerly SRF373), are being investigated in ongoing Phase 1 clinical trials, and our other 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 only have two product candidates in clinical development, and the rest of our programs are in preclinical development. 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 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 partnerships 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; and
- 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.

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.

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.

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 more rare, 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. 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. There are also several programs in development targeting cluster of differentiation, or CD, 47, SIRPα, including those by Aduro Biotech, Inc., ALX Oncology Inc., Arch Oncology, Aurigene, Inc., Blink Biomedical, Inc., Celgene, Inc., Forty Seven, Inc., Innovent, Novimmune, S.A., OSE Immunotherapeutics S.A., Sorrento, Inc., Synthon Holding B.V. and Trillium Therapeutics, Inc.

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.

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 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. 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 and scope of our SRF231 program and, based on the reallocation of capital, we anticipate that SRF388 will accelerate and be ready for IND filing before the end of 2019. 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 pursue on a less aggressive basis 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 to Novartis and will receive only milestone payments and royalties on sales of NZV930, 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 may seek Fast Track Designation by the FDA for a product candidate that we develop, and we may be unsuccessful. If we are successful, the designation may not actually lead to a faster development or regulatory review or approval process.

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. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

We may seek Orphan Drug Designation for other product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

As part of our business strategy, we have sought and received Orphan Drug Designation for SRF231 in the United States. We may seek Orphan Drug Designation for our other product candidates we develop, and we may be unsuccessful. 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 Europe, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug 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 Europe 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, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug 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 Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Even though we have obtained an Orphan Drug Designation for SRF231, and even if we obtain orphan drug exclusivity for SRF231 and other product candidates, that exclusivity may not effectively protect SRF231 or our other 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 Orphan Drug Designation for applicable indications for our current and any future product candidates in addition to SRF231, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

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; and
- a decline in our share price.

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

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA.

Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or TCJA, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." The effect that the ACA and its possible repeal and replacement may have on our business remains unclear.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes 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 2027 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Middle Class Tax Relief and Job Creation Act of 2012 required that the Centers for Medicare & Medicaid Services, or CMS, the agency responsible for administering the Medicare program, reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for any product candidate we develop or complementary diagnostics or companion diagnostics or additional pricing pressures.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. For example, the United States government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration recently released a "Blueprint", or plan, to reduce the cost of drugs. The current administration's Blueprint contains certain measures that the U.S. Department of Health and Human Services is already working to implement. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. Although a number of these, and other proposed measures, will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological 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.

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

Risks Related To Reliance On Third Parties

We are fully dependent on our collaboration with Novartis for the development of NZV930 and may depend on Novartis or 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 Collaboration Agreement, focused on researching, developing and commercializing cancer immunotherapies. Pursuant to the Collaboration Agreement, we granted Novartis a worldwide exclusive license to research, develop, manufacture and commercialize antibodies that target CD73, along with the right to purchase exclusive option rights to up to four specified targets, each an Option, to obtain certain development, manufacturing and commercialization rights. In March 2018, Novartis notified us of its decision to not exercise its previously purchased Option for SRF231, and in February 2019, Novartis notified us of its decision not to purchase the Option for SRF388. Novartis currently has one Option remaining eligible for purchase and potential exercise. The collaboration involves a complex allocation of rights, provides for milestone payments to us based on the achievement of specified clinical development, regulatory and commercial milestones, provides for additional payments upon Novartis' election to exercise rights to commercialize additional product candidates, and provides us with royalty-based revenue if certain product candidates are successfully commercialized. Novartis will have substantial ability to control the development and commercialization of any target it licenses on a global basis. Our lack of control over the clinical development of certain programs under the Collaboration Agreement 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 is solely responsible for the development and commercialization of NZV930 and as such, we are wholly dependent on Novartis for the success of this program. In the event Novartis terminates the Collaboration 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. Furthermore, in the event Novartis does not purchase and exercise its remaining Option, we will not be eligible to receive any future milestone payments under the Collaboration Agreement, other than from NZV930, if any, which could require us to seek additional funding in order to avoid delaying, reducing the scope of, or suspending, one or more of our research and development programs or clinical trials. In addition, any decision by Novartis not to purchase or exercise the Option may negatively impact public perception of the applicable program, or all of the programs, covered by the Collaboration Agreement, which could adversely affect the market price of our common stock. We cannot provide any assurance with respect to the success of the Collaboration 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 Agreement poses, 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 Collaboration 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 Collaboration Agreement, we have granted worldwide exclusive rights to Novartis for antibodies targeting CD73, and during the term of the agreement 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 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; or
- form relationships with other entities, some of which may be our competitors.

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.

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 intend to 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 may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality 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.

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.

We do not currently have any agreements with third-party manufacturers for the 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.

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 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. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate 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 material to a false or fraudulent claim to the federal government;
- 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 statutes or specific intent to violate them;
- 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 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 CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- 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.

On January 31, 2019, the Department of Health and Human Services (HHS) and HHS Office of Inspector General (OIG) proposed an amendment to one of the existing Anti-Kickback safe harbors (42 C.F.R. 1001.952(h)) which would prohibit certain pharmaceutical manufacturers from offering rebates to pharmacy benefit managers, PBMs, in the Medicare Part D and Medicaid managed care programs. The proposed amendment would remove protection for "discounts" from Anti-Kickback enforcement action, and would include criminal and civil penalties for knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or reward the referral of business reimbursable under federal health care programs. At the same time, HHS also proposed to create a new safe harbor to protect point-of-sale discounts that drug manufacturers provide directly to patients, and adds another safe harbor to protect certain administrative fees paid by manufacturers to PBMs. If this proposal is adopted, in whole or in part, it could affect the pricing and reimbursement for any products for which we receive approval in the future.

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 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.

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 March 7, 2019, we co-own and have exclusively licensed to Novartis our rights in three U.S. provisional patent applications and one U.S. non-provisional patent application that cover compositions of matter and methods of use for our CD73 therapeutic antibody candidate, NZV930. Additionally, we co-own nine foreign patent applications. Any patents issuing from these applications would be expected to expire in 2038 or 2039, absent any applicable patent term adjustment or extension.

As of March 7, 2019, we co-own three U.S. provisional patent applications that cover composition of matter and methods of use for our CD39 therapeutic antibody candidates, including SRF617. Any patents issuing from this application would be expected to expire in 2039 and 2040, absent any applicable patent term adjustment or extension. We do not yet own any non-provisional applications or issued patents for this program.

With respect to our IL-27 therapeutic antibody program, as of March 7, 2019, we own three U.S. provisional patent applications that cover composition of matter and methods of use for various antibodies. Any patents issuing from these applications would be expected to expire in 2039, absent any applicable patent term adjustment or extension. We do not own any non-provisional applications or issued patents for this program. In 2017, we entered into a license agreement involving U.S. patent rights, including one U.S. patent and a pending U.S. non-provisional patent application, controlled by the University of Pennsylvania. Our license is exclusive and is limited to the use of antagonists of IL-27 for the treatment of cancer. Any patent issuing from this application would be expected to expire in 2024, excluding any applicable patent term adjustment or extension.

As of March 7, 2019, we co-own U.S. Patent Nos. 9,803,016 and 9,650,441, which cover composition of matter and the treatment of cancer using our therapeutic CD47 antibody, SRF231. These patent rights are expected to expire in 2036, absent any applicable patent term adjustment or extension. Also, with respect to SRF231, we co-own two pending U.S. non-provisional applications and eleven pending foreign applications, and own one pending PCT patent application, one U.S. non-provisional patent application and three pending provisional U.S. patent applications, within five patent families. Collectively, these patent applications cover compositions of matter and methods of using SRF231 in combination with certain other therapeutic agents. Any patents issuing from these applications would be expected to expire in 2036, 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 filing, 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, including CD47 antibodies, 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 our CD47 antibody technology.

The field of therapeutic antibodies, including CD47 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.

We are subject to and may in the future 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 CD47 antibody technology. For example, we are aware of several separate families of U.S. patents, patent applications, and foreign counterparts that relate to CD47 antibodies and methods of treatment, where the earliest priority dates of each family pre-date the priority dates of our patents and patent applications, including PCT Publication No. WO 2009/091601 (and related U.S. Patent Nos. 8,562,997, 9,493,575, 9,399,682, 9,611,329 and other related U.S. patent applications and foreign counterparts) filed by Stanford University, which is reported to have exclusively licensed its rights to Forty Seven, Inc.

Stanford University also has rights to European Patent No. EP 2242512. In January 2017, we opposed this patent in the Opposition Division of the EPO, or the Opposition Division. Six third parties also filed oppositions against European Patent No. EP 2242512. Stanford filed a response to the seven oppositions and oral proceedings were held in August 2018. The Opposition Division maintained an amended version of the patent. As of March 7, 2019, we and three additional opponents have submitted notices of appeal to the Opposition Division's interlocutory decision to the Technical Boards of Appeal of the EPO.

Pending final resolution of this matter, Stanford, or other parties that may have rights to EP 2242512 may allege that the manufacture, use or sale of SRF231 infringes the patent in Europe. If, as part of any opposition or appeal proceeding before the Opposition Division or a Technical Board of Appeal, respectively, we are unsuccessful in invalidating or narrowing Stanford's claims, or if claims successfully invalidated by the Opposition Division are restored on appeal, our ability to commercialize SRF231 in Europe could be materially impaired. Moreover, we are aware of two pending divisional applications relating to EP 2242512 that are being pursued by Stanford. If either of these applications matures into a granted European patent or if any other related patent application matures into a granted European patent, our ability to commercialize SRF231 could be materially impaired. Similarly, related patents in the U.S. or other countries could materially impair our ability to commercialize SRF231 in those countries.

We are also aware of another family of third-party patents and patent applications that may be asserted to encompass certain combination therapies using our CD47 antibodies. This family of U.S. and foreign patents and patent applications relate to combination therapy using CD47 antibodies, and includes U.S. Patent No. 9,352,037 and related European Patent No. EP 2282772. This family was filed by Stichting Sanquin Bloedvoorziening of the Netherlands, or Sanquin, which is reported to have licensed its rights to Synthon Biopharmaceuticals B.V., also of the Netherlands. Sanquin or other parties that may have rights in the patents may allege that we are not entitled to market combination therapies involving SRF231 without a license, which could materially impair our ability to commercialize SRF231 combination therapies.

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 biosimiliar 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 our CD47 antibody product candidates or their uses.

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 March 7, 2019, we had 76 full-time employees, including 54 employees engaged in research and development. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, 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 will cease to be an EU Member State either on the effective date of a withdrawal agreement (entry into such a withdrawal agreement will require UK parliamentary approval) or, failing that, two years following the UK's notification of its intention to leave the EU, unless the European Council (together with the UK) unanimously decides to extend the two-year period. On March 29, 2017, the UK formally notified the European Council of its intention to leave the EU. The UK is, therefore, scheduled to leave the EU at 11:00p.m. GMT on March 29, 2019. If the UK and the EU are unable to negotiate acceptable withdrawal terms, barrier-free access between the UK and other European Member States or among the European Economic Area, or EEA, overall could be diminished or eliminated

The lack of clarity over which EU laws and regulations will continue to be implemented in the UK after Brexit (including financial laws and regulations, tax and free trade agreements, intellectual property rights, data protection laws, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws) 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.

These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the UK financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

Risks Related To Our 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.

In April 2018, we closed our initial public offering. Prior to that offering, there was no public market for shares of our common stock. Although we have completed our initial public offering and shares of our common stock are listed and trading on the Nasdaq Global Market, 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.

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.

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 28% 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.

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 will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending 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.

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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the U.S. government enacted the TCJA, which significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, effective January 1, 2018; limitation of the tax deduction for interest expense; limitation of the deduction for net operating losses and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs". The tax rate change resulted in (i) a reduction in the gross amount of our deferred tax assets recorded as of December 31, 2017, without an impact on the net amount of our deferred tax assets, which are recorded with a full valuation allowance, and (ii) no income tax expense or benefit being recognized as of the enactment date of the TCJA. We continue to examine the impact this tax reform legislation may have on our business. However, the effect of the TCJA on us and our affiliates, whether adverse or favorable, is uncertain and may not become evident for some period of time. We urge investors to consult with their legal and tax advisers regarding the implications of the TCJA 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 32,000 square feet located at 50 Hampshire Street, Cambridge, Massachusetts. Our lease expires on April 30, 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 January 2017, we filed an opposition in the European Patent Office, or EPO, opposing the grant of European Patent No. EP 2242512 to Stanford University. We were one of seven parties opposing the grant of the European patent, which relates generally to CD47 antibodies for use in treating cancer. Stanford filed a response to the seven oppositions and oral arguments were held in August 2018. The Opposition Division maintained an amended version of the patent. As of March 7, 2019, we and three additional opponents have submitted notices of appeal to the Opposition Division's interlocutory decision to the Technical Board of Appeal of the EPO. Accordingly, final resolution of the oppositions may be several years in the future.

The Opposition Division's interlocutory decision, if maintained at the appeals level, could have a substantial negative effect on our business and leave open the possibility that Stanford University or other parties that have rights to such patent could assert that SRF231 infringes on the Stanford Patent in a relevant European country. The timing and outcome of any such appeal cannot be predicted or determined as of the date of this report.

We are also aware of various pending divisional applications relating to EP 2242512 that are being pursued by Stanford University. If any of these divisional applications proceed to grant they may also materially impair our ability to commercialize SRF231 in Europe.

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. The following table shows the high and low sale prices per share of our common stock as reported on The Nasdaq Global Market for the periods indicated:

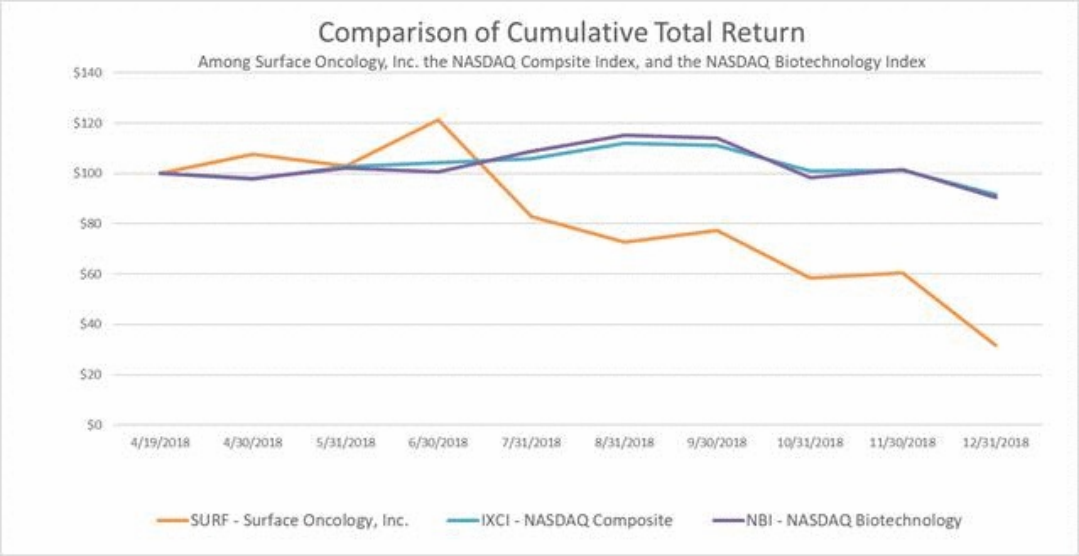
	High	Low
2018		
Second Quarter 2018 (From April 19, 2018)	$ 17.41	$ 12.83
Third Quarter 2018	$ 17.83	$ 8.92
Fourth Quarter 2018	$ 10.69	$ 3.65

On March 4, 2019, the last reported sale price for our common stock on the Nasdaq Global Market was $4.16 per share.

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, 2018, 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 March 4, 2019, there were approximately 20 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 2019 Annual Meeting of Stockholders and is incorporated herein by reference.

Unregistered Sales of Equity Securities

We had no unregistered sales of securities for the year ended December 31, 2018.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

During the year ended December 31, 2018, we repurchased 16,935 restricted shares for $0.0003 per share from employees pursuant to our equity programs. Unvested restricted stock units are subject to repurchase rights upon termination of service.

Item 6. Selected Consolidated Financial Data.

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this Annual Report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this Annual Report on Form 10-K. We have derived the consolidated statement of operations data for the years ended December 31, 2018, 2017, and 2016, and the consolidated balance sheet data as of December 31, 2018 and 2017 from our audited consolidated financial statements appearing at the end of this Annual Report on Form 10-K. Our historical results are not necessarily indicative of results that may be expected in the future.

	Year Ended December 31,		
	2018	2017	2016
	(in thousands, except per share data)		
Statement of Operations Data:			
Collaboration revenue	$ 59,417	$ 12,826	$ 6,632
Operating expenses:			
Research and development	52,492	47,783	20,492
General and administrative	16,076	11,033	4,144
Total operating expenses	68,568	58,816	24,636
Loss from operations	(9,151)	(45,990)	(18,004)
Interest and other income, net	2,554	613	551
Net loss	(6,597)	(45,377)	(17,453)
Accretion of redeemable convertible preferred stock to redemption value	(11)	(40)	(41)
Net loss attributable to common stockholders	$ (6,608)	$ (45,417)	$ (17,494)
Net loss per share attributable to common stockholders—basic and diluted (1)	$ (0.33)	$ (18.35)	$ (7.31)
Weighted average common shares outstanding—basic and diluted (1)	19,991	2,475	2,394

	As of December 31,		
	2018	2017	2016
		(in thousands)	
Balance Sheet Data:			
Cash, cash equivalents and marketable securities	$ 158,835	$ 63,309	$ 79,151
Working capital (2)	137,424	47,946	76,968
Total assets	174,065	81,454	98,139
Accounts payable and accrued expenses	12,215	13,058	9,181
Deferred revenue – related party	53,952	82,105	64,931
Total stockholders' equity (deficit)	102,862	(67,314)	(26,912)

(1) See Note 12 to our consolidated financial statements for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.
(2) We define working capital as current assets less current liabilities.

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, are 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, including metabolites, cytokines and macrophages.

NZV930 (formerly SRF373) and SRF617 are antibodies inhibiting 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. In June 2018, a Phase 1 trial of NZV930 was initiated by our partner, Novartis Institutes for Biomedical Research, Inc., or Novartis, and we expect to file an investigational new drug application, or IND, for SRF617 in the fourth quarter of 2019.

SRF388 is an antibody targeting interleukin 27, or IL-27, an immunosuppressive cytokine in the TME that is overexpressed in certain cancers. IL-27 is a cytokine secreted by macrophages and antigen presenting cells that plays an important physiologic role in suppressing the immune system. 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 expect to file an IND for SRF388 in the fourth quarter of 2019.

SRF231 is an antibody targeting CD47, which is a protein expressed on many cells, but often overexpressed on tumor cells. By targeting CD47, we believe we can promote macrophage activation to attack such tumors. We initiated a Phase 1 clinical trial of SRF231 in February 2018. In December 2018, we announced the deprioritization of SRF231 as a result of toxicities seen during the dose escalation portion of the ongoing Phase 1 trial and the evolving competitive landscape. We are continuing dose exploration in the Phase 1 trial and expect to provide additional data regarding SRF231 in the second half of 2019.

We also have several earlier stage programs that target other critical components of the TME, including regulatory T cells and natural killer, or NK, cells. 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.

On April 23, 2018, we completed an initial public offering of our common stock by issuing 7,200,000 shares of our common stock, at $15.00 per share for net proceeds of $97.2 million. Concurrent with the initial public offering, we issued to Novartis Institutes for BioMedical Research, Inc., or Novartis, 766,666 shares of our common stock at $15.00 per share for proceeds of $11.5 million in a private placement.

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, and SRF231, 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 the sales of preferred stock, payments received under the Collaboration Agreement, with Novartis, and proceeds from the Company's initial public offering of common stock and concurrent private placement. Through December 31, 2018, we had received gross proceeds of $48.6 million from our sales of preferred stock and $150.0 million from the Collaboration Agreement. As of December 31, 2018, we had cash, cash equivalents and marketable securities of $158.8 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 $6.6 million and $45.4 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $66.8 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially, 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, 2018 will enable us to fund our operating expenses and capital expenditure requirements into 2021, excluding milestone payments from Novartis. 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.

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 the Collaboration Agreement. 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 the Collaboration Agreement as well as any additional collaborations that we may enter into in the future.

Collaboration Agreement with Novartis

In January 2016, we entered into the Collaboration Agreement to develop next-generation cancer therapies. Under the Collaboration Agreement, as amended, we are responsible for performing research on antibodies that bind to CD73 and four other specified targets. We are responsible for all costs and expenses incurred by, or on behalf of, us in connection with the research. Novartis also has the right, but not the obligation, to conduct research at its own cost on antibodies that bind to CD73 in accordance with the agreement.

Pursuant to the Collaboration Agreement, we granted Novartis a worldwide exclusive license to research, develop, manufacture and commercialize antibodies that target CD73, along with the right to purchase exclusive option rights, each an Option, for up to four specified targets, each an Option Target, to obtain certain development, manufacturing and commercialization rights. If Novartis purchases an Option, following receipt of the IND acceptance for a candidate with respect to the applicable Option Target, Novartis will be entitled to exercise the Option for such Option Target. Pursuant to the Collaboration Agreement, Novartis initially had the right to exercise up to three purchased Options. In March 2018, Novartis notified us of its decision to not exercise its previously purchased Option for SRF231, our CD47 product candidate. In March 2018, we and Novartis also mutually agreed to cease development of one of the undisclosed programs subject to the Collaboration Agreement. As a result, as of December 31, 2018, Novartis had two Options remaining eligible for purchase, and potential exercise.

At the time we entered into the Collaboration Agreement in January 2016, Novartis made an upfront payment to us of $70.0 million. Under the Collaboration Agreement, Novartis will also pay us a fee to purchase each Option for each Option Target and another fee to exercise an Option. As of December 31, 2018, we had received $5.0 million in option purchase payments and we were entitled to an aggregate of up to $67.5 million of potential option purchase and option exercise payments. We are also eligible to receive payments on a target-by-target basis upon the achievement of specified development and sales milestones, and tiered royalties on annual net sales by Novartis of licensed products ranging from high single-digit to mid-teens percentages upon successful commercialization of any products. Under the Collaboration Agreement, as of December 31, 2018, we were entitled to potential option purchase, option exercise, and milestone payments aggregating up to $1.17 billion, of which $80.0 million had been received as of December 31, 2018. Such amount of potential option purchase, option exercise, and milestone payments assumes that Novartis purchases, and exercises both of the remaining Options available to it pursuant to the Collaboration Agreement, as well as the successful clinical development of and achievement of all sales milestones for all targets covered by the Collaboration Agreement.

In addition, we are required to pay Novartis tiered royalties on annual net sales by us of regional licensed products in the United States ranging from high single-digit to mid-teens percentages. The royalty payments are subject to reduction under specified conditions set forth in the Collaboration Agreement. In January 2016, Novartis also purchased $13.5 million of our Series A-1 preferred stock. The equity investment was made at fair value, and we determined it to be distinct from the Collaboration Agreement.

Under ASC 606 we account 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 Collaboration 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.

In February 2018, we received an additional milestone payment of $45.0 million from Novartis upon Novartis' receipt and acceptance of the first final audited GLP toxicology study report for NZV930. Upon achieving the milestone, we concluded this variable consideration was no longer constrained and included this amount in the transaction price. We recognized $27.9 million as collaboration revenue – related party in the year ended December 31, 2018, based on the ratio of our actual costs incurred as of the milestone achievement date to our total estimated costs with respect to performing research on antibodies that bind to CD73 and other specified targets under the Collaboration Agreement. The remaining unrecognized amount was initially recorded as deferred revenue and will subsequently be recognized as revenue over the performance period in proportion to the costs incurred by us under the Collaboration Agreement.

In March 2018, Novartis notified us of its decision not to exercise its option related to CD47. We recognized the $5.0 million exclusive option right payment as collaboration revenue – related party in the first quarter of 2018 because we no longer had any remaining performance obligations related to CD47.

Through December 31, 2018, we had received an aggregate of $150.0 million from Novartis in upfront payments, milestone payments, and option purchase payments. During the year ended December 31, 2018, 2017, and 2016 we recognized revenue of $59.4 million, $12.8 million and $6.6 million, respectively, related to the Collaboration Agreement.

In February 2019, Novartis notified us of its decision not to purchase its Option related to IL-27 (See Note 19 "Subsequent Events" for further discussion). Accordingly, as of February 4, 2019, Novartis had one Option remaining eligible for purchase and potential exercise. As a result, the maximum aggregate amount of potential option purchase, option exercise and milestone payments that we are entitled to receive under the Collaboration Agreement was reduced from $1.17 billion to $750 million.

The decision by Novartis to terminate the IL-27 target under the Collaboration Agreement will result in our removing all future costs associated with IL-27 from the estimated total costs in the cost-to-cost model in the first quarter of 2019. This change in the total estimated costs in the cost-to-cost model will result in our recognizing revenue of approximately $13.0 million in the first quarter of 2019.

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,				
	2018	2017	2016	2018 v 2017	2017 v 2016
SRF231	$ 19,781	$ 22,072	$ 7,724	$ (2,291)	$ 14,348
NZV930	956	2,295	1,281	(1,339)	1,014
SRF388	3,981	2,767	1,067	1,214	1,700
SRF617	4,784	—	—	4,784	—
Other early-stage programs	3,618	4,737	1,845	(1,119)	2,892
Unallocated research and discovery expenses	19,372	15,912	8,575	3,460	7,337
Total research and development expenses	$ 52,492	$ 47,783	$ 20,492	$ 4,709	$ 27,291

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase over the next several years as we initiate clinical trials and pursue later stages of development of SRF617 and SRF388, initiate clinical trials for the product candidates we develop and continue to discover and develop additional product candidates.

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 we increase our headcount to support research activities and development of our programs. We also anticipate that we will incur 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 consists primarily of interest earned on our cash, cash equivalents, and marketable securities.

Income Taxes

We have not recorded any income tax benefits for the net losses we incurred or for the research and development tax credits we generated during the years ended December 31, 2018 and 2017 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. As of December 31, 2018, we had federal and state net operating loss carryforwards of $19.1 million and $19.4 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2034. As of December 31, 2018, we also had federal and state research and development tax credit carryforwards of $1.4 million and $0.7 million, respectively, which begin to expire in 2034 and 2030, respectively. Through December 31, 2018, we had recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

Results of Operations

Comparison of Years Ended December 31, 2018, 2017, and 2016

The following table summarizes our results of operations for the years ended December 31, 2018, 2017, and 2016, along with the changes in those items:

	Year Ended December 31,				
	2018	2017	2016	2018 v 2017	2017 v 2016
			(in thousands)		
Collaboration revenue - related party	$ 59,417	$ 12,826	$ 6,632	$ 46,591	$ 6,194
Operating expenses:					
Research and development	52,492	47,783	20,492	4,709	27,291
General and administrative	16,076	11,033	4,144	5,043	6,889
Total operating expenses	68,568	58,816	24,636	9,752	34,180
Loss from operations	(9,151)	(45,990)	(18,004)	36,839	(27,986)
Interest and other income, net	2,554	613	551	1,941	62
Net loss	$ (6,597)	$ (45,377)	$ (17,453)	$ 38,780	$ (27,924)

Collaboration Revenue – Related Party

Collaboration revenue – related party was $59.4 million, $12.8 million, and $6.6 million for the years ended December 31, 2018, 2017, and 2016, respectively, all of which was derived from the Collaboration Agreement. The increase in collaboration revenue during the year ended December 31, 2017 was primarily due to the partial recognition of revenue related to a milestone payment of $30.0 million that we received in May 2017 from Novartis upon initiation of the first GLP toxicology study for NZV930 (formerly SRF373). The increase in collaboration revenue – related party during the year ended December 31, 2018 was primarily due to the partial recognition of $27.9 million in revenue related to a milestone payment of $45.0 million that we received in February 2018 from Novartis upon Novartis' receipt and acceptance of the first final audited GLP toxicology study report for NZV930. Additionally, we recognized $5.0 million of revenue upon Novartis' decision not to exercise its Option relating to CD47 in March 2018. The remaining unrecognized amount will subsequently be recognized as revenue over the performance period in proportion to the costs incurred by us under the Collaboration Agreement.

Research and Development Expenses

	Year Ended December 31,				
	2018	2017	2016	2018 v 2017	2017 v 2016
			(in thousands)		
Direct research and development expenses by program:					
SRF231	$ 19,781	$ 22,072	$ 7,724	$ (2,291)	$ 14,348
NZV930	956	2,295	1,281	(1,339)	1,014
SRF388	3,981	2,767	1,067	1,214	1,700
SRF617	4,784	—	—	4,784	—
Other early-stage programs	3,618	4,737	1,845	(1,119)	2,892
Research and discovery and unallocated expenses:					
Personnel related (including stock -based compensation)	13,646	10,212	5,342	3,434	4,870
Facility related and other	5,726	5,700	3,233	26	2,467
Total research and development expenses	$ 52,492	$ 47,783	$ 20,492	$ 4,709	$ 27,291

Research and development expenses were $52.5 million for the year ended December 31, 2018, compared to $47.8 million for the year ended December 31, 2017. The increase of $4.7 million was primarily due to increases of $1.2 million in external costs for our SRF388 program, $4.8 million in external costs for our SRF617 program, and $3.5 million for research and discovery and unallocated costs, partially offset by decreases of $2.3 million in external costs for our SRF231 program, $1.3 million in external costs for our SRF373 program, and $1.1 million in external costs for our other early-stage programs.

The increase in research and development expenses for our SRF388 program was primarily due to a payment made for an exclusive license to the antibodies related to this program as well as increased contract manufacturing work.

The increase in research and development expenses for our SRF617 program was primarily due to the commencement of contract manufacturing work.

The increase in research and discovery and unallocated expenses was primarily due to the increase of $3.4 million in personnel-related costs due to increased headcount.

The decrease in research and development expenses for our NZV930 program was primarily due to initiation of the Phase 1 clinical trial by Novartis in June 2018. Novartis has worldwide exclusive rights to this program, and as a result of the initiation of the Phase 1 clinical by Novartis, we are no longer incurring expenses for this program.

The decrease in research and development expenses for our other early-stage programs was primarily a result of costs related to SRF617, which were not tracked as a separate program until 2018. This decrease was offset by increases relating to the advancement and initiation of new early discovery programs.

Research and development expenses were $47.8 million for the year ended December 31, 2017, compared to $20.5 million for the year ended December 31, 2016. The increase of $27.3 million was primarily due to increases of $14.3 million in external costs for our SRF231 program, $1.0 million in external costs for our NZV930 program, $1.7 million in external costs for our SRF388 program, $2.9 million in external costs for our other early-stage programs and $7.3 million for research and discovery and unallocated costs.

The increase in research and development expenses for our SRF231 program was primarily related to advancing the program through IND-enabling activities and clinical material production costs.

The increases in research and development expenses for our NZV930 and SRF388 programs were primarily due to commencement of IND-enabling activities for each program.

The increase in research and development expenses for our other early-stage programs was primarily due to advancement and initiation of new early discovery programs.

The increase in research and discovery and unallocated expenses was primarily due to increases of $4.9 million in personnel-related costs (including an increase in stock-based compensation expense of $1.1 million) due to increased headcount and $2.5 million in increased facility and laboratory costs related to our new corporate headquarters.

General and Administrative Expenses

General and administrative expenses were $16.1 million for the year ended December 31, 2018, compared to $11.0 million for the year ended December 31, 2017. The increase of $5.1 million was primarily due to an increase of $2.6 million in personnel-related costs as a result of an increase in headcount; an increase of $1.0 million for professional fees related to legal and audit services, and an increase of $1.1 million in facility costs.

General and administrative expenses were $11.0 million for the year ended December 31, 2017, compared to $4.1 million for the year ended December 31, 2016. The increase of $6.9 million was primarily due to an increase of $5.5 million in personnel-related costs as a result of both an increase in headcount as well as a one-time charge of $2.3 million related to separation costs for our former chief executive officer, an increase of $0.9 million for professional fees related to legal and audit services, and an increase of $0.5 million in facility costs related to our new corporate headquarters.

Interest and Other Income (Expense), Net

Interest and other income was approximately $2.6 million, $0.6 million, and $0.6 million during the years ended December 31, 2018, 2017, and 2016, respectively, due primarily to interest income on invested balances of our cash, cash equivalents and marketable securities. The increase in interest income was due to investing of the initial public offering proceeds in April 2018.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have generated limited revenue to date from the Collaboration Agreement. 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 the sales of preferred stock, payments received under the Collaboration Agreement, and proceeds from our initial public offering of common stock and concurrent private placement. Through December 31, 2018, we had received gross proceeds of $48.6 million from our sales of preferred stock and $150.0 million from the Collaboration Agreement.

On April 23, 2018, we completed an initial public offering of our common stock by issuing 7,200,000 shares of common stock, at $15.00 per share for gross proceeds of $108.0 million, or net proceeds of $97.2 million. Concurrent with the initial public offering, we issued Novartis 766,666 shares of our common stock at $15.00 per share for proceeds of $11.5 million, in a private placement.

As of December 31, 2018, we had cash, cash equivalents and marketable securities of $158.8 million.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, in particular as we continue to advance our product candidates and our discovery programs and conduct research under the Collaboration Agreement. In addition, 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 7, 2019, will enable us to fund our operating expenses and capital expenditure requirements into 2021, excluding milestone payments from Novartis. 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 arrangements, including the Collaboration Agreement. We currently have no credit facility or committed sources of capital. 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,		
	2018	2017	2016
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ (13,222)	$ (12,422)	$ 41,413
Investing activities	(36,584)	25,918	(68,968)
Financing activities	110,376	(1,036)	25,942
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 60,570	$ 12,460	$ (1,613)

Operating Activities

During the year ended December 31, 2018, net cash used in operating activities was $13.2 million, primarily due to net cash used in our operating assets and liabilities of $12.8 million and our net loss of $6.6 million, partially offset by non-cash charges of $6.2 million. Net cash used in changes in our operating assets and liabilities for the year ended December 31, 2018 consisted primarily of a $14.4 million decrease in deferred revenue, a $0.5 million decrease in accrued expenses and other current liabilities, and a $2.2 million decrease in prepaid expenses and other current assets. The decrease in deferred revenue was due to the cumulative effect adjustment upon the adoption of ASC 606 in January 2018. The decrease in accrued expenses and other current liabilities was primarily due to the payment of $3.4 million of manufacturing costs to Novartis in the current year offset increased manufacturing costs incurred to support ongoing clinical trial activities and payroll related accruals. The decrease in prepaid expenses and other current assets was primarily due to a reduction in prepaid taxes, offset by an increase in other assets resulting from an insurance claim that had not been received as of December 31, 2018.

During the year ended December 31, 2017, net cash used in operating activities was $12.4 million, primarily due to our net loss of $45.4 million partially offset by net cash provided by changes in our operating assets and liabilities of $26.7 million and non-cash charges of $6.2 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2017 consisted primarily of a $17.2 million increase in deferred revenue, a $5.0 million decrease in amounts due from Novartis, a related party, a $2.9 million increase in accrued expenses and other current liabilities, and a $1.1 million decrease in prepaid expenses and other current assets. The increase in deferred revenue was due to the $35.0 million of aggregate milestone and option purchase payments received from Novartis during the year ended December 31, 2017, which were not fully recognized as revenue at that time. The increase in accrued expenses and other current liabilities was primarily due to increased manufacturing costs incurred to support ongoing clinical trial activities and payroll related accruals. The decrease in prepaid expenses and other current assets was primarily due to a reduction in prepaid taxes.

During the year ended December 31, 2016, net cash provided by operating activities was $41.4 million, primarily resulting from net cash provided by changes in our operating assets and liabilities of $58.6 million and net non-cash charges of $0.3 million, partially offset by our net loss of $17.5 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2016 consisted primarily of a $64.9 million increase in deferred revenue, a $5.4 million increase in accrued expenses and other current liabilities and a $1.8 million increase in accounts payable, partially offset by an $8.5 million increase in prepaid expenses and other current assets and a $5.0 million increase in amounts due from Novartis, a related party. The increase in deferred revenue was due to the $70.0 million upfront payment received from Novartis during the year ended December 31, 2016, which was not fully recognized as revenue at that time. The increase in accrued expenses and other current liabilities was due to accruals related to manufacturing costs. The increase in accounts payable was due to timing of invoices for clinical manufacturing costs. The increase in prepaid expenses and other current assets was due to prepayments for estimated taxes. The increase in amounts due from Novartis was the result of our achievement in December 2016 of a specified milestone under the Collaboration Agreement.

Investing Activities

During the year ended December 31, 2018, net cash used in investing activities was $36.6 million, primarily due to purchases of marketable securities of $107.3 million and $2.0 million of purchases of property and equipment, primarily related to leasehold improvements in our corporate headquarters facility. This was partially offset by $72.7 million in proceeds from sales or maturities of marketable securities.

During the year ended December 31, 2017, net cash provided by investing activities was $25.9 million, consisting primarily of $27.9 million of proceeds from sales or maturities of marketable securities, partially offset by $2.0 million of purchases of property and equipment, primarily related to leasehold improvements in our corporate headquarters facility.

During the year ended December 31, 2016, net cash used in investing activities was $69.0 million, consisting primarily of $97.0 million for purchases of marketable securities, an increase in restricted cash of $1.0 million and $0.8 million of purchases of property and equipment, all partially offset by $28.9 million of proceeds from sales or maturities of marketable securities.

Financing Activities

During the year ended December 31, 2018, net cash provided by financing activities was $110.4 million, consisting primarily of $100.4 million of net proceeds received upon the completion of the initial public offering in April 2018, $11.5 million from a private placement of common stock with Novartis, a related party, and $0.5 million of proceeds received from the exercise of stock options, partially offset by $2.0 million paid for initial public offering costs.

During the year ended December 31, 2017, net cash used in financing activities was $1.0 million, consisting primarily of payments of initial public offering costs of $1.2 million, partially offset by $0.1 million of proceeds received from the exercise of stock options.

During the year ended December 31, 2016, net cash provided by financing activities was $25.9 million, consisting primarily of net proceeds from the sales of our Series A and Series A-1 preferred stock.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2018 and the effects that such obligations are expected to have on our liquidity and cash flow in future periods:

	Payments Due by Period				
	Total	Less Than 1 Year	1 to 3 Years	4 to 5 Years	More Than 5 Years
			(in thousands)		
Operating lease commitments (1)	$ 60,221	$ 2,546	$ 9,434	$ 10,668	$ 37,573
Research and manufacturing commitments (2)	6,738	6,368	370	—	—
Total	$ 66,959	$ 8,914	$ 9,804	$ 10,668	$ 37,573

(1) Reflects payments due for leases of office and laboratory space that expire in May 2030.

(2) Reflects commitments for costs associated with external CMOs and CROs engaged to manufacture clinical trial materials as well as to conduct discovery research and preclinical development activities.

Under various license and collaboration agreements to which we are a party, we may be required to make milestone payments and pay royalties and other amounts to third parties. We have not included any such contingent payment obligations in the table above as the amount, timing and likelihood of such payments are not known.

Under our Collaboration Agreement, if Novartis obtains a regional license from us for a product under the agreement, we will be required to pay to Novartis tiered royalties of a high single-digit to mid-teens percentage on annual net sales in the United States by us or our sublicensees of regional licensed products under the agreement.

Under our license agreement with Harbour Antibodies H2L2 BV, or H2L2, we are obligated to pay to H2L2 a low five-digit upfront license fee for each antibody program that we initiate using the H2L2 mice. In addition, we may be obligated to pay up to an aggregate of $1.04 million in milestone payments to H2L2 for each antibody product we develop through Phase 3 clinical trials and regulatory approval. We are required to pay H2L2 a one-time sales performance payment of a low seven-digit dollar amount for each antibody product that is commercialized and achieves worldwide gross sales in excess of a low eight-digit dollar amount. If we enter into an agreement with a third party to further research or commercialize an antibody product developed under the H2L2 agreement, then we are obligated to pay H2L2 a one-time payment of the lesser of (i) a low double-digit percentage of the upfront fee paid to us by the third party or (ii) a low six-digit dollar amount.

Under our license agreement with Harbour Antibodies B.V., or Harbour, we are required to pay a nominal annual maintenance fee during the term of the agreement. In addition, we are obligated to pay up to an aggregate of $4.75 million upon the achievement of specified development and commercial milestones for each product licensed under the agreement. We are also obligated to pay Harbour royalties of a low single-digit percentage on the worldwide net sales of any licensed product on a country-by-country basis.

Under our development and option agreement with Adimab LLC, or Adimab, we are obligated to make milestone payments and to pay specified fees upon the exercise of the research or commercialization options under the agreement. 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 up to 20 antibodies for commercialization or (ii) foregoing the commercialization option entirely.

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

Effective January 1, 2018, we adopted Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers, using the modified retrospective transition method. Under this method, we recognized the cumulative effect of initially adopting ASC Topic 606, as an adjustment to the opening balance of accumulated deficit. Additionally, under this method of adoption, we apply the guidance to all incomplete contracts in scope as of the date of initial application. 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 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 the Collaboration Agreement with Novartis See Note 8, "Collaboration Agreement with Novartis" for additional details regarding the Company's collaboration arrangement.

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.

Income Taxes

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in our 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. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe, 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. We evaluate the potential recovery of deferred tax assets 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.

We account 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 the 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.

Stock-Based Compensation

We measure stock options and other stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, we issue stock options and restricted stock awards with only service-based vesting conditions and record the expense for these awards using the straight-line method.

For stock-based awards granted to non-employee consultants, we recognize compensation expense over the period during which services are rendered by such non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model referenced below.

We estimate the fair value of our stock-based awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (i) the expected volatility of our stock, (ii) the expected term of the award, (iii) the risk-free interest rate, and (iv) expected dividends. Due to the lack of company specific historical and implied volatility data, we based our estimate of expected volatility on the estimate and expected volatilities of a representative group of publicly traded companies. For these analyses, we select companies with comparable characteristics to ours including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. For awards that qualify as "plain-vanilla" options, we estimate the expected life of our employee stock options using the "simplified" method, whereby, the expected life equals the average of the vesting term and the original contractual term of the option. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. 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. We elect to account for forfeitures as they occur rather than apply an estimated forfeiture rate to share based payment expense.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable Securities and Exchange Commission rules.

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, 2018 consisted of cash, a money market fund invested primarily in short-term U.S. Treasury obligations, U.S. government agency bonds and corporate bonds. 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 Chief Executive Officer and Senior Vice President, Finance and Business Operations, 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* - This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

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.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Incorporated by reference from the information in our Proxy Statement for our 2019 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 2019 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 2019 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 2019 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 2019 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

(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
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)
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)
10.11#	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)
10.12#	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)
10.13#	Employment Agreement between Daniel S. Lynch and the Company, dated November 23, 2016 (filed as Exhibit 10.14 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#	Contingent Employment Termination Letter between Daniel S. Lynch and the Company, dated March 30, 2018 (filed as Exhibit 10.15 to the Company's Registration Statement on Form S-1/A filed on April 9, 2018 (File No. 333-223877) and incorporated herein by reference)
10.15#	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)
10.16#	Separation Agreement between Detlev Biniszkiewicz, Ph.D. and the Company, dated September 27, 2017 (filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1 filed on March 23, 2018 (File No. 333-223877) and incorporated herein by reference)
10.17	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)
10.18	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)
10.19†	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)
10.20†	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)
10.21†	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)
10.22#	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)
10.23#	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)

10.24†	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)
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.
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

* 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 7, 2019

By: /s/ J. Jeffrey Goater
J. Jeffrey Goater
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 J. Jeffrey Goater and Daniel S. Lynch, 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/ J. Jeffrey Goater J. Jeffrey Goater	Chief Executive Officer *(Principal Executive Officer and Duly Authorized Officer)*	March 7, 2019
/s/ Jessica Fees Jessica Fees	Senior Vice President, Finance and Business Operations *(Principal Financial and Accounting Officer)*	March 7, 2019
/s/ Daniel S. Lynch Daniel S. Lynch	Chairman of the Board	March 7, 2019
/s/ David S. Grayzel, M.D. David S. Grayzel, M.D.	Director	March 7, 2019
/s/ Geoffrey McDonough, M.D. Geoffrey McDonough, M.D.	Director	March 7, 2019
/s/ Armen B. Shanafelt, Ph.D Armen B. Shanafelt, Ph.D	Director	March 7, 2019
/s/ Elliott Sigal, M.D., Ph.D. Elliott Sigal, M.D., Ph.D.	Director	March 7, 2019
/s/ Laurie D. Stelzer Laurie D. Stelzer	Director	March 7, 2019

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, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for revenues from contracts with customers in 2018.

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 audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

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.

Emphasis of Matter

As discussed in Note 1 to the consolidated financial statements, the Company will require additional financing to fund future operations. Management's evaluation of the events and conditions and plans to mitigate this matter are also described in Note 1.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 7, 2019

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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 82,912	$ 22,455
Marketable securities	75,923	40,854
Restricted cash	—	85
Prepaid expenses and other current assets	5,766	7,936
Total current assets	164,601	71,330
Property and equipment, net	8,226	7,326
Restricted cash	1,198	1,000
Deferred offering costs	—	1,784
Other assets	40	14
Total assets	$ 174,065	$ 81,454
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,412	$ 3,215
Accrued expenses and other current liabilities	8,803	9,843
Deferred revenue - related party	14,610	9,837
Deferred rent	352	489
Total current liabilities	27,177	23,384
Deferred revenue - related party, non-current	39,342	72,268
Deferred rent, non-current	4,684	4,599
Total liabilities	71,203	100,251
Commitments and contingencies (Note 15)		
Redeemable convertible preferred stock (Series A and A-1), $0.0001 par value; no shares authorized, issued and outstanding at December 31, 2018 and 37,100,000 shares authorized, issued and outstanding at December 31, 2017	—	48,517
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value per share; 5,000,000 shares authorized at December 31, 2018 and no shares authorized at December 31, 2017; no shares issued and outstanding at December 31, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value; 150,000,000 and 53,000,000 shares authorized at December 31, 2018 and December 31, 2017, respectively; 27,772,600 and 2,686,350 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	3	—
Additional paid-in capital	169,784	6,877
Accumulated other comprehensive loss	(119)	(246)
Accumulated deficit	(66,806)	(73,945)
Total stockholders' equity (deficit)	102,862	(67,314)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 174,065	$ 81,454

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

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

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2018	**2017**	**2016**
Collaboration revenue - related party	$ 59,417	$ 12,826	$ 6,632
Operating expenses:			
Research and development	52,492	47,783	20,492
General and administrative	16,076	11,033	4,144
Total operating expenses	68,568	58,816	24,636
Loss from operations	(9,151)	(45,990)	(18,004)
Interest and other income, net	2,554	613	551
Net loss	(6,597)	(45,377)	(17,453)
Accretion of redeemable convertible preferred stock to redemption value	(11)	(40)	(41)
Net loss attributable to common stockholders	$ (6,608)	$ (45,417)	$ (17,494)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.33)	$ (18.35)	$ (7.31)
Weighted average common shares outstanding—basic and diluted	19,990,773	2,474,800	2,393,909
Comprehensive loss:			
Net loss	$ (6,597)	$ (45,377)	$ (17,453)
Other comprehensive loss:			
Unrealized gain (loss) on marketable securities, net of tax	127	107	(353)
Comprehensive loss	$ (6,470)	$ (45,270)	$ (17,806)

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

SURFACE ONCOLOGY, INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

	Series A and A-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Note Receivable From Officer	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balances at December 31, 2015	22,564,286	$ 22,498	2,386,538	$ —	$ 706	$ (31)	$ —	$ (11,115)	$ (10,440)
Issuance of Series A redeemable convertible preferred stock, net of issuance costs of $4	12,535,714	12,531	—	—	—	—	—	—	—
Issuance of Series A-1 redeemable convertible preferred stock, net of issuance costs of $93	2,000,000	13,407	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	12,727	—	4	—	—	—	4
Vesting of restricted common stock	—	—	—	—	26	—	—	—	26
Stock-based compensation expense	—	—	—	—	1,345	—	—	—	1,345
Accretion of redeemable convertible preferred stock to redemption value	—	41	—	—	(41)	—	—	—	(41)
Unrealized loss on marketable securities	—	—	—	—	—	—	(353)	—	(353)
Net loss	—	—	—	—	—	—	—	(17,453)	(17,453)
Balances at December 31, 2016	37,100,000	48,477	2,399,265	—	2,040	(31)	(353)	(28,568)	(26,912)
Issuance of common stock upon exercise of stock options	—	—	287,085	—	102	—	—	—	102
Vesting of restricted common stock	—	—	—	—	35	—	—		35
Stock-based compensation expense	—	—	—	—	4,709	—	—	—	4,709
Collection of note receivable from officer	—	—	—	—	31	31	—	—	62
Accretion of redeemable convertible preferred stock to redemption value	—	40	—	—	(40)	—	—	—	(40)
Unrealized gain on marketable securities	—	—	—	—	—	—	107	—	107
Net loss	—	—	—	—	—	—	—	(45,377)	(45,377)
Balances at December 31, 2017	37,100,000	48,517	2,686,350	—	6,877	—	(246)	(73,945)	(67,314)
Issuance of common stock upon exercise of stock options	—	—	272,895	—	467	—	—	—	467
Repurchases of unvested restricted stock	—	—	(16,935)	—	—		—	—	—
Stock-based compensation expense	—	—	—	—	5,217	—	—	—	5,217
Accretion of redeemable convertible preferred stock to redemption value	—	11	—	—	(11)	—	—	—	(11)
Conversion of redeemable convertible preferred stock to common stock	(37,100,000)	(48,528)	16,863,624	2	48,526		—	—	48,528
Issuance of common stock upon completion of initial public offering, net of commissions, underwriting discounts and offering costs	—	—	7,200,000	1	97,208		—	—	97,209
Issuance of common stock to a related party	—	—	766,666	—	11,500		—	—	11,500
Adjustment due to the adoption of ASC 606	—	—	—	—	—	—	—	13,736	13,736
Unrealized gain on marketable securities	—	—	—	—	—	—	127	—	127
Net loss	—	—	—	—	—	—	—	(6,597)	(6,597)
Balances at December 31, 2018	—	$ —	27,772,600	$ 3	$ 169,784	—	$ (119)	$ (66,806)	$ 102,862

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,		
	2018	**2017**	**2016**
Cash flows from operating activities:			
Net loss	$ (6,597)	$ (45,377)	$ (17,453)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization expense	1,347	964	331
Stock-based compensation expense	5,217	4,709	1,345
Premiums paid on marketable securities	—	—	(1,841)
Net amortization of premiums and discounts on marketable securities	(377)	516	477
Realized losses on marketable securities	—	2	(13)
Loss on disposal of property and equipment	14	35	—
Changes in operating assets and liabilities:			
Amounts due from related party	—	5,000	(5,000)
Prepaid expenses and other current assets	2,170	1,088	(8,549)
Other assets	(26)	(12)	41
Accounts payable	23	285	1,800
Accrued expenses and other current liabilities	(524)	2,945	5,430
Deferred rent	(52)	249	(86)
Deferred revenue - related party	(14,417)	17,174	64,931
Net cash (used in) provided by operating activities	(13,222)	(12,422)	41,413
Cash flows from investing activities:			
Purchases of property and equipment	(2,019)	(1,973)	(836)
Purchases of marketable investments	(107,257)	—	(97,048)
Proceeds from sales or maturities of marketable securities	72,692	27,891	28,916
Net cash (used in) provided by investing activities	(36,584)	25,918	(68,968)
Cash flows from financing activities:			
Proceeds from issuances of redeemable convertible preferred stock, net of issuance costs	—	—	25,938
Payments of initial public offering costs	(2,031)	(1,200)	—
Proceeds from initial public offering of common stock, net of commissions and underwriting discounts	100,440	—	—
Proceeds from issuance of common stock to a related party	11,500	—	—
Collection of note receivable from officer	—	62	—
Proceeds from exercise of stock options	467	102	4
Net cash provided by (used in) financing activities	110,376	(1,036)	25,942
Net increase (decrease) in cash and cash equivalents and restricted cash	60,570	12,460	(1,613)
Cash and cash equivalents and restricted cash at beginning of period	23,540	11,080	12,693
Cash and cash equivalents and restricted cash at end of period	$ 84,110	$ 23,540	$ 11,080
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 28	$ 3,297	$ 7,673
Supplemental disclosure of non-cash investing and financing activities:			
Accretion of redeemable convertible preferred stock to redemption value	$ 11	$ 40	$ 41
Purchases of property and equipment included in accounts payable and accrued expenses	$ 692	$ 450	$ 352
Deferred offering costs included in accrued expenses	$ —	$ 584	$ —
Reclassification of restricted cash from non-current assets to current assets	$ —	$ 85	$ —
Reclassification of deposit liability for restricted stock upon vesting of shares	$ —	$ 35	$ 26
Landlord incentives for construction of leasehold improvements recorded as deferred rent	$ —	$ 2,377	$ 2,426

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 April 6, 2018, the Company effected a one-for-2.2 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's Redeemable Convertible Preferred Stock. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

On April 23, 2018, the Company completed its initial public offering of its common stock by issuing 7,200,000 shares of common stock, at $15.00 per share for gross proceeds of $108,000, or net proceeds of $97,209 after deducting underwriting discounts, commissions and offering expenses. Concurrent with the initial public offering, the Company issued Novartis Institutes for Biomedical Research, Inc. (Novartis) 766,666 shares of its common stock at $15.00 per share for proceeds of $11,500, in a private placement.

Upon the closing of the Company's initial public offering on April 23, 2018, all shares of Series A and A-1 redeemable convertible preferred stock (the "Series A Preferred Stock" and "Series A-1 Preferred Stock", respectively) automatically converted into 16,863,624 shares of common stock.

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 the sales of redeemable convertible preferred stock, proceeds from a collaboration agreement with Novartis, and proceeds from the Company's initial public offering of common stock. The Company has incurred losses and negative cash flows from operations since its inception, including net losses of $6,597, $45,377, and $17,453 for the years ended December 31, 2018, 2017, and 2016. As of December 31, 2018, the Company had an accumulated deficit of $66,806. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. As of March 7, 2019, the issuance date of the consolidated financial statements for the year ended December 31, 2018, the Company expects that its cash, cash equivalents and marketable securities of $158,835, will be sufficient to fund its operating expenses and capital expenditure requirements through 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.

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, 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, the accrual of research and development expenses, and the valuation of common stock and stock-based awards. 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 loss, which is a separate component of stockholders' equity (deficit). 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 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, 2018 and 2017, restricted cash consisted of cash deposited in a separate bank account as collateral for the Company's facilities lease obligations. At December 31, 2018, $1,198 of restricted cash was classified as non-current. At December 31, 2017, $85 and $1,000 of restricted cash was classified as current and non-current, respectively.

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 one 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 accounts payable, accrued expenses, and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs (non-current) until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' deficit as a reduction of additional paid-in capital generated as a result of the offering. Should the planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statement of operations and comprehensive loss. The Company did not record any deferred offering costs as of December 31, 2018. Deferred offering costs totaled $1,784 at December 31, 2017.

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 loss from operations.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. 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

Effective January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers, using the modified retrospective transition method. Under this method, the Company recognized the cumulative effect of initially adopting ASC Topic 606, as an adjustment to the opening balance of accumulated deficit. Additionally, under this method of adoption, the Company applies the guidance to all incomplete contracts in scope as of the date of initial application. 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 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, 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 the Collaboration Agreement with Novartis See Note 8, "Collaboration Agreement with Novartis" for additional details regarding the Company's collaboration arrangement.

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.

The Company measures stock-based awards granted to non-employee consultants based on the fair value of the award on the date on which the related service is complete. Compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

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 expected term of stock options granted to non-employees is equal to the contractual term of the option award. 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.

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 collaboration revenue is derived from the Company's collaboration partner 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 Loss

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

Net Loss per Share

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net 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 loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding options to purchase common stock or redeemable convertible preferred stock are considered potential dilutive common shares.

The Company's redeemable convertible preferred stock contractually entitled the holders of such shares to participate in dividends but contractually did not require the holders of such stock to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (or FASB) issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations*, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies how a company identifies promised goods or services and clarifies whether an entity's promise to grant a license provides a customer with either a right to use the entity's intellectual property (which is satisfied at a point in time) or a right to access the entity's intellectual property (which is satisfied over time). In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients* related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. In December 2016 the FASB issued ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*, which amends certain narrow aspects of the guidance issued in ASU 2014-09 including guidance related to the disclosure of remaining performance obligations and prior-period performance obligations, as well as other amendments to the guidance on loan guarantee fees, contract costs, refund liabilities, advertising costs and the clarification of certain examples. ASU 2016-08, ASU 2016-10 and ASU 2016-12 have the same effective dates and transition requirements as ASU 2014-09, all of which collectively are herein referred to as Revenue ASUs.

The Company adopted the Revenue ASUs effective January 1, 2018 using the modified retrospective method. Under the modified retrospective method, the cumulative effect of adopting the Revenue ASUs is recognized as an adjustment to deferred revenue and accumulated deficit. Under ASC 606, the Company will recognize revenue from its collaboration agreement with Novartis (see Note 8) earlier during the performance period as a result of applying the cost-to-cost method, in contrast to recognizing revenue on a straight-line basis over the estimated ten-year performance period under the previous standard. The following reflects the impact of the cumulative effect of the accounting changes upon the adoption of the Revenue ASUs (in thousands):

Consolidated Balance Sheets

	December 31, 2017	Cumulative Effect	January 1, 2018
Deferred revenue - related party, current and net of current portions	$ 82,105	$ (13,736)	$ 68,369
Accumulated deficit	(73,945)	13,736	(60,209)

	December 31, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Deferred revenue - related party	$ 14,610	$ 14,421	$ 189
Deferred revenue, net of current portion - related party	39,342	84,195	(44,853)
Accumulated deficit	(66,806)	(97,734)	30,928

(In thousands, except share and per share amounts)

Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Collaboration revenue - related party	$ 59,417	$ 28,489	$ 30,928
Loss from operations	$ (9,151)	(40,079)	30,928
Net loss	$ (6,597)	(37,525)	30,928
Comprehensive loss	$ (6,470)	(37,398)	30,928

Condensed Consolidated Statements of Cash Flows

	Year Ended December 31, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Net loss	$ (6,597)	$ (37,525)	$ 30,928
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Deferred revenue - related party	(14,417)	16,511	(30,928)

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230)* ("ASU 2016-18"), which requires that amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company adopted ASU 2016-18 as of the required effective date of January 1, 2018 and has reflected the adoption retrospectively to all periods presented. The Company's consolidated statements of cash flows include restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on such statements.

	As of December 31,		
	2018	2017	2016
Cash and cash equivalents	$ 82,912	$ 22,455	$ 9,995
Restricted cash included in current assets	—	85	—
Restricted cash included in non-current assets	1,198	1,000	1,085
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 84,110	$ 23,540	$ 11,080

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2017-09 as of the required effective date of January 1, 2018. There were no modifications to stock-based awards in 2018.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 will require lessees to recognize most leases on their balance sheet as a right-of-use asset and a lease liability. Leases will be classified as either operating or finance, and classification will be based on criteria similar to current lease accounting, but without explicit bright lines. In July 2018, the FASB issued ASU No. 2018-10, *"Codification Improvements to Topic 842, Leases"* ("ASU 2018-10"), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU No. 2018-11, "Leases (Topic 842) – Targeted Improvements" (ASU 2018-11), which addresses implementation issues related to the new lease standard. The guidance is effective for annual reporting periods beginning after December 15, 2018 and interim periods within those fiscal years, and early adoption is permitted. The standard permits two transition methods, (1) to apply the new lease requirements at the beginning of the earliest period presented, or (2) to apply the new lease requirements at the effective date. Under both transition methods there is a cumulative effect adjustment.

The Company adopted the standard on the effective date of January 1, 2019 by applying the new lease requirements at the effective date. The Company also elected the package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allows the Company to carry forward the historical lease classification. The Company expects the standard to have an impact of approximately $17.0 million on its assets and $22.0 million on its liability for the recognition of right-of-use-assets and lease liabilities, which are primarily related to the lease of the Company's corporate headquarters in Cambridge, Massachusetts. The Company does not expect the standard to have a material impact on its results of operations or cash flows.

In July 2017, the FASB issued *ASU 2017-11, Earnings Per Share, Distinguishing Liabilities from Equity, Derivatives and Hedging—(Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"). This guidance is intended to reduce the complexity associated with accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, a down round feature would no longer cause a freestanding equity-linked financial instrument (or an embedded conversion option) to be considered "not indexed to an entity's own stock" and therefore accounted for as a derivative liability at fair value with changes in fair value recognized in current earnings. Down round features are most often found in warrants and conversion options embedded in debt or preferred equity instruments. In addition, the guidance re-characterized the indefinite deferral of certain provisions on distinguishing liabilities from equity to a scope exception with no accounting effect. This guidance becomes effective January 1, 2019. Early adoption is permitted. The Company does not expect the impact that the adoption of ASU 2017-11 will have on its consolidated financial statements to be material.

In June 2018, the FASB issued ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). The new standard simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new standard will be effective beginning January 1, 2019 and early adoption is permitted. The Company does not expect the impact that the adoption of ASU 2018-07 to be material.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement, ("ASU 2018-13").* The new standard removes certain disclosures, modifies certain disclosures and adds additional disclosures related to fair value measurement. The new standard will be effective beginning January 1, 2020 and early adoption is permitted. The Company is currently evaluating the potential impact ASU 2018-13 may have on its disclosures upon adoption.

In June 2016, the FASB issued Accounting Standards Update (ASU) 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. The standard is effective on January 1, 2020, with early adoption permitted. The Company is currently evaluating the expected impact of ASU 2016-13 on its consolidated financial statements.

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.

(In thousands, except share and per share amounts)

3. Marketable Securities

As of December 31, 2018, the fair value of available-for-sale marketable debt securities by type of security was as follows:

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable debt securities:				
U.S. Treasury notes	$ 62,866	$ —	$ (24)	$ 62,842
U.S. Government agency bonds	2,900	—	(15)	2,885
Corporate bonds	10,276	—	(80)	10,196
	$ 76,042	$ —	$ (119)	$ 75,923

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

	December 31, 2018	
	Amortized Cost	Fair Value
Maturing in one year or less	$ 76,042	$ 75,923
	$ 76,042	$ 75,923

As of December 31, 2017, the fair value of available-for-sale marketable securities by type of security was as follows:

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable debt securities:				
U.S. government agency bonds	$ 7,300	$ —	$ (38)	$ 7,262
Corporate bonds	33,800	—	(208)	$ 33,592
	$ 41,100	$ —	$ (246)	$ 40,854

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

	December 31, 2017	
	Amortized Cost	Fair Value
Maturing in one year or less	$ 27,769	$ 27,672
Maturing after one year but less than two years	13,331	13,182
	$ 41,100	$ 40,854

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, 2018 there were no realized gains (losses) on sales of marketable securities. During the year ended December 31, 2017 and 2016, realized gains (losses) on sales of marketable securities were $(2) and $13, respectively. There were no marketable securities that required adjustment for other-than-temporary declines in fair value during the years ended December 31, 2018, 2017, and 2016.

(In thousands, except share and per share amounts)

The aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months as of December 31, 2018 and 2017 was $62,842 and $27,672, respectively. The aggregate fair value of securities held by the Company in an unrealized loss position for more than twelve months as of December 31, 2018 and 2017 was $13,081 and $13,182, respectively. 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, 2018 and 2017.

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, 2018 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 77,737	$ —	$ —	$ 77,737
Marketable securities:				
U.S. Treasury notes	—	62,842	—	$ 62,842
U.S. Government agency bonds	—	2,885	—	$ 2,885
Corporate bonds	—	10,196	—	$ 10,196
	$ 77,737	$ 75,923	$ —	$ 153,660

	Fair Value Measurements as of December 31, 2017 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 17,409	$ —	$ —	$ 17,409
Marketable securities:				
U.S. government agency bonds	—	7,262	—	7,262
Corporate bonds	—	33,592	—	33,592
	$ 17,409	$ 40,854	$ —	$ 58,263

As of December 31, 2018 and 2017, the Company's cash equivalents were invested in money market funds and were valued based on Level 1 inputs. As of December 31, 2018 and 2017, the Company's marketable securities consisted of U.S. treasury notes, U.S. government agency bonds and corporate bonds and were valued based on Level 2 inputs. In determining the fair value of its U.S. treasury notes, U.S. government agency bonds and corporate 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, 2018 and 2017, 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,	
	2018	2017
Laboratory equipment	$ 2,970	$ 2,469
Leasehold improvements	6,531	5,472
Computer equipment	305	133
Furniture and office equipment	1,074	646
Construction in progress	79	13
	10,959	8,733
Less: Accumulated depreciation and amortization	(2,733)	(1,407)
	$ 8,226	$ 7,326

(In thousands, except share and per share amounts)

For the years ended December 31, 2018, 2017, and 2016 depreciation and amortization expense was $1,347, $964, and $331 respectively.

During the years ended December 31, 2018 and 2017, the Company recorded a loss on disposal of property and equipment of $14 and $35, respectively. No gain or loss was recorded on the disposal of property and equipment during the year ended December 31, 2016.

6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	Year Ended December 31,	
	2018	2017
Prepaid income taxes	$ 923	$ 6,657
Prepaid expenses	4,520	1,005
Interest receivable on marketable securities	323	274
	$ 5,766	$ 7,936

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	Year Ended December 31,	
	2018	2017
Accrued external research and development costs	$ 5,011	$ 3,005
Amounts due to related party	—	3,437
Accrued payroll and payroll-related costs	2,618	1,955
Accrued professional fees	634	874
Other	540	572
	$ 8,803	$ 9,843

8. Collaboration Agreement with Novartis

Overview

In January 2016, the Company entered into a collaboration agreement with Novartis (the "Collaboration Agreement"), which was subsequently amended in May 2016, July 2017, September 2017, and October 2018 (the "October 2018 Amendment"). Pursuant to the Collaboration Agreement, the Company granted Novartis a worldwide exclusive license to research, develop, manufacture and commercialize antibodies that target CD73, along with the right to purchase exclusive option rights (each an "Option") for up to four specified targets (each an "Option Target") to obtain certain development, manufacturing and commercialization rights. Novartis may exercise up to three purchased Options. Under the Collaboration Agreement, Novartis initially had the ability to exclusively license the development and manufacturing rights for up to four targets (inclusive of CD73). Of these, the Company would retain the U.S. commercial rights to two of such targets. The Collaboration Agreement is governed by a joint steering committee that is co-chaired by a chairperson designated by each of the Company and Novartis. The October 2018 Amendment, among other things, modified certain definitions and provisions of the Collaboration Agreement to make them consistent with the amended and restated development and option agreement the Company entered into with Adimab LLC in October and clarified the parties' rights and responsibilities relating to the amended agreement with Adimab LLC and diagnostic products.

Novartis is a related party because it is a principal stockholder of the Company. In January 2016, the Company entered into the Collaboration Agreement and sold 2,000,000 shares of its Series A-1 preferred stock to Novartis. 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, 2018, the Company made a payment of $3,437 to Novartis for the reimbursement of manufacturing costs incurred by Novartis prior to December 31, 2017. During the year ended December 31, 2017, the Company made no cash payments to Novartis related to the Collaboration Agreement.

Research on Targets

Under the Novartis Collaboration, the Company is responsible for performing preclinical research through the first investigational new drug application ("IND") acceptance on antibodies that bind to CD73 and each Option Target, pursuant to a research plan directed toward each target. The Company is responsible for all costs and expenses incurred by or on its behalf, in connection with such research. Novartis also has the right, but not the obligation, to conduct research at its own cost on antibodies that bind to CD73 in accordance with the terms of the Novartis Collaboration.

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, to 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 the Company with updates on its development and commercialization activities through the joint steering committee, joint development committee and joint commercialization committee.

Option Targets

Prior to the filing of an IND for an Option Target, Novartis may purchase the Option to obtain certain development, manufacturing and commercialization rights for antibodies that bind to the Option Target. To the extent Novartis does not elect to purchase an Option to an Option Target, the Option for such Option Target will expire and all rights to such Option Target under the Collaboration Agreement will terminate. Novartis may exercise up to a total of three purchased Options. Each exercised Option will be designated as either a regional or global option, with each such designation determining the development and commercialization rights between the parties with respect to such Option Target, corresponding antibody candidates and licensed products, as summarized below. The Company had the ability to designate the first Option as either regional or global. Of the other two Options, the Company and Novartis each have the ability to designate the geographical scope of one Option. Following Novartis' exercise of an Option with respect to an Option Target, the Company will grant to Novartis licenses that are necessary to effectuate the development, manufacturing or commercialization rights associated with a regional or global option, as described below.

In December 2016, Novartis purchased the Option for antibodies that bind to CD47 for $5,000, and as of December 31, 2017, there were three remaining Options that may be purchased by Novartis. In March 2018, Novartis notified the Company of its decision not to exercise its Option related to CD47. In March 2018, the Company and Novartis also mutually agreed to cease development of one of the undisclosed programs subject to the Collaboration Agreement. Accordingly, as of December 31, 2018, Novartis had two Options remaining eligible for purchase and potential exercise. In February 2019, Novartis notified the Company of its decision not to purchase the Option related to IL-27 (See Note 19).

Development and Commercialization of Regional Licensed Products

To the extent an exercised Option is designated as regional, the Company is primarily responsible for the early clinical development of each corresponding regional antibody candidate and regional licensed product at its own cost. Unless the Company chooses to opt out of its development right, it will collaborate with Novartis on the further clinical development of regional antibody candidates and regional licensed products. Pursuant to a regional development plan for each regional licensed product, the Company will be responsible for development activities related to obtaining regulatory approval in the United States, with Novartis responsible for development activities related to obtaining regulatory approval elsewhere in the world. The development costs of such later clinical development activities will be split evenly among the parties. Thereafter, the Company is responsible for the commercialization of regional licensed products in the United States, and Novartis is responsible for the commercialization of regional licensed products outside of the United States, each pursuant to a commercialization plan. Each party must use commercially reasonable efforts to commercialize such products within their respective territories. The Company is obligated to work with Novartis to agree to a global commercialization strategy with respect to the regional licensed products prior to commercialization.

Development and Commercialization of Global Licensed Products

To the extent an exercised Option is designated as global, the Company is primarily responsible for the early clinical development of each global antibody candidate and global licensed product at the Company's own cost, and Novartis is solely responsible for the later worldwide clinical development of global antibody candidates and global licensed products, pursuant to a development plan for such global licensed product, at its own cost. Novartis is solely responsible for the worldwide commercialization of global licensed products and must use commercially reasonable efforts to commercialize such products, pursuant to a commercialization plan, at its own cost. Novartis agrees to provide the Company with development and commercialization updates regarding global licensed products through the joint steering committee, joint development committee and joint commercialization committee.

Exclusivity

Neither the Company nor Novartis may, alone or with any affiliate or third party, (i) research or develop any antibody that specifically binds to an Option Target for a specified period of time outside of the Collaboration Agreement or (ii) develop or commercialize any antibody that specifically binds to CD73 or any Option Target that subsequently becomes a licensed target for a specified period of time outside the Collaboration Agreement. The October 2018 Amendment clarified that Novartis is permitted to research, develop, manufacture or commercialize any diagnostic product that specifically binds to a licensed target, subject to Novartis' compliance with its rights and obligations under the Collaboration 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.

Financial Terms

Upon entering into the Collaboration Agreement in January 2016, Novartis made an upfront payment to the Company of $70,000. In addition, Novartis is obligated to pay the Company a fee to the extent it desires to purchase an Option for any Option Target and another fee to exercise such purchased Option, which entitles the Company to an aggregate of up to $67,500 in option purchase and option exercise payments, of which $5,000 has been received. The Company is also eligible to receive payments on a target-by-target basis upon the achievement of specified development and sales milestones as well as tiered royalties on annual net sales by Novartis of licensed products ranging from high single-digit to mid-teens percentages upon successful commercialization of any products. Under the Collaboration Agreement, the maximum aggregate amount of potential option purchase, option exercise and milestone payments the Company was entitled to was up to $1,167,500, of which $80,000 had been received as of December 31, 2018. Such amount of potential option purchase, option exercise and milestone payments assumed that Novartis purchased, and exercised, all of the Options available to it pursuant to the Collaboration Agreement as well as the successful clinical development of and achievement of all sales milestones for all targets covered by the Collaboration Agreement. In March 2018, Novartis notified the Company of its decision not to exercise its Option related to CD47. In February 2019, Novartis notified the Company of its decision not to purchase the Option related to IL-27 (See Note 19). The Company is required to pay Novartis tiered royalties ranging from high single-digit to mid-teens percentages on annual net sales by the Company of regional licensed products in the United States. The royalty payments are subject to reduction under specified conditions set forth in the Collaboration Agreement.

Termination

Unless terminated earlier, the Collaboration Agreement will continue in effect until neither the Company nor Novartis is researching, developing, manufacturing or commercializing any antibody candidates or licensed products under the Collaboration Agreement. Novartis may terminate the Collaboration Agreement on a target-by-target basis for any reason upon prior notice to the Company within a specified time period. However, Novartis cannot terminate the Collaboration Agreement with respect to CD73 for a certain period of time following the effective date. Either party may terminate the Collaboration Agreement in full, or on a target-by-target basis, 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 for the Company's material breach or insolvency, 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 certain products.

Revenue Recognition Related to the Collaboration Agreement

On January 1, 2018, the Company adopted ASC 606 under the modified retrospective method. Prior to January 1, 2018, the Company accounted for the collaboration agreement with Novartis under ASC 605-25, Multiple Element Arrangements.

Accounting under ASC 605

The Company determined that the deliverables under the Collaboration Agreement included (i) the worldwide exclusive license to CD73 antibody candidates, which was delivered to Novartis in January 2016 upon entering into the agreement, and (ii) the Company's research and development and joint steering committee participation obligations under the agreement. The Company also determined that none of these deliverables have standalone value due to the specialized nature of the services to be provided by the Company in connection with the Collaboration Agreement. Therefore, at the inception of the arrangement, the Company concluded that the deliverables were not separable and, accordingly, the Company treated the license and undelivered services as a single unit of accounting and recognized revenue on a straight-line basis over the period that the Company expected to complete its performance obligations under the agreement, which was estimated to be ten years. Accordingly, the Company recognized the upfront payment and milestone payments received over the estimated ten-year period of performance.

In December 2016, Novartis purchased an exclusive option right to antibodies that bind to CD47 for $5,000. At that time, the Company concluded that the license and other obligations underlying the exclusive option right held by Novartis represented separate and additional deliverables that Novartis may receive from the Company in future periods. In December 2017, the Company included $5,000 in deferred revenue for the option purchase payment. In March 2018, Novartis decided not to exercise this option.

Accounting under ASC 606

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 accounts 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 collaboration agreement with Novartis. Novartis' right to purchase exclusive options to obtain certain development, manufacturing and commercialization rights are 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 use a separate cost-to-cost model for purposes of revenue recognition under ASC 606.

In February 2018, the Company received an additional milestone payment of $45,000 from Novartis upon Novartis' receipt and acceptance of the first final audited GLP toxicology study report for NZV930 (formerly SRF373). Upon achieving the milestone, the Company concluded this variable consideration associated with this milestone was no longer constrained and included the $45,000 in the transaction price. The Company recognized $27,850 as collaboration revenue – related party in the twelve months ended December 31, 2018, based on the ratio of actual costs incurred as of the milestone achievement date to the total estimated costs with respect to performing research on antibodies that bind to CD73 and other specified targets under the Collaboration Agreement. The remaining unrecognized amount of $17,150 is recorded as deferred revenue – related party as of December 31, 2018 and will subsequently be recognized as revenue over the performance period in proportion to the costs incurred under the Collaboration Agreement.

In March 2018, Novartis notified the Company of its decision not to exercise its option related to CD47. The Company recognized the $5,000 exclusive option right payment as collaboration revenue – related party in the first quarter of 2018 because the Company no longer has any remaining performance obligations related to CD47.

In March 2018, the Company and Novartis elected to terminate a specified target under the Collaboration Agreement. Future costs associated with this target were removed from the estimated total costs in the cost-to-cost model.

For the years ended December 31, 2018, 2017, and 2016, the Company recognized the following totals of collaboration revenue – related party:

	Year Ended December 31,		
	2018	2017	2016
Collaboration revenue - related party	$ 59,417	$ 12,826	$ 6,632

The following table presents changes in the Company's contract liabilities during the twelve months ended December 31, 2018 (in thousands):

	December 31, 2017	Additions	Deductions	December 31, 2018
Contract Liabilities (1)				
Total deferred revenue - related party	$ 82,105	45,000	$ (73,153)	$ 53,952

(1) Additions to contract liabilities relate to consideration from Novartis during the reporting period. Deductions to contract liabilities relate to deferred revenue recognized as revenue during the reporting period and cumulative catch-up adjustment recognized upon adoption of ASC 606 on January 1, 2018.

During the year ended December 31, 2018, the Company recognized $26,568 of revenue related to the amounts included in contract liability balance at the beginning of the period. The aggregate amount of the transaction price allocated to the single performance obligation that are partially unsatisfied was $53,952.

The Company considers the total consideration expected to be earned in the next twelve months for services to be performed as current deferred revenue-related party, and consideration that is expected to be earned subsequent to twelve months from the balance sheet date as noncurrent deferred revenue-related party.

9. Redeemable Convertible Preferred Stock

The Company has authorized redeemable convertible preferred stock amounting to 37,100,000 shares as of December 31, 2017. The Company's redeemable convertible preferred stock ("Preferred Stock") has been classified as temporary equity on the accompanying balance sheets instead of in stockholders' equity (deficit) in accordance with authoritative guidance for the classification and measurement of redeemable securities as the redeemable convertible preferred stock is redeemable at the option of the holder after the redemption date.

On April 23, 2018, upon the closing of the Company's initial public offering, all shares of the Redeemable Convertible Preferred Stock automatically converted into 16,863,624 shares of common stock. See Note 10 "Stockholders' Equity (Deficit)". There are no shares of redeemable convertible preferred stock authorization or outstanding as of December 31, 2018.

The holders of the Redeemable Convertible Preferred Stock had the following rights and preferences:

Voting Rights

The holders of Redeemable Convertible Preferred Stock were entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote and have the right to vote the number of shares equal to the number of shares of common stock into which such Redeemable Convertible Preferred Stock could convert on the record date for determination of stockholders entitled to vote. The holders of Redeemable Convertible Preferred Stock, exclusively and as a separate class, were entitled to elect four directors of the Company.

Dividends

The holders of Redeemable Convertible Preferred Stock were entitled to receive noncumulative dividends when and if declared by the board of directors.

The Company may not declare or pay any dividends on shares of any other class or series of capital stock of the Company unless the holders of the Redeemable Convertible Preferred Stock then outstanding first receive a dividend on each outstanding share of Redeemable Convertible Preferred Stock in an amount at least equal to (i) in the case of a dividend on common stock or any class or series of stock that is convertible into common stock, that dividend per share of Redeemable Convertible Preferred Stock as would equal the product of (A) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (B) the number of shares of common stock issuable upon conversion of each share of Redeemable Convertible Preferred Stock, or (ii) in the case of a dividend on any class or series that is not convertible into common stock, at a rate per share of Redeemable Convertible Preferred Stock determined by (A) dividing the amount of the dividend payable on each share of such class or series of capital stock by the Original Issue Price (as specified below) of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination of or other similar recapitalization affecting such shares) and (B) multiplying such fraction by an amount equal to the Original Issue Price of each series of Redeemable Convertible Preferred Stock. If the Company declares or pays on the same date a dividend on shares of more than one class or series of capital stock of the Company, the dividend payable to the holders of the Redeemable Convertible Preferred Stock will be calculated based upon the dividend on the class or series of capital stock that would result in the highest Redeemable Convertible Preferred Stock dividend. No dividends have been declared or paid by the Company through December 31, 2018.

The Original Issue Price of Series A preferred stock is $1.00 per share, and the Original Issue Price of Series A-1 preferred stock is $6.75 per share, each subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Redeemable Convertible Preferred Stock.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or Deemed Liquidation Event (as defined below), holders of Redeemable Convertible Preferred Stock were entitled to receive, prior and in preference to any distributions to the holders of common stock, an amount per share equal to (i) in the case of Series A-1 preferred stock, the greater of (A) the Series A-1 preferred stock Original Issue Price, plus any dividends declared but unpaid thereon, or (B) such amount per share as would have been payable had all shares of Series A-1 Preferred Stock been converted into common stock and (ii) in the case of the Series A preferred stock, the Series A preferred stock Original Issue Price, plus any dividends declared but unpaid thereon. In the event that proceeds are not sufficient to permit payment in full to the holders of the Redeemable Convertible Preferred Stock, the proceeds will be ratably distributed among the holders of Redeemable Convertible Preferred Stock on a *pari passu* basis. After payments have been made in full to the holders of Redeemable Convertible Preferred Stock, then, to the extent available, the remaining assets of the Company available for distribution to its stockholders will be distributed among the holders of Redeemable Convertible Preferred Stock and common stock pro rata based on the number of shares held by each holder, treating all securities as if they had been converted into common stock prior to any dissolution, liquidation or winding up of the Company or Deemed Liquidation Event.

Unless the holders of at least 61% of the then outstanding shares of the Redeemable Convertible Preferred Stock, voting together as a single class on an as-converted to common stock basis, elect otherwise, a Deemed Liquidation Event includes a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

Conversion

Shares of Series A and A-1 Redeemable Convertible Preferred Stock were convertible into common stock on a 2.2-for-one basis. Conversion was at the option of the holder at any time, although was automatic upon the earlier of (i) the closing of a firm commitment underwritten public offering with a price of at least 300% of the Series A preferred stock Original Issue Price per share resulting in proceeds of not less than $35,000, net of underwriting discounts and commissions, or (ii) upon the vote or written consent of the holders of at least 61% of the outstanding shares of the Redeemable Convertible Preferred Stock, voting together as a single class on an as-converted to common stock basis.

(In thousands, except share and per share amounts)

Redemption Rights

At the written election of at least 61% of the holders of the outstanding Redeemable Convertible Preferred Stock, voting together as a single class on an as-converted to common stock basis, the shares of Redeemable Convertible Preferred Stock outstanding were redeemable at any time on or after January 8, 2020 in three equal annual installments commencing 60 days after receipt of the required vote, in an amount equal to the Original Issue Price per share of each series of Redeemable Convertible Preferred Stock, plus all declared but unpaid dividends.

The carrying value of the Redeemable Convertible Preferred Stock was being accreted to its redemption value through January 8, 2020. Such accretion amounts relate solely to the original issuance costs of the Redeemable Convertible Preferred Stock.

10. Stockholders' Equity (Deficit)

Common Stock

As of December 31, 2018 and 2017, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 150,000,000 and 53,000,000 shares, respectively, 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 the Redeemable Convertible Preferred Stock. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of Redeemable Convertible Preferred Stock equivalent to the dividend amount they would receive if each preferred share were converted into common stock. The Company may not pay dividends to common stockholders until all dividends accrued or declared but unpaid on the Redeemable Convertible Preferred Stock have been paid in full. No dividends have been declared or paid by the Company through December 31, 2018.

As of December 31, 2018 and 2017, the Company had reserved 6,083,202 and 20,703,575 shares, respectively, of common stock for the conversion of the outstanding shares of Redeemable Convertible Preferred Stock, the exercise of outstanding stock options and the number of shares remaining available for future grant under the Company's 2014 Stock Incentive Plan, the Company's 2018 Stock Option and Incentive Plan, and the Company's 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,	
	2018	**2017**
Options to purchase common stock	4,414,225	3,106,891
Shares available for future grant	1,412,159	733,060
2018 Employee Stock Purchase Plan	256,818	—
Conversion of preferred stock	—	16,863,624
Total reserved	6,083,202	20,703,575

On April 23, 2018, the Company completed its initial public offering of its common stock by issuing 7,200,000 shares of common stock, at $15.00 per share for gross proceeds of $108,000, or net proceeds of $97,209. Concurrent with the initial public offering, 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.

11. 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.

The total number of shares of common stock that may be issued under the 2014 Plan was 4,489,839 shares as of December 31, 2017. On February 12, 2018, the Company effected an increase in the total number of shares of the Company's common stock reserved for issuance under the 2014 Plan from 4,489,839 shares to 4,498,930 shares. On March 2, 2018, the Company effected an increase in the total number of shares of the Company's common stock reserved for issuance under the 2014 Plan from 4,498,930 shares to 5,089,839 shares. On March 9, 2018, the Company effected an increase in the total number of shares of the Company's common stock reserved for issuance under the 2014 Plan from 5,089,839 shares to 5,203,730 shares.

As of December 31, 2018 all remaining shares available under the 2014 Plan were transferred to the 2018 Plan. As of December 31, 2017, 733,060 shares were available for future issuance under the 2014 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 is 1,545,454, plus the shares of common stock remaining available for issuance under the 2014 Plan, which shall be cumulatively increased on January 1, 2019 and each January 1 thereafter 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, 2018, 1,412,159 shares were available for future issuance under the 2018 Plan.

Stock options granted under the 2014 Plan and 2018 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.

(In thousands, except share and per share amounts)

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,		
	2018	2017	2016
Risk-free interest rate	2.67%	2.04%	1.73%
Expected term (in years)	6.18	6.25	6.25
Expected volatility	72.70%	78.60%	76.39%
Expected dividend yield	0.0%	0.0%	0.0%

Stock Options

The following table summarizes the Company's stock option activity for the year ended December 31, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
			(in years)	
Outstanding as of December 31, 2017	3,106,891	$ 3.68	8.69	$ 14,361
Granted	1,794,198	11.25		
Exercised	(272,895)	1.71		
Forfeited	(213,969)	5.47		
Outstanding as of December 31, 2018	4,414,225	$ 6.79	8.29	$ 2,031
Options exercisable at December 31, 2018	1,751,546	$ 4.51	7.59	$ 1,743
Vested and expected to vest at December 31, 2018	4,414,225	$ 6.79	8.29	$ 2,031

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2018 and 2017, was $7.47 and $3.72, respectively.

The aggregate fair value of stock options vested during the years ended December 31, 2018 and 2017, was $4,493 and $2,828, 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, 2018, 2017, and 2016 was $1,887, $1,876, and $46 respectively.

As of December 31, 2018, and 2017, there were outstanding stock options held by non-employees for the purchase of 317,957 and 369,645 shares of common stock, respectively, with service-based vesting conditions.

Restricted Common Stock

The Company has granted restricted common stock with service-based vesting conditions. The purchase price of the restricted common stock is determined by the Company's board of directors. 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 Company has the option to repurchase the restricted stock at the original purchase price if the grantee terminates its working relationship with the Company prior to the stock becoming vested.

(In thousands, except share and per share amounts)

In May 2015, the Company issued to an executive officer 350,073 shares of restricted common stock, which are restricted as to sale or transferability until vested, over a four-year vesting period. As consideration for the award, the executive officer made an upfront cash payment of $62 and issued to the Company a promissory note for $62, which bore interest at a rate of 1.53% per annum and was due and payable in May 2020, unless earlier due upon specified events. At that time, the Company concluded that the promissory note was a recourse note with respect to half of the amount, or $31, and was a non-recourse note for the remaining amount.

Upon issuance of the award, the Company recorded the $62 of upfront cash received as a liability in the consolidated balance sheet as it represented a deposit for the exercise price. The deposit liability is reclassified to additional paid-in capital over vesting term of the award as the restrictions of the award lapse. The Company determined upon issuance that the non-recourse portion of the note of $31 was not substantive and, as a result, the amount is being recognized as stock-based compensation expense over the vesting term of the award. The recourse portion of the note of $31 was recorded as a note receivable from officer within stockholders' deficit in the accompanying consolidated balance sheet. In October 2017, the promissory note was repaid in full by the executive officer.

The following table summarizes the Company's restricted stock activity for the year ended December 31, 2018:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested restricted common stock as of December 31, 2017	84,666	$ 0.42
Issued	—	
Vested	(67,731)	0.44
Forfeited and repurchased	(16,935)	
Unvested restricted common stock as of December 31, 2018	—	$ —

The aggregate intrinsic value of restricted stock awards that vested during the years ended December 31, 2018 and 2017, were $810 and $1,834, respectively.

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 reserved for issuance under this plan. In addition, the number of shares of common stock that may be issued under the ESPP will automatically increase on January 1, 2019, and 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.

Stock-Based Compensation

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

	Year Ended December 31,		
	2018	2017	2016
Research and development expenses	$ 2,557	$ 1,917	$ 852
General and administrative expenses	2,660	2,792	493
	$ 5,217	$ 4,709	$ 1,345

As of December 31, 2018, the Company had an aggregate of $13,993 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.89 years.

(In thousands, except share and per share amounts)

12. Net Loss per Share

Net Loss per Share

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

	Year Ended December 31,		
	2018	2017	2016
Basic and diluted net loss per share attributable to common stockholders:			
Numerator:			
Net loss	$ (6,597)	$ (45,377)	$ (17,453)
Accretion of redeemable convertible preferred stock to redemption value	(11)	(40)	(41)
Net loss attributable to common stockholders	$ (6,608)	$ (45,417)	$ (17,494)
Denominator:			
Weighted average commons shares outstanding—basic and diluted	19,990,773	2,474,800	2,393,909
Net loss per share attributable to common stockholders—basic and diluted	$ (0.33)	$ (18.35)	$ (7.31)

The Company's potential dilutive securities, which include stock options, unvested restricted common stock and redeemable convertible preferred stock, have been excluded from the computation of diluted net loss per share attributable to common stockholders whenever the effect of including them would be to reduce the net loss per share. In periods where there is a net loss, 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 following potential common shares, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2018	2017
Redeemable convertible preferred stock (as converted to common stock)	—	16,863,624
Outstanding options to purchase common stock	4,414,225	3,106,891
Unvested Restricted Stock	—	84,666
	4,414,225	20,055,181

13. License Agreements

H2L2 License Agreement

In April 2014, the Company entered into a license agreement with Harbour Antibodies H2L2 BV ("H2L2"). Pursuant to the H2L2 agreement, H2L2 granted the Company a worldwide, non-exclusive license under H2L2's technology to (i) make, use, manufacture, import and export (but not sell) H2L2 mice, which are capable of generating fully human antibodies, for research, development, clinical and manufacturing purposes and (ii) to make, use, sell, offer for sale, import and export antibodies discovered or generated using H2L2 technology, and products incorporating such antibodies. Such licenses are sublicensable only to the Company's affiliates or third-party contractors, other than in the case of the license to sell antibody products, which the Company may license to any third party.

Under the agreement, the Company is obligated to pay to H2L2 a low five-digit dollar amount as an upfront license fee for each antibody program that it initiates using the H2L2 mice. In addition, the Company may be obligated to pay up to an aggregate of $1,035 in milestone payments to H2L2 if it develops an antibody product through Phase 3 clinical trials and regulatory approval. The Company is required to pay H2L2 a one-time sales performance payment of a low seven-digit dollar amount for each antibody product that is commercialized and achieves worldwide gross sales in excess of a low eight-digit dollar amount. If the Company enters into an agreement with a third party to further research or commercialize an antibody product developed under the H2L2 agreement, then the Company is obligated to pay H2L2 a one-time payment of the lesser of (i) a low double-digit percentage of the upfront fee paid to the Company by the third party or (ii) a low six-digit dollar amount.

Unless earlier terminated, the H2L2 agreement will expire in April 2019. Either party may terminate this agreement upon an uncured material breach by the other party. The Company may also terminate the agreement at will upon providing prior written notice to H2L2.

During the years ended December 31, 2018 and 2017, the Company did not recognize any research and development expense under the agreement. During the year ended December 31, 2016, the Company recognized research and development expense under the agreement of $270.

Harbour License Agreement

In September 2015, the Company entered into an exclusive license agreement with Harbour Antibodies B.V. ("Harbour") to receive an exclusive license to Harbour's materials and patent rights directed to CD47. Pursuant to the agreement, Harbour granted to the Company a worldwide, royalty-bearing exclusive license, with the right to sublicense, to exploit products that incorporate Harbour's materials or that would infringe Harbour's patent rights. The Company is obligated to use commercially reasonable efforts to develop and commercialize such licensed products.

In consideration for the license, the Company paid Harbour a one-time upfront payment of $125 and is required to pay a nominal annual maintenance fee during the term of the agreement. In addition, the Company is obligated to pay up to an aggregate of $4,750 upon the achievement of specified development and commercial milestones for each product licensed under the agreement. In March 2018, the Company paid Harbour a $200 milestone payment due upon the dosing of the first patient in the Company's SRF231 Phase 1 trial. The Company is also obligated pay Harbour royalties of a low single-digit percentage on the worldwide net sales of any licensed product on a country-by-country basis.

The Harbour CD47 exclusive license agreement will expire on the last to expire royalty term on licensed product-by-licensed product basis, unless terminated earlier by the parties. The Company may terminate the agreement for any reason on with proper prior notice to Harbour. Harbour may terminate if the Company fails to pay an amount due after Harbour provides the Company written notice or upon the Company's uncured material breach, subject to completion of a dispute resolution process and subsequent cure.

During the years ended December 31, 2018, 2017, and 2016, the Company recognized research and development expense under the agreement of $203, $10, and 60, respectively.

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.

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, 2018, 2017, and 2016, the Company recognized research and development expense under the agreement of $2,480, $2,172, and $1,181, respectively.

14. Income Taxes

2017 U.S. Tax Reform

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act ("TCJA") that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, effective as of January 1, 2018; limitation of the tax deduction for interest expense; limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs."

The staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. The Company finalized its accounting for the income tax effects of the TCJA during 2018, with no adjustment.

(In thousands, except share and per share amounts)

Income Taxes

During the years ended December 31, 2018, 2017, and 2016, 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.

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,		
	2018	2017	2016
Federal statutory income tax rate	(21.0)%	(35.0)%	(35.0)%
State taxes, net of federal benefit	(6.2)	(5.2)	(5.2)
Permanent differences	1.1	0.3	0.2
Stock-based compensation	5.2	2.6	2.4
Research and development tax credits	(13.7)	(0.9)	(1.2)
Increase in deferred tax asset valuation allowance	34.5	18.6	38.8
Other	0.1	—	—
Change in statuatory tax rate	—	19.6	—
Effective income tax rate	—%	—%	—%

Net deferred tax assets consisted of the following:

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 5,240	$ 5,618
Research and development tax credit carryforwards	1,945	1,013
Deferred revenue	14,740	21,065
Deferred rent	1,376	1,390
Intangible assets	791	623
Accrued expenses	687	67
Stock-based compensation	1,468	620
Other	73	345
Total deferred tax assets	26,320	30,741
Valuation allowance	(18,602)	(19,956)
Deferred tax assets	7,718	10,785
Deferred tax liabilities:		
Depreciation	(1,629)	(1,651)
Deferred revenue tax accounting method change	(6,089)	(9,134)
Total deferred tax liabilities	(7,718)	(10,785)
Net deferred tax assets	$ —	$ —

As of December 31, 2018, the Company had federal and state net operating loss carryforwards of $19,120 and $19,380, respectively, and federal and state research and development tax credit carryforwards of $1,401 and $689, respectively, available to reduce future income tax liabilities. The federal and state net operating loss carryforwards each begin to expire in 2034. The federal and state research and development tax credit carryforwards begin to expire in 2034 and 2030, respectively.

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

(In thousands, except share and per share amounts)

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 February 1, 2016 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 February 1, 2016 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, 2018 and 2017. The valuation allowance decrease primarily relates to the decrease in deferred revenue, and were as follows:

	Year Ended December 31,		
	2018	2017	2016
Valuation allowance at beginning of year	$ (19,956)	$ (11,531)	$ (4,636)
Increases recorded to income tax provision	(5,644)	(17,302)	(7,408)
Decreases recorded as a benefit to income tax provision	6,998	8,877	513
Valuation allowance at end of year	$ (18,602)	$ (19,956)	$ (11,531)

The Company had no unrecognized tax benefits or related interest and penalties accrued for the years ended December 31, 2018 and 2017. 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 is currently under examination by the Internal Revenue Service ("IRS") for the period ended December 31, 2016. The Company's tax years are still open under statute from 2015 to present. All years may be examined to the extent the tax credit or net operating loss carryforwards are used in future periods.

15. Commitments and Contingencies

Lease Agreements

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. 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 December 31, 2018 and 2017, the Company became entitled to $4,803 of such incentives, which were recorded as deferred rent on the consolidated balance sheets and are being amortized to rent 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. The original lease term was extended to co-terminate with the additional space. The Company will pay annual rent of $71.00 per rentable square foot for the first year, with annual increases of $1.00 per rentable square foot for the remainder of the term. The additional space will be ready for occupancy in 2020.

In November 2014, the Company entered into an operating sublease agreement with CoStim Pharmaceuticals, Inc. ("CoStim"), a subsidiary of Novartis, for office and laboratory space that expired in March 2018 (see Note 16). The Company began to sublease this space to a third-party tenant in April 2017. Sublease payments received from the third-party tenant for the year ended December 31, 2018 and 2017, totaled $231 and $305, respectively, and were recorded as a reduction of rent expense.

(In thousands, except share and per share amounts)

The Company recognizes rent expense on a straight-line basis over the lease period and has recorded deferred rent for rent expense incurred but not yet paid. During the years ended December 31, 2018, 2017, and 2016, the Company recognized total rent expense of $1,649, $1,194, and $449, respectively, related to office and laboratory space under the leases.

Future minimum lease payments for the Company's operating leases as of December 31, 2018 were as follows:

Year Ending December 31,	
2019	2,546
2020	4,258
2021	5,176
2022	5,292
2023	5,376
Thereafter	37,573
	$ 60,221

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. As of December 31, 2018, the Company had committed to minimum payments under these arrangements totaling $6,738, of which $6,368 is due in 2019 and $370 is due in 2020.

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, 2018.

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.

16. Related Party Transactions

Novartis Institutes for BioMedical Research, Inc.

Novartis is a related party because it is a principal stockholder of the Company. In January 2016, the Company entered into the Collaboration Agreement (see Note 8) 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, 2018, the Company received cash payments totaling $45,000 from Novartis upon the achievement of a specified milestone in February 2018 and recognized $59,417 of collaboration revenue under the Collaboration Agreement. As of December 31, 2018 and 2017, no amounts were due from Novartis.

During the twelve months ended December 31, 2018, the Company made a payment of $3,437 to Novartis for the reimbursement of manufacturing costs incurred by Novartis prior to December 31, 2017. During the twelve months ended December 31, 2017 and 2016, the Company made no cash payments to Novartis related to the Collaboration Agreement.

Unrelated to the Collaboration Agreement, the Company subleased office and laboratory space from CoStim, a subsidiary of Novartis (see Note 15). Payments made by the Company to CoStim for this sublease during the years ended December 31, 2018, 2017, and 2016 totaled $106, $569, and $557, respectively. As of December 31, 2018, 2017, and 2016, no amounts were due by the Company to CoStim for this sublease.

Research Agreement with Vaccinex, Inc.

On November 30, 2017, the Company entered into an agreement with Vaccinex, Inc. ("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. The Company's Chief Executive Officer is a member of the board of directors of Vaccinex. During the year ended December 31, 2018 and 2017, the Company paid Vaccinex an aggregate of $199 and $250 relating to the agreement. The amount of the payment was recognized as research and development expense during the years ended December 31, 2018 and 2017. As of December 31, 2018, $83 was due by the Company to Vaccinex. No amounts were due by the Company to Vaccinex as of December 31, 2017.

Note Receivable from Officer

In May 2015, an executive officer of the Company entered into a promissory note for $62 payable to Company, which bore interest at a rate of 1.53% per annum and was due and payable in May 2020, unless earlier due upon specified events (see Note 11). In October 2017, the promissory note was repaid in full by the executive officer.

17. 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 50% of employees' contributions to the 401(k) Plan up to 6% of compensation. The Company's contributions made under the 401(k) Savings Plan for the years ended December 31, 2018 and 2017, totaled $339 and $207, respectively. The Company made no contributions under the 401(k) Savings Plan during the year ended December 31, 2016.

18. Selected Quarterly Financial Data (Unaudited)

The following table contains quarterly financial information for 2018 and 2017. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

(In thousands, except share and per share amounts)

	2018			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Collaboration revenue - related party	$ 45,495	$ 2,428	$ 1,730	$ 9,764
Total operating expenses	14,452	19,011	19,760	15,345
Loss from operations	31,043	(16,583)	(18,030)	(5,581)
Net loss	31,212	(15,852)	(17,222)	(4,735)
Net loss per share attributable to common stockholders—basic	$ 1.59	$ (0.73)	$ (0.62)	$ (0.17)
Net loss per share attributable to common stockholders— diluted	$ 1.05	$ (0.73)	$ (0.62)	$ (0.17)

	2017			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Collaboration revenue - related party	$ 1,672	$ 6,195	$ 2,480	$ 2,479
Total operating expenses	10,226	12,724	16,752	19,114
Loss from operations	(8,554)	(6,529)	(14,272)	(16,635)
Net loss	(8,626)	(6,573)	(14,405)	(15,773)
Net loss per share attributable to common stockholders—basic and diluted	$ (3.60)	$ (2.73)	$ (5.75)	$ (6.16)

19. Subsequent Events

Collaboration Agreement with Novartis

In February 2019, Novartis notified the Company of its decision not to purchase its Option related to IL-27 (see Note 8). Accordingly, as of February 4, 2019, Novartis had one Option remaining eligible for purchase and potential exercise. As a result, the maximum aggregate amount of potential option purchase, option exercise and milestone payments that the Company is entitled to receive under the Collaboration Agreement was reduced from $1,167,500 to $750,000. The decision by Novartis to terminate the IL-27 target under the Collaboration Agreement will result in the Company removing all future costs associated with IL-27 from the estimated total costs in the cost-to-cost model in the first quarter of 2019. This change in the total estimated costs in the cost-to-cost model will result in the Company recognizing revenue of approximately $13,000 in the first quarter of 2019.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-224403) of Surface Oncology, Inc. of our report dated March 7, 2019 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 7, 2019

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, J. Jeffery Goater, 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2019

By: /s/ J. Jeffrey Goater

J. Jeffrey Goater
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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313)

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2019

By: /s/ Jessica Fees

Jessica Fees
Senior Vice President, Finance and Business Operations
(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, 2018 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 7, 2019

By: /s/ J. Jeffrey Goater
J. Jeffrey Goater
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, 2018 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 7, 2019

By: /s/ Jessica Fees

Jessica Fees
Senior Vice President, Finance and Business Operations
(Principal Financial and Accounting Officer)