

**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**

Commission File Number: 001-38554

**FORTY SEVEN, INC.**

(Exact name of Registrant as specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**1490 O'Brien Drive, Suite A**  
**Menlo Park, California 94025**  
(Address of principal executive offices)

**47-4065674**  
(I.R.S. Employer  
Identification No.)

**94025**  
(Zip Code)

**Registrant's telephone number, including area code: (650) 352-4150**

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

Common Stock, Par Value \$0.0001 Per Share  
(Title of each class)

The Nasdaq Global Select Market  
(Name of each exchange on which registered)

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES  NO

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

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

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

Indicate by check mark 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 Annual Report on Form 10-K or any amendment to this Annual Report on Form 10-K.

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Small reporting company	<input checked="" type="checkbox"/>
Emerging Growth Company	<input checked="" type="checkbox"/>		

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 held by non-affiliates of the Registrant as of June 29, 2018, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately \$179.7 million, based on the closing price of the Registrant's common stock on the Nasdaq Global Select Market of \$16.00 per share. Although the Registrant commenced trading on the Nasdaq Global Select Market on June 28, 2018, the Registrant's initial public offering did not close until July 2, 2018. This calculation assumes (i) the conversion of all outstanding shares of the Registrant's preferred stock into common stock immediately upon the closing of the Registrant's initial public offering and (ii) the issuance of the 7,035,000 shares of common stock in connection with the Registrant's initial public offering.

As of March 15, 2019, the Registrant had 31,271,913 shares of common Stock, \$0.0001 par value per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

The Registrant's Definitive Proxy Statement relating to the 2019 Annual Meeting of Stockholders will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K and portions of such are incorporated by reference into Part III of this Annual Report on Form 10-K.

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*This Annual Report on Form 10-K for the year ended December 31, 2018, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the “safe harbor” created by those sections, concerning our business, operations, and financial performance and condition as well as our plans, objectives, and expectations for business operations and financial performance and condition. Any statements contained herein that are not of historical facts may be deemed to be forward-looking statements. You can identify these statements by words such as “anticipate,” “assume,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “should,” “will,” “would,” and other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business and the industry in which we operate and management’s beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be inaccurate. Factors that could materially affect our business operations and financial performance and condition include, but are not limited to, those risks and uncertainties described herein under “Item 1A - Risk Factors.” You are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are based on information available to us as of the filing date of this Annual Report on Form 10-K. Unless required by law, we do not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission, or the SEC, after the date of this Annual Report on Form 10-K.*

## PART I

### Item 1. Business.

#### Overview

We are a clinical-stage immuno-oncology company focused on developing novel therapies to activate macrophages in the fight against cancer. We founded Forty Seven based on the insight that blocking CD47, a key signaling molecule that is overexpressed on cancer cells, renders tumors susceptible to macrophages. By harnessing macrophages, we believe that our lead product candidate, 5F9, can transform the treatment of cancer. 5F9 has demonstrated promising activity in six Phase 1b/2 clinical trials in which we have treated over 290 cancer patients with solid or hematologic tumors. In addition, we have two additional product candidates in preclinical development; FSI-189 an anti- SIRP $\alpha$  antibody and FSI-174 an anti-cKIT antibody. We hold worldwide rights to all of our product candidates.

We focus our efforts on targeting the CD47 pathway as a way to engage macrophages in fighting tumors. Macrophages function as first responders, swallowing foreign and abnormal cells, including cancer cells, and mobilizing other components of the immune system including T cells and antibodies. Cancer cells use CD47, a “don’t eat me,” signal, in order to evade detection by the immune system and subsequent destruction by macrophages. Overexpression of CD47 is common to nearly all types of tumors and is also correlated with poor prognosis in multiple cancers including acute myelogenous leukemia, or AML, colorectal cancer, or CRC, gastric cancer, lung cancer, Non-Hodgkin’s lymphoma, or NHL, and ovarian cancer. Despite the central role of macrophages as cell-eating scavengers and first responders, the pharmaceutical industry is only beginning to bring this key group of cells into the fight against cancer.

Our company was founded by leading scientists at Stanford University who uncovered the fundamental role of CD47 in cancer evasion. They discovered that CD47 sends out a “don’t eat me” signal to macrophages that prevents macrophages from ingesting abnormal cells. This has been supported by multiple lines of evidence, including elevated levels of CD47 in a wide range of cancer cells and an observed correlation of a decrease in survival in patients with high levels of CD47.

Preclinical work performed in the laboratory of our co-founder, Irv Weissman, at Stanford University and at Forty Seven demonstrated that:

- Blocking the CD47 “don’t eat me” signaling pathway leads to elimination of many types of tumors and increased survival;
- Boosting an “eat me” signal found on cancer cells using tumor targeting antibodies results in a synergistic effect with blocking CD47;
- Macrophages digest cancer cells in a process called phagocytosis and present tumor-specific antigens that can activate T cells against the cancer, thus creating the potential for synergy with T cell checkpoint inhibitors; and
- Inducing an “eat me” signal on cancer cells using certain chemotherapies results in improved targeting of tumor cells which is synergistic with blocking CD47.

Our clinical trials are investigating four different strategies for developing CD47 therapies: as a monotherapy, in combination with tumor targeting antibodies, in combination with chemotherapies and in combination with checkpoint inhibitors, in a wide variety of tumors, including both solid and hematological cancers.

The targeting of CD47 to make cancer cells susceptible to macrophages, a component of the innate immune system, is analogous to the approach used with checkpoint inhibitors and T cells, a component of the adaptive immune system. In less than five years on the market, T cell checkpoint inhibitors have become frontline therapies for certain cancers and we estimate that they generated over \$9 billion in sales in 2017. Despite the success of T cell checkpoint inhibitors, these therapies have been shown to be effective only in a subset of tumors, highlighting the need for additional therapies. Analogous to the way cancer cells overexpress PD-L1 to avoid attack by T cells, cancer cells overexpress CD47 as a way to avoid destruction by macrophages. We believe targeting CD47 represents a compelling and complementary approach.

Our lead product candidate, 5F9, is a humanized IgG4 subclass monoclonal antibody against CD47 that is designed to interfere with recognition of CD47 by the SIRPa receptor on macrophages, thus blocking the “don’t eat me” signal. The design of 5F9 combined with our proprietary dosing regimen overcomes the toxicity limitations of previously tested anti-CD47 therapies. Across all study populations, 5F9 has been well tolerated with no maximum tolerated dose, or MTD, observed in any study despite dosing up to 45 mg/kg. The most common treatment-associated effects observed to date were the expected CD47-mechanism-based effects on red blood cells that leads to a temporary and reversible anemia. Other reported treatment related adverse events include infusion reactions, headache, fatigue, chills, fever and nausea. The majority of these adverse events were mild to moderate severity and were generally easily managed. See “Business—Our Lead Product Candidate, 5F9—Safety Profile of 5F9.”

We have treated over 290 cancer patients with 5F9 as a monotherapy, in combination with tumor targeting antibodies, in combination with chemotherapies and in combination with T-cell checkpoint therapies. While the primary goal of our trials has been to demonstrate safety, we also observed early signs of clinical activity in multiple tumor types.

In our ongoing monotherapy trials, 5F9 treatment has demonstrated biological responses including a confirmed partial response and multiple cases of stable disease in Phase 1 patients with refractory AML. In biologic responders, we confirmed the presence of macrophages in tumor tissues and we observed that other components of the immune system, including T cells, had been recruited.

We are also investigating 5F9 as a monotherapy in ovarian cancer and other solid tumors. In a Phase 1 trial of 5F9, we observed confirmed partial responses in 2 out of 21 evaluable patients in a cohort with ovarian cancer receiving either 20 mg/kg or higher doses of 5F9, as of April 2018. Both were heavily pre-treated patients failing seven or more previous treatment regimens. One of these patients had a durable partial response of more than six months in duration. We believe the signals from these monotherapy trials have been encouraging, however, the limited responses in these late stage patients are not adequate to trigger a registration trial as a single agent.

We are also pursuing multiple trials of 5F9 in combination with tumor targeting antibodies and chemotherapies in order to test the synergistic potency of these combinations. We believe that we can enhance the effect of 5F9 on cancer by using tumor targeting antibodies that bind to cancer cells and present an “eat me” signal to macrophages. Hence, we are combining 5F9 with tumor targeting antibodies such as rituximab and cetuximab. Based on our preclinical research and on publications by academic groups, we believe that this combination of an “eat me” signal by these antibodies and the blocking of a “don’t eat me” signal by 5F9 could be highly effective. We are conducting a Phase 1b/2 combination trial using 5F9 and rituximab in patients with relapsed and refractory NHL. As of April 2018, 30 patients with refractory NHL have been evaluated in Phase 1b/2 and 14 (47%) have had an objective response during the dose finding study of 5F9 in combination with rituximab. In 10 (33%) of these patients, we observed a complete response, an uncommon therapeutic finding for such a heavily pre-treated population. In November 2018, the Phase 1b NHL findings were published in the New England Journal of Medicine. Based on our application summarizing the early NHL trial data, the FDA granted Fast Track designations to 5F9 for the treatment of both relapsed and/or refractory diffuse large b cell lymphoma, or DLBCL, and relapsed and/or refractory follicular lymphoma, or FL, in April 2018. Having obtained Fast Track status, we held an end of Phase 1 meeting with the FDA in July 2018 to further discuss our NHL trials. Interim results from this trial are expected in mid-2019. We are also conducting a Phase 1b/2 combination clinical trial using 5F9 and cetuximab in patients with CRC. Results from this trial are expected in the second half of 2019.

We are also exploring a combination of azacitidine, a chemotherapeutic, with 5F9 in patients with untreated AML and myelodysplastic syndromes, or MDS. We have shown in preclinical studies that azacitidine induces “eat me” signals on AML cells which leads to enhanced phagocytosis when combined with 5F9. These results were presented at the 2018 American Society of Hematology meeting. We are conducting a Phase 1b trial of 5F9 with azacitidine in untreated AML and MDS patients to evaluate the safety and efficacy of this combination therapy. Initial results are expected in mid-2019.

We believe there is a strong rationale to combine 5F9 and T cell checkpoint inhibitors and we plan to pursue combination clinical trials in both solid and hematological tumors. 5F9 induces a potent anti-tumor T cell response by enabling macrophages to ingest cancer cells and present antigens derived from these cancer cells to T cells. Thus, we believe the combination of a T cell checkpoint inhibitor with 5F9 is likely to further enhance an anti-tumor T cell response and to further mobilize both the innate and adaptive immune systems to eliminate cancer.

In early 2018, we announced clinical trial collaboration and supply agreements with two pharmaceutical companies to combine 5F9 with PD-L1 checkpoint inhibitors, while retaining full economic rights to our products. Pursuant to these agreements, we are conducting clinical trials with Merck KGaA on the combination of 5F9 with BAVENCIO (avelumab) in ovarian cancer patients; and with Genentech, a member of the Roche Group, on the combination of 5F9 and TECENTRIQ (atezolizumab) in patients with bladder cancer and in patients with AML. The avelumab combination trial is underway and we dosed the first patient in June 2018. We believe the combination trials with atezolizumab will be initiated in the second half of 2019. We will supply 5F9, and Merck KGaA and Genentech will supply their respective drug products for these trials.

Our company was founded by leading scientists at Stanford University who uncovered the fundamental role of CD47 in immune regulation and applied these findings to the field of immuno-oncology. We have an exclusive license to this technology and to our lead product candidate, 5F9, from Stanford. Our goal is to accelerate regulatory approval of 5F9 through execution of multiple clinical trials in parallel to identify areas of highest efficacy. We have assembled a team of executives with broad industry experience in biologics and other therapeutics, as well as strong academic and clinical backgrounds. Our management team has worked for pharmaceutical and biotechnology companies such as Abbott Laboratories, Amgen, Genentech, Gilead, Janssen R&D, PDL Biopharma, Inc., Premier Research, Sandoz Inc. and Zogenix. We have funded our operations to date primarily from the issuance and sale of our preferred stock to investors, including Lightspeed Venture Partners, Sutter Hill Ventures, Clarus, GV and Wellington Management Company, as well as, through the proceeds of our initial public offering, or IPO, of common stock which closed on July 2, 2018. We have supplemented funding through the receipt of government and private grants. We are eligible to receive up to \$19.2 million in grants from CIRM and LLS as financial support for our clinical trials in AML, CRC and NHL, of which \$13.5 million has been received through December 31, 2018.

## Select Corporate Highlights for 2018 and early 2019

- We expanded our board of directors to include two independent Directors, Ian T. Clark, the former Chief Executive Officer of Genentech, and Kristine M. Ball, the current chairperson of our Audit Committee.
- We completed our executive team with the key hire of Ann D. Rhoads, our Chief Financial Officer.
- We formed a Scientific Advisory Board of leading scientists in the field of immunotherapy and oncology to support the company in advancing 5F9 for the treatment of hematologic and solid tumors. The initial members of Forty Seven's Scientific Advisory Board include Nobel Laureate James Allison, Ph.D., Ronald Levy, M.D., Padmanee Sharma, M.D., Ph.D. and Louis Weiner, M.D.
- We completed our IPO and our common stock is now listed on The Nasdaq Global Select Market under the symbol "FTSV." Gross proceeds from the offering totaled \$129.4 million.
- We announced clinical trial agreements with Merck-KGaA and Genentech that co-fund the investigation of 5F9 in combination with checkpoint inhibitors for the treatment of ovarian cancer, bladder cancer and AML.
- We announced the results of our Phase 1b trial of 5F9 for the treatment of NHL at ASCO and these results were published in the New England Journal of Medicine.
- Together with our clinical collaborators we advanced the development and understanding of 5F9 including:
  - The initiation of Phase 1b trials of 5F9 in combination with avelumab in ovarian cancer and in combination with azacytidine in AML and MDS.
  - The initiation of the Phase 2 portion of trials of 5F9 in combination with rituximab and cetuximab in NHL and colorectal cancers respectively.
  - The presentation of the following two posters at the American Society of Hematology:
    - RBC-Specific CD47 Pruning Confers Protection and Underlies the Transient Anemia in 5F9 Anti-CD47 "Combination Treatment with 5F9"
    - Azacitidine Enhances Phagocytic Elimination of Acute Myeloid Leukemia"
- Selected a lead candidate for our cKIT program, FSI-174, while continuing preclinical development.
- Selected a lead candidate for our SIRP $\alpha$  program, FSI-189, while continuing preclinical development.
- We completed a license agreement with BliNK wherein we acquired all of BliNK's assets relating to its research and development program for antibodies directed against CD47 and in a subsequent transaction resolved a patent dispute with Synthon and acquired a license to use 5F9 in combination with anti-cancer therapies including rituximab and cetuximab.
- We successfully defended our European patent number EP 2 242 512, or the EP '512 Patent, in the European Patent Office's Opposition Division.

## Our Development Pipeline

The following table summarizes our development programs, target indications and current stages of development.

Drug Candidate/Focus		Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Worldwide Rights
Blocking Macrophage Checkpoints	5F9 Anti-CD47 Antibody	Chemotherapy	AML Combo: Azacitidine				
		Tumor Targeting Antibody Combinations	NHL Combo: Rituximab				
			CRC Combo: Cetuximab				
	T cell Checkpoint Inhibitor Combinations	Ovarian: Avelumab					
		Bladder: Atezolizumab					
		AML: Atezolizumab					
	FSI-189 Anti-SIRP $\alpha$ Antibody	Solid Tumor					Forty Seven
Targeting Stem Cells	FSI-174 Anti-CKIT Antibody	Transplant Conditioning					Forty Seven

## Strategy

Our goal is to transform the treatment of cancer by leveraging our scientific expertise and lead product candidate to engage macrophages to help patients defeat their cancer.

Our strategy includes the following components:

- Maintain a focus on our core mission of helping patients defeat their cancer.** By focusing on patients first, we believe we can realize the full potential of our therapies. Our initial efforts are directed at patients with high unmet medical needs, such as those diagnosed with AML, CRC, NHL or ovarian cancer. We believe there are patients with many other types of cancers that our product candidates can help.
- Maximize the therapeutic and commercial potential of 5F9 by exploring its treatment of both solid and hematological tumors.** Based on our understanding of the CD47 SIRP $\alpha$  pathway and data from preclinical animal models, we believe 5F9 has the potential to benefit patients in a broad range of tumor types and in combination with other approved oncology therapeutics. We are currently evaluating 5F9 in multiple clinical trials. These trials will read out in 2019 and 2020. Based on these data we expect to initiate additional trials with 5F9 to support regulatory approval and to explore the use of 5F9 in multiple cancer indications.
- Invest early to secure a clinical and commercial supply of 5F9 to mitigate risk and ensure a timely regulatory approval.** Although 5F9 utilizes standard antibody manufacturing processes, we recognize that any regulatory approval requires experience and expertise in the commercial manufacturing of 5F9. In 2016, we completed a strategic manufacturing agreement with Lonza, a global leader in biologics manufacturing. The multi-year arrangement helps ensure sufficient clinical material for our existing trials and provides a path to generate the required manufacturing information that is part of a BLA and initial commercial supplies.

- ***Pursue collaborative relationships and in-licensing opportunities to help advance and expand our product candidate portfolio.*** In addition to our internal drug discovery and development efforts, we plan to identify and pursue strategic collaborative relationships, partnerships and in-licensing opportunities to enhance the development of our current programs and access additional novel product candidates. As examples, in January 2018 we announced clinical trial collaboration and supply agreements with both Merck KGaA and Genentech to explore the utility of 5F9 in combination with approved checkpoint inhibitors. As part of those collaborations, we initiated the combination trial with avelumab in ovarian cancer in June 2018.
- ***Prepare for an active role in commercialization in the United States while considering opportunities to engage with partners to access commercialization capabilities outside the United States.*** We have worldwide rights to 5F9. If 5F9 receives marketing approval in the United States, we intend to commercialize it with our own focused, specialty sales and marketing organization. We may explore partnering with a third party to commercialize and market 5F9 in certain geographies outside the United States.
- ***Leverage our knowledge and expertise in immune system and cancer biology to develop a pipeline of novel therapeutics.*** We intend to utilize CD47 and its associated immune activation pathways to their fullest potential to help patients defeat their cancer. This includes the development of our existing programs and the pursuit of new programs in the future. As an example, we recently advanced the product candidate FSI-174 for our cKIT program. The cKIT program extends the utility of anti-CD47 therapies to antibody conditioning regimens for a variety of transplant indications.

## Scientific Background

### ***The Role of Macrophages in the Treatment of Cancer***

The innate and adaptive components of the human immune system form a complex organization of tissues, cells and proteins that serve to protect the body from invading pathogens. For the body to mount an effective response to a foreign cell or a cancer cell, the innate and adaptive immune systems must generally work in concert.

Macrophages, a key component of the innate immune system, serve as a first line of immune defense and initiate an immune response based on non-specific signals of foreign or abnormal cells. Macrophages also play a key role in alerting cells of the adaptive immune system to the presence of potential targets such as cancer cells. By making cancer cells susceptible to macrophages, we believe that our therapeutic candidates can be effective both as a monotherapy and in combination with other immunotherapies, such as the PD-1/PD-L1-directed and CTLA-4-directed checkpoint inhibitors.

### ***The Role of Macrophages in the Innate and Adaptive Immune Response***

The innate immune system, of which macrophages are a key component, serves as the first line of immune defense. Macrophages specialize in engulfing and digesting cellular debris, foreign substances, invading microorganisms and other cells. Macrophages determine what to attack by recognizing certain “eat me” signals common to pathogens or cancer cells.

Macrophages also play a key role in alerting highly-specialized cells of the adaptive immune system to the presence of potential targets, including cancer cells. Although these highly specialized adaptive immune cells take longer to mobilize, they are capable of providing long-term, effective protection against specific antigens and, importantly, can recall antigens to which they have previously been exposed. As first responders, macrophages swallow the abnormal cells in a process called phagocytosis, digest them and recruit and activate the second line of defense, the adaptive immune system.

### ***Interfering with Suppression of Immune Signaling Pathways***

A critical capability of both the innate and adaptive immune systems is the ability to distinguish cells that are normally found in the body from foreign invaders. Components of both immune systems rely on the presence of certain surface proteins on cells that serve as markers for normal cells to prevent immune attacks. For the innate immune system, CD47 is expressed on cells throughout the body and functions as a “don’t eat me” signal to prevent attack by macrophages. Similarly, for the adaptive immune system, PD-L1 expression prevents attack by T cells.



Recent developments in the field of immuno-oncology have demonstrated that interfering in the PD-L1-based immune suppression system allows the adaptive immune system to attack cancer cells, resulting in significant reduction in tumor burden and increasing overall survival in some cancers. These therapies are generally referred to as checkpoint inhibitors and include both therapies that target PD-1 or PD-L1 such as nivolumab, pembrolizumab, atezolizumab, durvalumab and avelumab as well as therapies such as ipilimumab that target another checkpoint known as CTLA-4. These agents, all of which target the adaptive immune system, have resulted in remarkable efficacy in some patients and, as of September 2018, were the focus of 2,250 active clinical trials.

To date, there have been no therapies approved that target the CD47 checkpoint of the innate immune system. Preclinical data have demonstrated that binding by a CD47 antibody increases antigen presentation by macrophages and stimulates the development of anti-tumor cytotoxic T cell responses. We believe that by targeting CD47 and activating the macrophage and other components of the innate and adaptive immune system, we can create a new class of therapies with the potential to treat multiple types of solid and hematological tumors.

The below table outlines our macrophage-focused approach targeting the innate immune system as compared to T cell checkpoint inhibitors targeting the adaptive immune system.

	T cells	Macrophages
<b>Immune System Targeted</b>	Adaptive immune system	Innate immune system
<b>Percentage of Tumor Infiltrating Immune Cells</b>	10-20%	20-40%
<b>Cell-Surface Checkpoints and Their Receptors</b>	PD-1/PD-L1, CTLA-4	CD47/SIRPα
<b>Applicability to Tumor Targets</b>	Target limited	Not target limited
<b>Dependency</b>	Requires antigen presentation by innate immune cells	Works independently and can recruit adaptive immune cells

### *The Role of CD47 in the Treatment of Cancer*

There are two opposing mechanisms that macrophages rely on to determine whether to attack a cell: one set of markers found on some cells, including bound IgG and calreticulin, triggers an “eat me” signal; the other, centered around CD47, found on both healthy cells as well as many cancer cells, sends a “don’t eat me” signal. This “don’t eat me” signal is essential to prevent macrophages from attacking. Macrophages recognize CD47 through a receptor, SIRPα, that can specifically bind to CD47. Binding of SIRPα receptors on macrophages to CD47 on cancer cells prevents macrophages from attacking and digesting these cancer cells. Macrophages only remove cells whose balance of “eat me” signals outweigh the CD47 “don’t eat me” signals.

Nearly all types of tumors overexpress CD47 as a way to avoid the innate immune system. Sending this “don’t eat me” signal prevents the initial attack by macrophages and other phagocytic cells. Because these cancer cells are not digested, the macrophages cannot present components of the cancer cells to the adaptive immune system thereby preventing the activation of T cells that could specifically target them. Expression of CD47 by cancer cells can thus render these cells invisible to innate immune recognition. Interfering with CD47 binding to SIRPa has the potential to activate an immune response to cancer cells that is upstream of current checkpoint inhibitors that target PD-1/PD-L1 or CTLA-4. As shown in the following figure the overexpression of CD47 in many types of cancer has been demonstrated by a variety of scientific techniques.

<b>CD47 Overexpression in Cancer Compared to Normal Tissue</b>				
	<b>RNA</b>	<b>Protein Immuno-histochemistry</b>	<b>Protein Western Blot</b>	<b>Protein Flow Cytometry</b>
<b>Pancreatic Cancer</b>	✓	✓		
<b>Lung Cancer</b>	✓		✓	✓
<b>Ovarian Cancer</b>	✓	✓	✓	
<b>Laryngeal Cancer</b>	✓	✓	✓	
<b>Stomach Cancer</b>				✓
<b>Kidney Cancer</b>				✓
<b>Colon Cancer</b>				✓
<b>Acute Myeloid Leukemia</b>				✓
<b>Non-Hodgkin’s Lymphoma</b>				✓
<b>Acute Lymphoblastic Leukemia</b>				✓

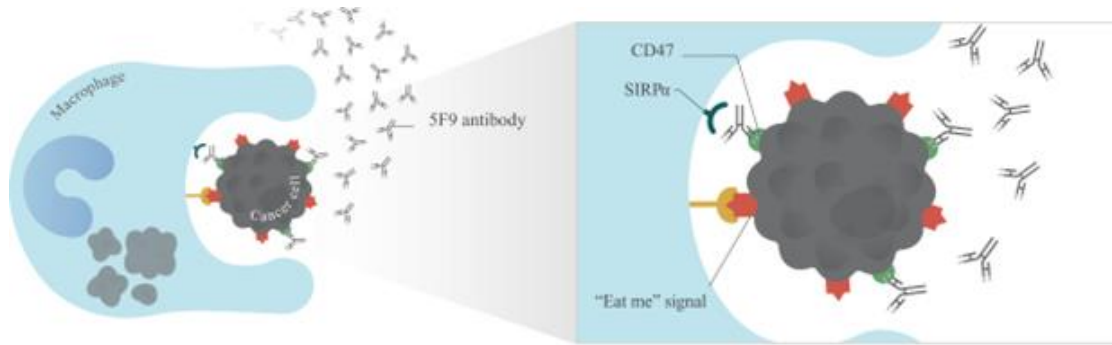
Overexpression of CD47 is associated with poor prognosis in multiple cancers including AML, gastric cancer, lung cancer, NHL and ovarian cancer. In CRC patients with tumors containing high levels of macrophages and low levels of CD47 have increased long-term survival.

The progression from normal cell to cancer cell involves changes in genes and/or gene expression that can subvert normal cellular control mechanisms, and overexpression of CD47 represents an important checkpoint allowing the cancer cells to survive. In animal models, CD47-blocking antibodies have been shown to inhibit human cancer growth and metastasis by enabling the phagocytosis of cancer cells. CD47-blocking antibodies have been shown to exhibit potent synergy with tumor targeting monoclonal antibodies, such as rituximab, cetuximab and trastuzumab. Thus, we believe CD47 has a strong potential as a therapeutic target for the treatment of a variety of cancers.

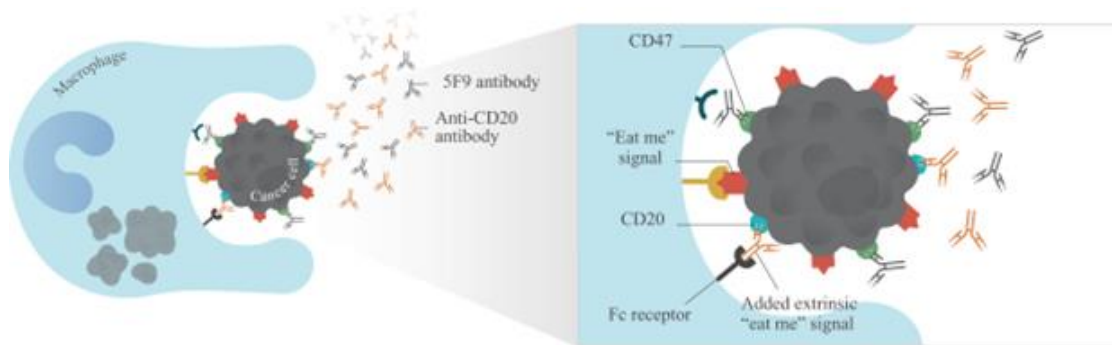
#### **Our Lead Product Candidate, 5F9**

Our lead product candidate, 5F9, is a humanized IgG4 subclass monoclonal antibody against CD47 that is designed to interfere with recognition of CD47 by the SIRPa receptor on macrophages. By blocking this recognition, 5F9 removes a key self-recognition or “don’t eat me” signal, which allows the innate immune system to attack and dispose of cancer cells. We are currently investigating 5F9 in multiple Phase 1 and Phase 2 trials in various cancers including AML, CRC, NHL, and ovarian cancer, as both a monotherapy and in combination with other therapies such as rituximab, cetuximab, avelumab and azacitidine.

The following figure shows the mechanism of action of 5F9.



5F9 activation of macrophages to attack cancer cells can be further stimulated in combination therapies by supplying a tumor targeting antibody that can specifically recognize tumor-specific antigens. By binding to cancer cells, these antibodies become an "eat me" signal to macrophages. There are many tumor-specific antibodies in current clinical practice in oncology, including rituximab, approved for various lymphomas and some types of leukemia, and cetuximab, approved in CRC and certain head and neck cancers. The following figure shows the mechanism of action of 5F9 in combination with a CD20 therapeutic antibody, such as rituximab.



Importantly, most normal cells lack an "eat me" signal and are therefore unaffected by the blocking of CD47.

## 5F9 Clinical Trials

5F9 monotherapy trials started in 2014 at a clinical trial center at Stanford University and in 2015 at a clinical trial center at Oxford University. The clinical trials with 5F9 and tumor targeting antibody combinations started in 2016 at multiple trial centers in the United States and United Kingdom. We currently have trials taking place in over 20 clinical centers in the US and the UK. We have treated over 290 cancer patients in the Phase 1 trials with 5F9 both as a monotherapy and in combination with therapeutic antibodies such as rituximab, cetuximab and avelumab. The primary endpoint of these trials was to determine the MTD and dose limiting toxicities, or DLTs, in addition to objective anti-tumor responses. No MTD has been achieved in any trial despite maximum tested doses of 45 mg/kg weekly. The MTD for our trials was defined using the standard Phase 1 trial definition of being the highest dose level tested that generated a DLT rate of less than 33% in at least 6 evaluable patients. Secondary endpoints of these trials include evaluation of the serum concentrations of 5F9 and measures of clinical activity including how long patients responded to 5F9 and combination therapies, and their overall survival. These trials completed enrollment in 2018 and formal statistical analyses are ongoing.

Our reported results use clinical assessment criteria that are in broad use as standard endpoints in solid tumor and lymphoma trials. In brief, patient tumor size is assessed at approximately eight week intervals by CT or MRI scan while on treatment and the greatest reduction or smallest increase in tumor size is reported as the “best response” per the criteria below. Patients who withdrew from the trial after receiving drug are reported by their best assessment if they completed an assessment or as “progressive disease” if they did not. The specific response measurements are RECIST 1.1 for ovarian and CRC trials, and the Lugano classification for NHL trials. Per RECIST criteria, a “partial response” is a result in which the tumor shrinks at least 30% without the growth of new tumors and a “complete response” is the abolishment of tumor mass without new tumor growth. Per Lugano criteria, a “partial response” is a result in which the tumor shrinks at least 50% or in which the metabolic activity of the tumor has reduced activity compared to baseline, without the growth of new tumors. A “complete response” is a result with the abolishment of tumor mass or tumor metabolic activity without new tumor growth. Patients with “objective responses” are those with either a partial or a complete response. Per RECIST criteria, a patient with “stable disease” has a tumor size that is between a less than 30% reduction and less than 20% growth without growth of new tumors. Per Lugano criteria, “stable disease” is defined as less than a 50% reduction in tumor size and less than 50% growth or no increase in metabolic tumor activity, without growth of new tumors. In our AML trials, response assessment criteria were per ELN 2017 recommendations. Using these criteria, the best monotherapy responses we observed were a “partial response” and cases of “stable disease,” which are defined as patients who lack a partial or complete response yet did not exhibit disease progression. Progression in AML is defined by increases in blast (or cancer) cells and in partial and complete responses there is a substantial reduction in blast cells. In addition, we report “biological responses” that indicate notable biological changes in the bone marrow that were associated with 5F9 therapy but did not meet the definition of a partial or complete response.

### ***5F9 in B-cell Non-Hodgkin’s Lymphoma***

#### *Combination Trial and Early Signs of Clinical Activity*

Our most advanced ongoing clinical trial is an open-label, multi-site Phase 1b/2 trial of 5F9 in combination with rituximab in patients with relapsed or refractory NHL. The rationale behind this combination trial is to release the CD47 inhibition of the innate immune system, thus eliminating the “don’t eat me” signal, and use rituximab to provide the “eat me” signal through its binding to CD20 on the surface of NHL cells. We began recruitment in November 2016 and, as of April 2018, we had evaluated 30 patients in the Phase 1b/2 trial and continued to enroll patients in the Phase 2 portion. We anticipate enrolling at least 70 patients in this trial. In the Phase 1b portion of this trial, patients received full doses of rituximab with cohorts evaluating escalating doses of 5F9. The Phase 2 portion of this trial has separate treatment arms for relapsed or refractory patients with non-aggressive, or indolent FL, and those with aggressive DLBCL.

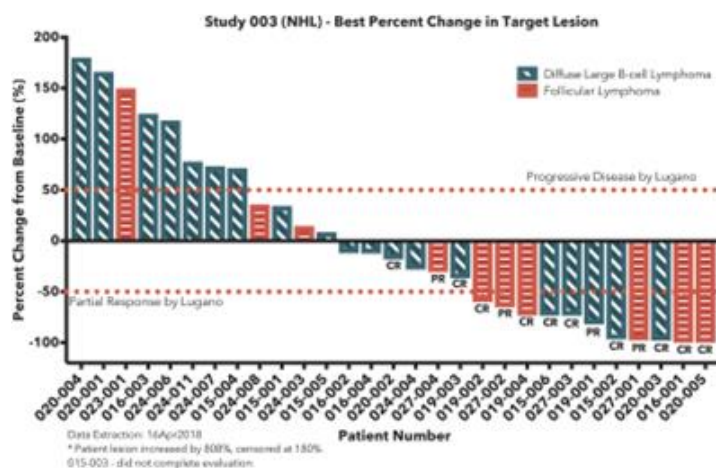
As of April 2018, we have obtained clinical response data from 30 patients in this Phase 1b/2 trial receiving 10 mg/kg, 20 mg/kg or 30 mg/kg 5F9. Progression of the disease was controlled in 17 patients (57%), and 14 patients (47%) displayed an objective response. Ten patients (33%) were reported to have a complete response and 4 patients (13%) were reported to have partial responses. Importantly, the rate of clinical response increased with the

5F9 dosage. Clinical activity was observed in both DLBCL and FL patients. This is notable because these patients all entered the trial after failing multiple lines of previously approved therapies, including rituximab. Particularly, multiple complete remissions have been observed in both DLBCL and FL patients, which are uncommon given the heavily pre-treated nature of these patients. For example, one DLBCL patient had failed four lines of prior therapy and entered the trial with extensive disease that was rapidly progressing. After treatment for eight weeks, this patient achieved a complete response, with no evidence of lymphoma lesions or bone marrow disease.

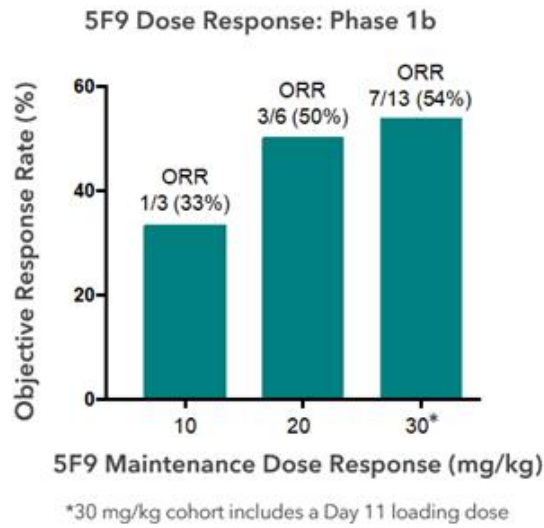
The figure below shows the preliminary results as of April 2018 from a Phase 1b/2 trial of 5F9 in combination with rituximab in relapsed or refractory NHL. Complete and partial response were evaluated by the Lugano criteria, which measures tumor size and metabolic activity.

Response	All patients n=30	DLBCL n=20	Follicular Lymphoma n=10
Objective Response Rate (ORR)	47% (14)	35% (7)	70% (7)
Partial Response (PR)	13% (4)	5% (1)	30% (3)
Complete Response (CR)	33% (10)	30% (6)	40% (4)
Disease control rate (CR+PR+SD)	57% (17)	50% (10)	70% (7)

Data extraction April 2018



A secondary analysis of Phase 1b patients (n=22) in the NHL trial showed a trend with higher incidence of responses at higher doses. This trend was not statistically significant given the low number of patients but as a result we expanded the number of cohorts in Phase 2 to explore both higher doses and a more intensive loading dose regimen.



An important consideration is the effect of rituximab treatment. Rituximab refractory is defined as nonresponse to a rituximab-containing regimen (monotherapy or combined with chemotherapy) or progression during any prior rituximab-containing regimen or progression within six months of the last rituximab dose in the induction or maintenance settings. A full 90% of responders met this definition of being rituximab refractory before dosing. Failure of prior therapies containing rituximab did not prevent patients from responding to the combination of 5F9 and rituximab in this trial. As of April 2018, approximately 90% of the patients who had an initial response continue to respond, suggesting durability. The duration of response is the time between initial response and subsequent disease progression or relapse. A common measure of durability is the midpoint of all responding patients' response durations (the median duration of response). When the median duration of response is reached, 50% of patients will have relapsed and 50% will still be in response. As of April 2018, the median duration of response had not been reached for either Phase 1b DLBCL or FL patients and the median time on treatment was over six months and eight months for DLBCL and FL patients, respectively. We have observed some patients with extended responses or improving responses. For example, 1 patient continued in complete remission for over 14 months on treatment. Furthermore, 2 DLBCL patients converted to complete responses in follow-up assessments after an initial assessment of stable disease and partial response, respectively. While these results represent early data from a limited number of patients, the clinical activity reported is comparable to the durable response rates (responses of greater than eight months duration) seen with other approved therapies such as the CAR-T product YESCARTA (axicabtagene ciloleucel) in DLBCL and the kinase inhibitors ALIQOPA (copanlisib) and COPIKTRA (duvelisib), in FL. Furthermore, 5F9 has been well tolerated to date with no MTD observed, is easy to administer and in the majority of responding patients begins to show clinical activity at the first assessment made at eight weeks. The most common treatment-associated effects observed to date were the expected CD47-mechanism-based effects on red blood cells, which led to a temporary and reversible anemia. Other reported treatment-related adverse events include infusion reactions, headache, fatigue, chills, fever and nausea. The majority of these adverse events were mild to moderate in severity and were generally easily managed. See "Business—Our Lead Product Candidate, 5F9—Safety Profile of 5F9." These attributes may make 5F9 suitable for a broad range of patients. Based on our application summarizing the early NHL trial data, the FDA granted Fast Track designations to 5F9 for the treatment of both relapsed and/or refractory DLBCL and relapsed and/or refractory FL in April 2018.

The Phase 1b/2 portion of the NHL trial is ongoing and we anticipate presenting updated results including durability of responses and response rates from multiple dosing regimens at a major medical conference in mid-2019.

## *Market Opportunity*

We believe there is a broad market opportunity for 5F9 in the treatment of NHL. B-cell NHL is a diverse group of cancers derived from B cells. The American Cancer Society estimated that 74,680 people would be diagnosed with NHL in the United States in 2018. The natural progression of NHL varies widely across multiple forms, including aggressive forms such as DLBCL and more slowly growing or indolent forms such as FL, which according to a publication in *Frontiers in Oncology* in 2013, account for 31% and 22% of all NHL cases, respectively. Without treatment, survival of aggressive NHL, such as DLBCL, is only a few months in duration.

As with other B cell lymphomas, FL and DLBCL cells express CD20 on the cell surface. Monoclonal antibodies targeting CD20 are a key component of current therapy for B cell lymphomas. Rituximab was the first anti-CD20 monoclonal antibody developed and approved for the treatment of B cell NHL. The addition of rituximab to combination chemotherapy could result in an approximately 10-15% overall increase in survival at one year in patients of all ages. Unfortunately, not all patients respond to rituximab and of those that initially responded after treatment with rituximab as a monotherapy, but subsequently relapsed, a study has shown that approximately 60% are resistant to rituximab.

In 2017, a new approach to treating DLBCL known as CAR-T cell therapy was approved. This therapy requires removing blood stem cells from patients, genetically modifying them in the lab to attack DLBCL cells and transplanting them back into the patient, a process which can take several weeks. Although this approach has had some success, there remain significant safety limitations. This therapy is not available to patients who have highly proliferative disease, who cannot wait for treatment, or who cannot tolerate the transplantation procedure. We believe that 5F9 will not have these limitations.

## **5F9 in Ovarian Cancer**

### *Monotherapy Trial and Early Signs of Clinical Activity*

The first in human trial of 5F9 as a monotherapy was a multi-arm trial designed to test the safety and tolerability and to determine dosing in patients with advanced solid tumors. The trial began in August 2014 and, as of April 2018, we have observed confirmed partial responses in 2 out of 21 evaluable patients in a cohort with ovarian cancer receiving either 20 mg/kg or higher doses of 5F9, as of April 2018. Both were heavily pre-treated patients failing seven or more previous treatment regimens. One of these patients had a durable partial response of more than six months in duration. Although the monotherapy response we saw was encouraging, we now believe the response rate in these late phase patients is not sufficient to justify a registrational trial. However, these observations, along with preclinical data, supported our clinical collaboration with Merck KGaA in the 5F9 avelumab combination study.

### *Combination Trial with Checkpoint Inhibitor*

In January 2018, we announced a clinical trial collaboration with Merck KGaA to test 5F9 in combination with the T cell checkpoint inhibitor avelumab in ovarian cancer patients. We believe 5F9 activity will be enhanced due to avelumab binding PD-L1 on the cancer cells and stimulating phagocytosis via binding of the IgG1 isotype antibody to macrophage receptors. We selected the combination of 5F9 and avelumab based on the unique dual ability for avelumab to enhance both a T cell response as a checkpoint inhibitor and serve as a tumor-targeted antibody. Since PD-L1 is expressed on cancer cells, antibodies that target PD-L1 could serve as a tumor targeting antibody, similar to rituximab and cetuximab in NHL and CRC, respectively. However, an active Fc domain capable of inducing antibody-dependent cellular phagocytosis is required. Avelumab is the only FDA approved T cell checkpoint inhibitor targeting PD-L1 that has an active IgG1 Fc domain. Thus, the combination of 5F9 and avelumab may be a key competitive differentiator for combination strategies of CD47 blocking agents and checkpoint inhibitors. Indeed, our preclinical studies demonstrate that the addition of avelumab to 5F9 significantly enhances macrophage phagocytosis of cancer cells. In June 2018, we dosed the first patient of a Phase 1b trial in relapse refractory ovarian cancer patient. We expect to share initial results of the ovarian avelumab combination trial at a major medical conference in the second half of 2019.

## Market Opportunity

The Centers for Disease Control and Prevention, or CDC, estimates that ovarian cancer is the fifth leading cause of cancer death in women in the United States with over 20,000 women in the United States diagnosed with ovarian cancer and approximately 14,000 die from this disease each year. The International Agency for Research on Cancer estimates that, worldwide, there were approximately 225,000 cases of ovarian cancer leading to 140,000 deaths yearly.

Surgery and cytotoxic chemotherapies are widely used to treat ovarian cancer; however, the outcomes have changed little over the last several decades. According to the National Cancer Institute, the relative five-year survival rate has improved only marginally from 43.8%, observed from 2001 to 2007, to 46.5%, observed from 2007 to 2013. Treatment of patients with advanced, relapsed ovarian cancer with a combination of gemcitabine and carboplatin increased the progression free survival to 8.6 months from 5.8 months with carboplatin alone but has had no significant effect on overall survival. Recently a number of products that target poly ADP ribose polymerase, or PARP, a specific component of a DNA repair pathway, have been approved for use in ovarian cancers. These products include olaparib, rucaparib and niraparib. Research published in Molecular Oncology has demonstrated that the efficacy of these products is greatly enhanced in the subset of 5-15% of ovarian cancers with mutations in the BRCA1 and BRCA2 genes. Given the historical lack of improvement in survival rates and limitations of PARP therapies for the majority of cancer patients, we believe 5F9 has the potential to deliver an effective new class of therapy to address this unmet medical need.

### 5F9 in Colorectal Cancer

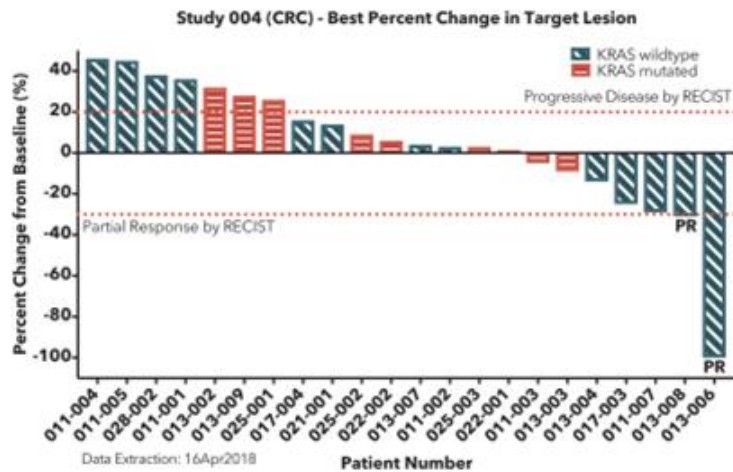
#### Combination Trial and Early Signs of Clinical Activity

We are investigating the combination of 5F9 and cetuximab in an open-label Phase 1b/2 trial in patients with advanced relapsed or refractory solid tumors, including CRC. The trial began in December 2016, and as of December 2018, we had enrolled over 70 patients at multiple sites in the United States. The first arm of this trial was a dose escalation stage with doses of cetuximab increasing up to the standard approved dose level combined with increasing doses of 5F9. Data from the 10 mg/kg, 20 mg/kg and 30 mg/kg cohorts of the Phase 1b portion of the trial is available for 22 patients with CRC. Of these 22 patients, 2 (9%) had a partial response and 9 (41%) had stable disease as their best response. Importantly, at time of data cutoff in April 2018, the initial responding patient had maintained a durable response over eight months that was ongoing. This trial is ongoing and we expect to present data from patients in the Phase 2 arm of this trial in the second half of 2019. The following figure shows the responses in patients from this trial as of April 2018.

Best Response	CRC Patients n= 22
Objective Response Rate (ORR)	9% (2)
Partial Response (PR)	9% (2)
Complete Response (CR)	0%
Stable Disease (SD)	41% (9)
Disease control rate (CR+PR+SD)	50% (11)

Data cut April 2018





**Market Opportunity**

According to CDC estimates, CRC is the second leading cause of cancer deaths in the United States. The National Cancer Institute estimates that there were 135,430 new cases of CRC and 50,260 CRC related deaths in the United States in 2017. Almost 35% of the patients with a new diagnosis of CRC will die within five years. The risk of CRC increases with age, with 90% of cases diagnosed in individuals 50 years of age or older. Despite effective screening, leading to a reduction in the mortality from CRC, the number of cases remains high and is expected to increase worldwide to 2.2 million by the year 2030.

Treatment of CRC typically involves the use of cytotoxic chemotherapy and radiation. Treatment with anti-epidermal growth factor receptor or EGFR antibodies as a monotherapy or in combination with chemotherapy has been shown to be effective in a subset of CRC patients, however according to a publication in Current Oncology in 2010, over 40% of patients do not respond to anti-EGFR antibody therapies and of those that do, resistance often develops. Specifically, cetuximab is ineffective in patients who have a mutation in the RAS gene, which represents approximately 40% of all patients. In addition, after initial treatments, the currently approved therapies for advanced CRC patients, such as regorafenib and triflouradine/tipracil (TAS-102), have significant toxicities, negligible response rates (less than 2%) and only a minimal survival benefit, increasing median survival by 1.4 to 1.8 months. We believe that there is an unmet medical need for a treatment option that improves outcomes for patients with CRC.

**5F9 in Acute Myeloid Leukemia and Myelodysplastic Syndrome**

*Monotherapy Trial with Signs of Biologic Activity*

We are conducting a Phase 1 monotherapy trial in patients with relapsed or refractory AML in collaboration with the University of Oxford at multiple sites in the United Kingdom. Leukemic cells, called blasts or blast precursors, are the main driver and indicator of disease burden in AML. The trial began in November 2015, and reductions in the number of blast cells in patient bone marrow samples have been observed in 7 of the 18 patients (39%) in cohorts receiving 10 mg/kg or higher doses of 5F9, as of April 2018. One of these patients had a 50% decrease in blast count and prolonged stable disease for 11.8 months on study before progressing, which is more than double the average life expectancy for this refractory patient population. This patient also had a significant increase in T cells in the bone marrow during treatment, suggesting that 5F9 may have activated the adaptive immune system.

### *Combination Trial with Azacitidine*

In February 2018, based on additional preclinical data supporting treatment using 5F9 in combination with azacitidine, we initiated a combination trial with azacitidine in AML and MDS patients. This trial is enrolling treatment-naïve patients that have AML and are unfit for intensive induction chemotherapy or have high-risk MDS where the standard of care is VIDAZA (azacitidine). We expect to present data from this follow-on trial at a major medical conference in mid-2019.

### *Combination Trial with Checkpoint Inhibitor*

Based in part on these data and similar observations in preclinical models, in January 2018, we announced a clinical collaboration with Genentech to initiate a clinical trial exploring a combination of 5F9 with atezolizumab in patients with AML.

We have received orphan drug designation from both the FDA and the EMA for AML.

### *Market Opportunity AML*

AML is a hematologic cancer characterized by excessive proliferation of myeloid stem cells and their failure to properly differentiate into mature blood cells. AML is the second most common subtype of leukemia in adults. The American Cancer Society estimates an incidence of approximately 19,500 new cases in the United States in 2018. AML is generally a disease of elderly people, with more than 60% of diagnosed patients being older than 60 years. According to Cancer Research UK, the average five-year survival rate for patients with AML is 20%, but there are significant differences in prognosis depending on several factors, including the age of the patient and the presence of co-morbidities at the time of diagnosis. For patients under the age of 45, the five-year survival rate is approximately 57%, while for those over the age of 65 it is only 6%. There are likely multiple reasons for this difference, including the ability of younger patients to tolerate more aggressive therapy.

Current first-line treatments in AML typically involve aggressive chemotherapy, including alkylating agents and cytarabine potentially followed by stem cell transplantation, for younger patients with the aim to induce and then maintain long-term remission. This therapy is not recommended for older patients or patients with comorbidities, who are often not treated at all or are treated with low dose cytarabine or azacitidine. There is a single biologic, MYLOTARG (gemtuzumab ozogamicin), approved by the FDA for AML. Mean survival in AML patients over 75 years of age treated with gemtuzumab ozogamicin as a monotherapy was 4.9 months versus 3.6 months for those treated with the best supportive care. Significant myeloid and liver toxicities have also complicated the use of gemtuzumab ozogamicin in patients. Other more recently approved therapeutics for AML target subsets of patients with tumors containing specific mutations such as RYDAPT (midostaurin) by Novartis for those with FLT3 mutations and IDHIFA (enasidenib) by Celgene/Agios for those with mutations in IDH2. Additional combinations, such as VENCLEXTA (venetoclax) in combination with azacitidine, have also been recently approved for newly diagnosed AML patients who are age 75 years or older or had comorbidities that precluded the use of intensive induction chemotherapy. Despite these advancements, we believe there is a significant need for a safe, broadly effective AML treatment. CD47 is expressed to a higher degree in AML cells, including leukemia stem cells, than in normal blood cells, making AML an attractive potential indication for 5F9.

### *Additional Trials: Combinations with Checkpoint Inhibitors*

We believe there is a strong rationale to combine 5F9 with T cell checkpoint inhibitors. 5F9 may induce a potent anti-cancer T cell response by enabling macrophages to ingest cancer cells and present antigens derived from these cancer cells to T cells. Thus, the combination of a T cell checkpoint inhibitor with 5F9 is likely to further enhance an anti-cancer T cell response and to further mobilize both the innate and adaptive immune systems to eliminate cancer. In this context, we collaborated with Merck KGaA to test the safety and clinical activity of 5F9 in combination with avelumab, an antibody targeting PD-L1 in patients with ovarian cancer. Furthermore, we and our partner Genentech, are planning to test the safety and clinical activity of 5F9 in combination with atezolizumab, a monoclonal antibody targeting PD-L1, an adaptive immunity checkpoint, in bladder cancer. We believe that these trials will help us test a key hypothesis by determining whether 5F9 can further enhance the anti-tumor activity of checkpoint inhibitors that already have activity as a monotherapy. We anticipate atezolizumab combination trials to start in mid-2019.

### ***Safety Profile of 5F9***

In our clinical studies, 5F9 has demonstrated signs of early clinical activity while being generally well-tolerated. The design of 5F9, combined with our proprietary dosing regimen, overcomes the toxicity limitations of previously tested anti-CD47 therapies. Across all study populations, 5F9 has been well tolerated with no MTD observed in any study despite dosing up to 45 mg/kg. The most common treatment-associated effects observed to date were the expected CD47-mechanism-based effects on red blood cells which led to a temporary and reversible anemia. Other reported treatment-related adverse events include infusion reactions, headache, fatigue, chills, fever and nausea. The majority of these adverse events were mild to moderate in severity and were generally easily managed. Importantly, dosing 5F9 in combinations with other therapeutic antibodies and chemotherapeutic agents did not appear to adversely impact the safety profile of either 5F9 or the combination agent.

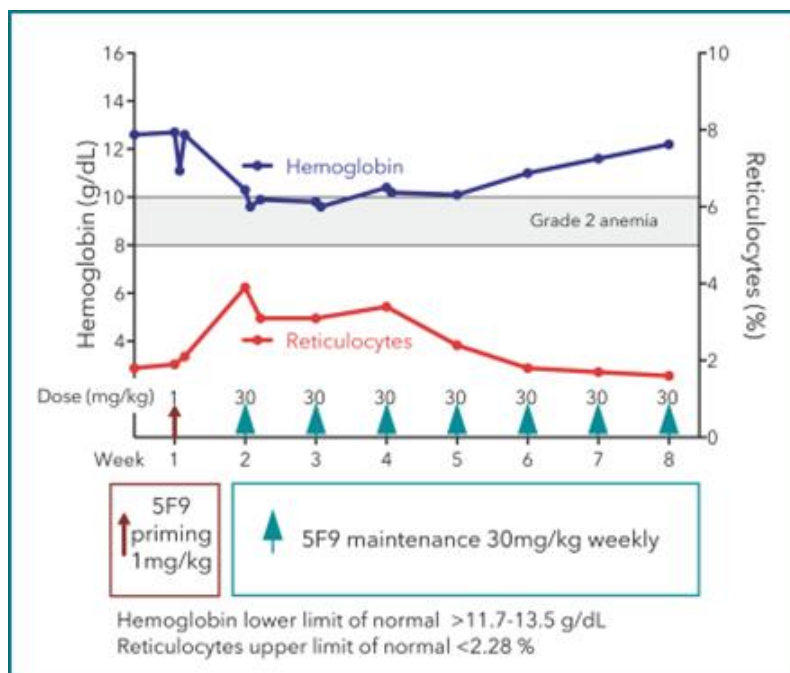
#### ***Minimizing the Effects on Red Blood Cells***

Red blood cells, like other cells in the body, express CD47 as a “don’t eat me” signal to prevent phagocytosis by macrophages. As red blood cells age, the levels of CD47 gradually decrease and the levels of “eat me” signals such as phosphatidylserine or IgG increase such that at some point aged red blood cells are engulfed by macrophages and removed from circulation. The levels of red blood cells in the body, however, are tightly regulated and the removal of aged or damaged red blood cells stimulates the production of new red blood cells. The administration of CD47 antibodies, such as 5F9, would be expected to block the “don’t eat me” signal on red blood cells resulting in premature loss of those aged red blood cells that bear sufficiently high levels of “eat me” signals. Indeed, this predicted loss of red blood cells and the associated anemia has been observed in preclinical studies and clinical trials of 5F9 but it is generally temporary and reversible in nature. The loss of red blood cells is compensated for by reticulocytosis, which is the synthesis of new red blood cells that leads to the gradual resolution of the anemia. Eventually the red blood cell level stabilizes as the average age of red blood cells shifts toward younger cells.

To address this expected anemia, we designed a proprietary dosing regimen into our clinical trials in which clinicians administer a priming dose of 1 mg/kg of 5F9 that is sufficient to eliminate the aged red blood cells and trigger the process of reticulocytosis. A mild anemia with the first priming dose is therefore expected. This priming dose then enables administration of much higher and more efficacious maintenance doses of 30 or 45 mg/kg in subsequent weeks that do not induce further clearance of red blood cells. We believe our approach of administering a priming dose followed by maintenance doses is an important element in mitigating the known on-target effect of anemia that results from therapeutic blocking of CD47.

The initial first-in-human Phase 1 clinical trial of 5F9 was initiated by researchers at Stanford University in 24 patients with relapsed or refractory solid tumors. This design allowed dose exploration of both a priming dose and then potential therapeutic doses of 5F9. Eleven patients were treated in Part A of the trial, which was designed as a dose escalation trial with the goal of establishing a priming dose of 5F9 that would be tolerable while also still fully saturating CD47 on red blood cells. After a single dose of 1 mg/kg of 5F9, approximately 90% of CD47 molecules on red blood cells were blocked, whereas at doses of 0.1 mg/kg and 0.3 mg/kg approximately 50% of CD47 molecules were blocked. The 1 mg/kg dose was well tolerated with no dose-limiting toxicities.

Part B of the trial investigated the safety and tolerability of weekly maintenance dosing of 5F9 in 14 patients treated at 1, 10, 20, 30 and 45 mg/kg, each following a single priming dose of 1 mg/kg. The study showed that this dosing regimen results in an early, temporary decline in hemoglobin levels corresponding to mild to moderate anemia during the first two weeks of starting therapy. In many patients, hemoglobin levels return to baseline by week four or later, even with continued treatment with 5F9 at significantly higher doses. The figure below illustrates the physiological response associated with the priming dose in a solid tumor patient.



An additional common treatment-associated effect related to red blood cells is hemagglutination, or the clumping of red blood cells, which we believe is driven by the direct interaction of 5F9 with CD47 on red blood cells. We observe hemagglutination by microscopic examination of a blood sample typically in conjunction with the initial priming or maintenance doses. In the over 290 patients treated with 5F9 across indications, hemagglutination has not been correlated with significant adverse events or other clinical symptoms.

In order to evaluate the clinical risk of hemagglutination and to monitor for any effects this might have on the microvasculature, our Phase 1 monotherapy trial of 5F9 in solid tumor patients included baseline and weekly high resolution retinal imaging studies during the trial. The 163 scans obtained in solid tumor patients did not reveal any treatment related pathology, outside of a solitary, asymptomatic transient abnormal finding on the retina known as a cotton wool spot in a single patient who did not exhibit hemagglutination. We removed the requirement for retinal imaging due to the lack of significant retinal findings in a protocol amendment, which was accepted by the FDA without any related issues being raised. In addition, we presented at the 2018 American Society of Hematology meeting new information demonstrating that the priming dose utilized on our trials induces an elimination or “pruning” of CD47 from RBCs so that binding of 5F9 would be eliminated.

Patients with AML do not have the bone marrow capacity to stimulate reticulocytosis due to their disease and thus have to rely on blood transfusions to replace aged red blood cells that are eliminated by 5F9 treatment. Hemagglutination continues to be observed in these patients beyond the first or second dose of 5F9 as the transfused blood contains a substantial population of untreated red blood cells. These transfusions have been well tolerated. Similar to solid tumor patients, to date, no clinical consequences have been correlated with hemagglutination.

### *Other Safety Observations*

5F9 has been dosed in over 290 patients with both solid and hematological tumors as of December 2018. Across all study populations, 5F9 has been well tolerated with no MTD observed in any study including in doses of up to 45 mg/kg. The most common treatment-associated effects observed were CD47-mechanism-based effects on red blood cells such as anemia. Other reported treatment-related adverse events include infusion reactions, headache, fatigue, chills, fever and nausea. Common drug-related abnormal laboratory observations have included transient hyperbilirubinemia, transient reticulocytosis and spherocytosis, all of which are consistent with the on-target effect of aged red blood cell clearance by 5F9. Lymphopenia was also observed but not associated with any clinical consequences including infections. These findings were more frequent following the first or second infusion, with substantially fewer drug-related events reported beyond the first 28-day treatment cycle. Infusion-associated reactions including fevers, chills, headache, chest/abdominal/back pain and infusion/hypersensitivity reactions are observed in patients with solid tumors and lymphoma during the initial two doses with 5F9 and generally not with subsequent doses. No consistent adverse events were observed at high or extended exposure and there were no consistent overlapping toxicities with other antitumor antibodies. In addition, no significant immune-mediated toxicities found in other T cell checkpoint inhibitors have been observed. Patients have been treated over two years without increases in safety signals.

Summaries of reported adverse events from the solid tumor and NHL combination trials are presented in the figures below.

Solid Tumor* Summary (n = 73)			
Adverse Event (AE) Term Patients treated at 10 (3 pts), 20 (39 pts), 30 (25 patients), or 45 (6 patients) mg/kg weekly	AE Grade		
	Any	3	4
Anemia	36 (49%)	8 (11%)	0
Hemagglutination	22 (30%)	1 (1%)	0
Hyperbilirubinemia/Blood bilirubin increased	11 (15%)	3 (4%)	0
Thrombocytopenia	9 (12%)	0	0
Neutropenia	2 (3%)	0	0
Lymphopenia/Lymphocyte count decreased	12 (16%)	7 (10%)	3 (4%)
Fatigue	36 (49%)	0	0
Headache	33 (45%)	1 (1%)	0
Chills	28 (38%)	0	0
Pyrexia	26 (36%)	0	0
Infusion-related reaction	16 (22%)	4 (5%)	0
Nausea	13 (18%)	0	0
Photopsia	7 (10%)	0	0
Back pain	7 (10%)	1 (1%)	0
Myalgia	7 (10%)	0	0
AST elevation	4 (5%)	1 (1%)	1 (1%)
ALT elevation	4 (5%)	0	1 (1%)

\* Ovarian expansion cohort not included in analysis  
 AEs observed in ≥ 10% or selected for clinical interest; Data cutoff 24 Jul 2018

Phase 1b: SF9 + Rituximab Summary (n = 22)					
Adverse Event (AE) Term All Phase 1b patients (SF9 10 mg/kg to 30 mg/kg weekly + rituximab)	AE Grade related to SF9 and/or rituximab				
	Any	1	2	3	4
Chills	9 (41%)	4 (18%)	4 (18%)	1 (4.5%)	0 (0%)
Headache	9 (41%)	6 (27%)	3 (14%)	0 (0%)	0 (0%)
Anemia	9 (41%)	2 (9%)	3 (14%)	4 (18%)	0 (0%)
Infusion related reaction	8 (36%)	0 (0%)	7 (32%)	1 (4.5%)	0 (0%)
Pyrexia	7 (32%)	5 (23%)	1 (4.5%)	1 (4.5%)	0 (0%)
Fatigue	5 (23%)	1 (4.5%)	4 (18%)	0 (0%)	0 (0%)
Nausea	5 (23%)	4 (18%)	1 (4.5%)	0 (0%)	0 (0%)
Back pain	4 (18%)	0 (0%)	4 (18%)	0 (0%)	0 (0%)
Myalgia	3 (14%)	3 (14%)	0 (0%)	0 (0%)	0 (0%)
Neutropenia	3 (14%)	2 (9%)	0 (0%)	0 (0%)	1 (4.5%)*
Thrombocytopenia	3 (14%)	1 (4.5%)	1 (4.5%)	0 (0%)	1 (4.5%)
Vomiting	3 (14%)	1 (4.5%)	2 (9%)	0 (0%)	0 (0%)
Immune thrombocytopenic purpura	1 (4.5%)	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)*
Pulmonary embolism	1 (4.5%)	0 (0%)	0 (0%)	1 (4.5%)*	0 (0%)

AEs ≥ 10% and DLTs regardless of frequency are shown. \*DLT  
 Data extraction April 2018

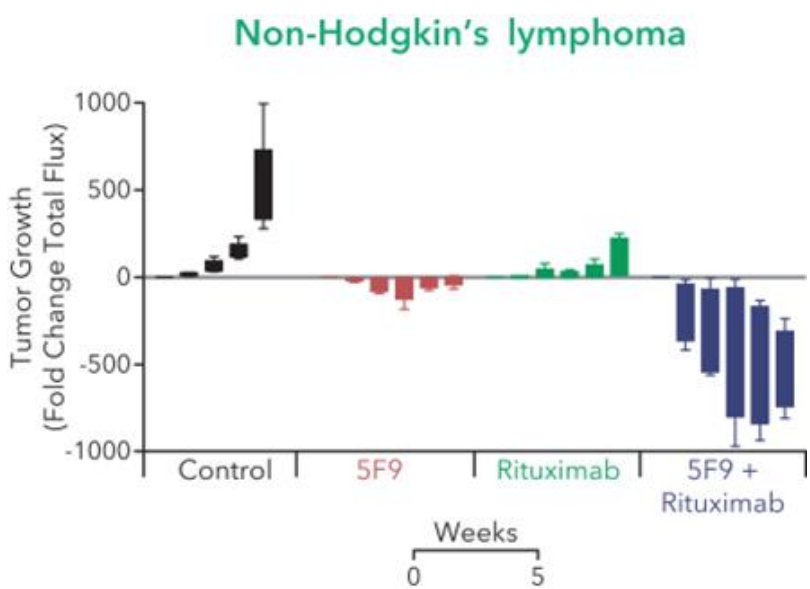
As part of the Phase 1 solid tumor trial design we measured the concentration of 5F9 in the serum of treated patients at various doses. At doses of 10 mg/kg and above the half-life of 5F9 is approximately two weeks. When dosed weekly at 10 mg/kg and higher the serum concentrations of 5F9 exceeded concentrations associated with activity in preclinical models. Our initial signs of clinical activity in patients with AML, CRC, NHL or ovarian cancers were all observed at doses of 10 mg/kg weekly or higher suggesting our preclinical model results are consistent with our clinical observations. Anti-drug antibodies were detected in 15 of 190 evaluable patients in our clinical trials; however, the presence of such antibodies were not associated with changes in 5F9 pharmacokinetics or clinical consequences. The anti-drug antibody rate for 5F9 (7.7%) is similar to other humanized antibodies.

***Preclinical and Translational Data***

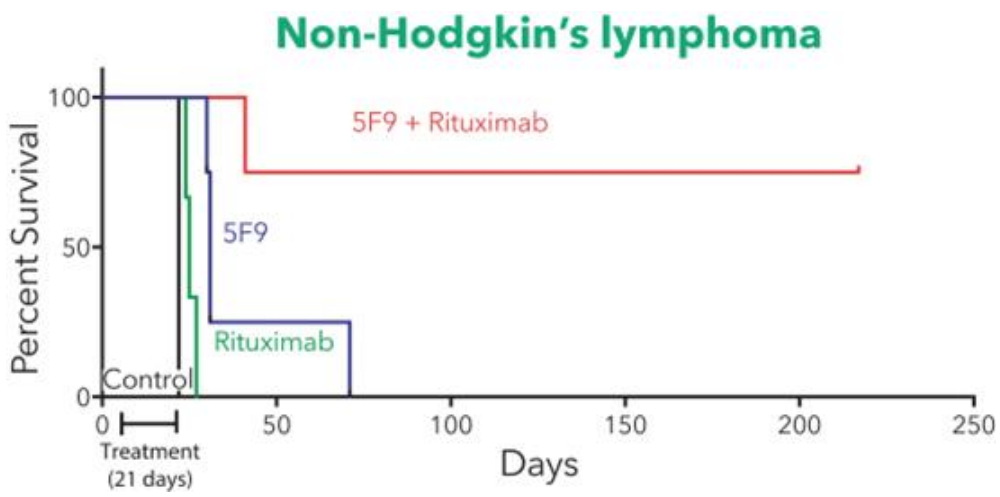
The role of CD47 as a key component of self-recognition in the innate immune system and its potential role as an immuno-oncology target has been published by Forty Seven and by our founders at Stanford University. These findings have been validated by independent publications from multiple academic groups. Some key findings of this preclinical research include:

- CD47 is overexpressed in a majority of tumor types;
- Expression levels of CD47 are correlated with evasion of phagocytosis by macrophages;
- High expression of CD47 is associated with poor prognosis in patients with hematologic cancer and solid tumors;
- Antibodies against CD47 promote antitumor activity in over 25 types of tumors including AML, CRC, NHL, ovarian cancer and others;
- The therapeutic cancer treatment azacitidine can synergize with 5F9 in animal models of AML;
- Addition of therapeutic cancer antibodies can synergize with CD47 antibodies in animal models including rituximab, cetuximab, trastuzumab and others;
- CD47 antibody-mediated phagocytosis of cancer cells enables macrophages to present tumor antigens to recruit and activate anti-tumor T cells and therefore can synergize with T cell checkpoint therapies; and
- Dosing with anti-CD47 induces a “pruning” of the CD47 receptor from red blood cells such that the ability of 5F9 to bind to red blood cells is eliminated over time.

An example of the anti-tumor potential of combining inhibition of the CD47 “don’t eat me” signal by 5F9 and the “eat me” signal from rituximab was observed in a mouse models of NHL. In these models, a highly aggressive human NHL cell line is used to introduce tumors into mice. When given as a monotherapy, 5F9 or rituximab monotherapy was only able to keep the tumor from growing larger. However, when 5F9 and rituximab were dosed together, significant shrinkage of tumors was observed within two to five weeks, as shown in the figure below.

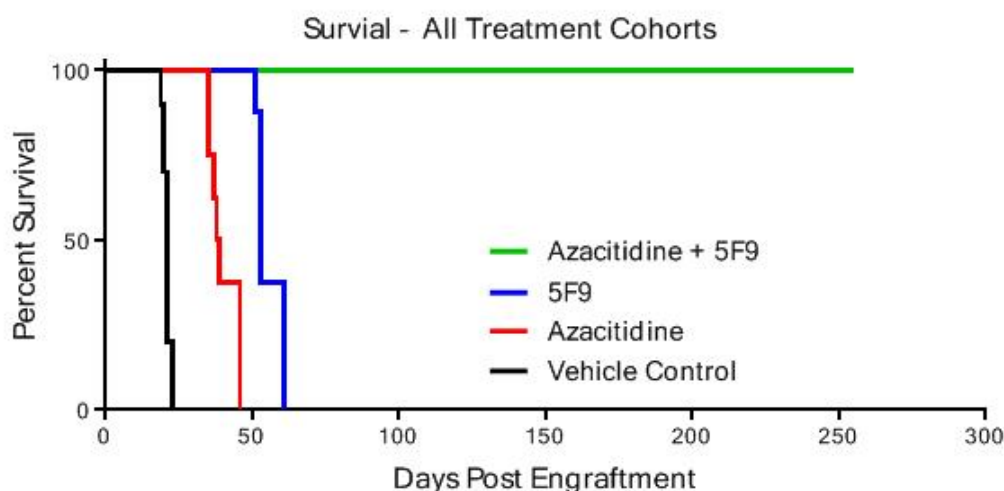


This reduction in tumor burden was associated with a significant improvement in overall survival with the majority of the mice exhibiting the disappearance or near-disappearance of their tumors, as shown in the figure below. This preclinical data and similar preclinical data in other animal models serve as the basis for our ongoing and future clinical trials.





In an in vitro experiment we showed that exposing AML cells to azacitidine induces a specific “eat me” signal called calreticulin. By combining inhibition of the CD47 “don’t eat me” signal by 5F9 with the “eat me” signal stimulated from azacitidine we observed significant combination activity in mouse models of AML. In these models, a human AML cell line is used to introduce tumors into mice. When given as a monotherapy, 5F9 or azacitidine modestly prolonged survival. However, when 5F9 and azacitidine were dosed together, there was significant shrinkage of tumors and prolonged survival for the animals treated with the combination as shown in the figure below.



### Translational Data

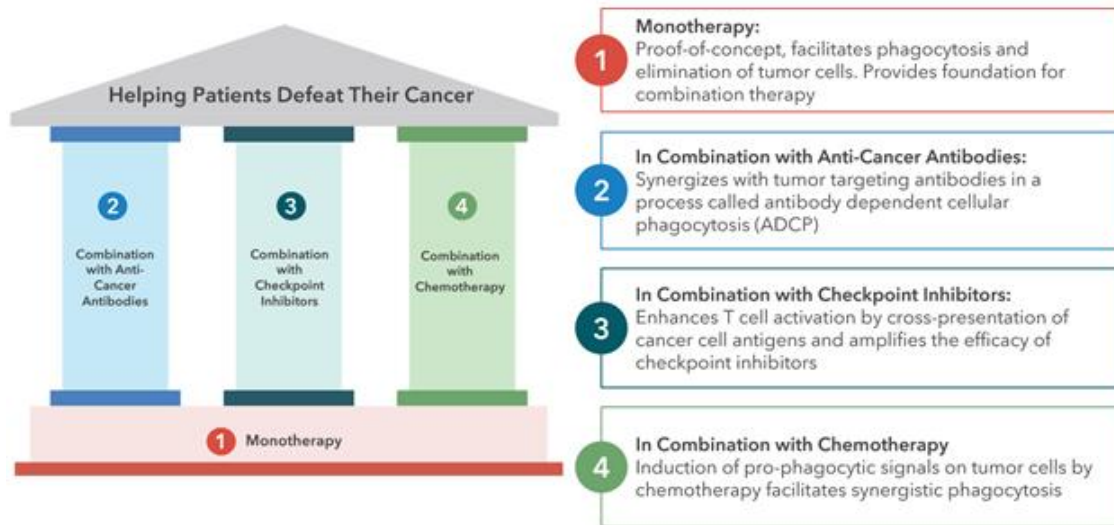
Analysis of the levels of 5F9 binding to CD47 during the clinical trials revealed that the priming dose of 5F9 not only triggered clearance of a subset of red blood cells, or RBCs, but also resulted in a near complete loss of CD47 on all RBCs—a phenomenon we term “CD47 pruning.” This pruning effect was RBC-specific; white blood cells and AML bone marrow blasts did not exhibit CD47 pruning. These clinical findings have been recapitulated in preclinical studies in mice and the observations were again RBC specific. We believe the loss of CD47 receptors from RBCs after the priming dose suggests that any 5F9 effects on RBCs during maintenance doses will be substantially reduced. These findings were presented at the American Society of Hematology in 2018 and provide a fundamental insight into the mechanism underlying how 5F9 is safely dosed using our proprietary dosing regimen.

### Importance of 5F9 in a Multipronged Approach to Treating Cancer

5F9 has the potential to be an important therapeutic contributing to a multipronged approach to oncology treatment. While the field of immunoncology is a growing area of scientific focus, macrophage activation is missing from the current repertoire of biological oncology agents. Agents that target the CD47-SIRPa interaction can address this missing component.

- **Monotherapy.** Direct blockage of the CD47-SIRPa interaction enables macrophages to recognize cancer cells via endogenous “eat me” signals such as calreticulin as well as by antibodies to surface expressed antigens. Antibodies that are present endogenously or are provided therapeutically bind to surface antigens on cancer cells leading to their capturing and engulfing by macrophages in a process called antibody dependent cellular phagocytosis or ADCP. To date, no therapies have been approved that release macrophages from CD47-dependent inhibition. In our Phase 1 trials of 5F9 as a monotherapy we observed signs of clinical activity in AML and ovarian cancer patients validating the CD47 target and providing a foundation for exploring 5F9 in combinations.

- **Combination with Tumor Targeting Antibodies.** Antibodies, such as rituximab, that recognize specific cancer cells trigger activation of natural killer or NK cells which result in antibody dependent cellular cytotoxicity or ADCC. Over twenty antibody products have been approved as therapeutics in oncology. These include antibodies that target antigens such as CD20 (rituximab, obinutuzumab, ofatumumab), epidermal growth factor receptor or EGFR (cetuximab, panitumumab), human epidermal growth factor receptor 2 (HER2) (trastuzumab, pertuzumab), among others. These therapeutics represent a mainstay of cancer therapy, but have limited efficacy as monotherapies. Importantly, binding of these antibodies to cancer cells can also provide strong “eat me” signals triggering attack by macrophages.
- **Combination with Checkpoint Inhibitors.** Cytotoxic T cells are components of the adaptive immune system that are specialized for targeting specific antigens on cancer cells. These may include naturally derived T cells that target tumor-specific antigens including neoantigens or antigens that arise from mutations within tumors. T cell agents also include a new class of cellular therapeutics such as CAR-T cells that are generated by genetic engineering, such as KYMRIAH (tisagenlecleucel) and YESCARTA (axicabtagene ciloleucel). A series of pharmacological agents known as checkpoint inhibitors have been approved as cancer therapeutics that function by relieving the active suppression of cytotoxic T cell activity. These agents include antibodies against PD-1, such as nivolumab and pembrolizumab, and PD-L1, such as atezolizumab and avelumab, as well as CTLA-4, such as ipilimumab. T-cell checkpoint inhibitors agents have limited efficacy when used as a monotherapy, and are currently the subject of over 2,250 clinical trials investigating their efficacy when used in combination. Phagocytosis of cancer cells by macrophages results in processing and presentation of tumor antigens to T cells, potentially increasing their efficacy.
- **Combination with Chemotherapy.** Chemotherapy is the standard of care for many cancers but has limitations as normal cells are also sensitive to toxins used in chemotherapy. In addition, cancer cells can become resistant to these drugs, limiting clinical benefit, while the treatments produce many unwanted side effects. We and others have demonstrated that treatment of cancer cells with chemotherapies can produce “eat me” signals on the cells triggering attack by macrophages, enhancing the potential for 5F9 combinations.



### ***Benefit of Macrophage Activation in Other Indications***

In addition to the application of our technology in cancer treatment, anti-CD47 therapies could help macrophages target abnormal cells. Such cells may upregulate CD47 to escape detection by the immune system. Macrophages are the first line of defense against pathogens and the expression of CD47 on patient cells infected with viruses may prevent recognition of some viral infections such as Human Immunodeficiency Virus, or HIV, or Hepatitis B Virus, or HBV. We have worldwide rights to 5F9 in all indications.

### ***Other Preclinical Programs***

We are working to develop additional products aimed at enhancing anti-cancer phagocytosis. This includes, but is not limited to the addition or enhancement of pro-phagocytic signals and further inhibition of anti-phagocytic signals. This development pipeline is balanced with preclinical agents at various stages of development, including a mix of both clinically validated and novel targets.

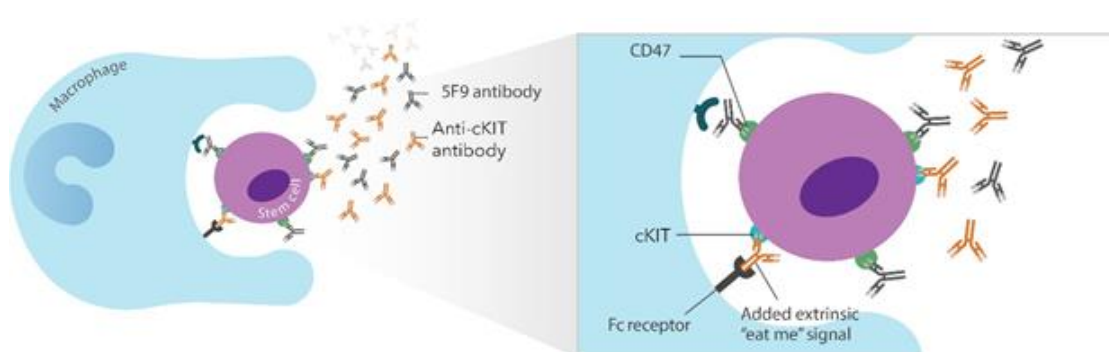
### ***Other Potential Ways to Interfere with CD47-SIRPa Interaction***

There are multiple types of pharmaceutical interventions that have been used to inhibit receptor-target interactions such as CD47-SIRPa. These have included antibodies that block the interaction by binding to either of the partners; small molecules and peptides that prevent the target from binding to the receptor or block downstream signaling events; and soluble decoy molecules that bind to one of the partners thereby preventing the other partner from binding productively. In addition to the 5F9, which is an antibody that binds to CD47 blocking its binding to SIRPa, we have also explored the potential of interfering with CD47 activity through other modalities. Our product candidate, FSI-189, is an antibody that binds to SIRPa. We plan to initiate Phase 1 solid tumor trials for FSI-189 in 2020.

Each of the different modalities has advantages and disadvantages and we believe that the central role of the CD47-SIRPa in regulating self-recognition in the innate immune system provides opportunities for multiple products to have therapeutic benefit in specific indications. Some SIRPa decoy molecules have a lower affinity for CD47 and thereby reduce the risk of red blood cell attack and subsequent anemia. However, these product candidates exhibited dose limiting toxicities at less than 1 mg/kg due to their toxicities on platelets. Antibodies that target SIRPa would be expected to be effective without targeting red blood cells, but, depending on their specific properties, these antibodies may not have any monotherapy activity. Specific variants of all of these modalities, such as whether antibodies are of the IgG1 subtype versus the IgG4 subclass, are expected to have different profiles based on interactions with other components of the immune system.

### ***cKIT FSI-174 Program***

cKIT, also known as CD117, or stem cell growth factor receptor is expressed on the surface of hematopoietic stem cells, or HSCs, as well as other cell types. Alterations of this receptor have been found in certain cancers including leukemia, melanoma and gastrointestinal stroma tumors. Anti-cKIT antibodies can bind to cancer cells and provide an “eat me” signal to macrophages and have been shown to exhibit anti-cancer efficacy in both in vitro and in vivo mouse models. In addition, preclinical studies with anti-cKIT antibodies in combination with anti-CD47 antibodies have been shown to deplete endogenous HSCs. This depletion allows for space in the bone marrow to facilitate transplantation of donor HSCs. The removal or depletion of endogenous HSCs is the goal of a pre-transplant procedure known as “conditioning.”



Transplantation of HSCs is a well-established procedure that may be a potential cure for numerous severe and life-threatening diseases such as genetic blood disorders, blood cancers and autoimmune diseases. While significant advances have been made on stem cell preparation, the “conditioning” itself is still dependent on decades-old chemotherapeutic and radiation-based procedures. “Conditioning” has both acute and long-term toxicities and therefore limits the current use of HSC transplantation to a tiny fraction of patients that could benefit.

Forty Seven aims to overcome this challenge with the development of its cKIT antibody, FSI-174. We believe that FSI-174 when combined with 5F9 or with FSI-189 would be an antibody-based conditioning regimen for HSC transplantation that is free of toxic chemotherapy and radiation. FSI-174 is in pre-clinical development and the first clinical trial is expected to start in early 2020.

## License and Collaboration Agreements

### *Exclusive (Equity) Agreement with The Board of Trustees of the Leland Stanford Junior University*

In November 2015, we entered into a license agreement with Stanford under which we obtained a worldwide, royalty-bearing, sublicenseable license under certain patents, know-how and other intellectual property, including rights associated with the composition of matter of 5F9, to develop, manufacture and commercialize products for use in certain licensed fields, the scope of which would include the application of the licensed intellectual property in oncology. The license granted to us in the agreement is exclusive, subject to certain pre-existing non-exclusive or exclusive rights that Stanford granted to third parties with respect to certain categories of the licensed patents in certain fields of use and retained rights by Stanford and all other non-profit institutions to use and practice the licensed patents and technology for internal research and other non-profit purposes.

In consideration for the rights granted to us under the agreement, we paid Stanford non-refundable license fees totaling \$200,000, reimbursed Stanford for past patent expenses totaling approximately \$933,000 and in November 2016 we issued to Stanford 1,000,160 shares of our common stock. In addition, we are obligated to pay Stanford ongoing patent expenses and an annual license maintenance fee ranging from \$20,000 to \$70,000, depending on the year, which will be creditable against any royalties payable to Stanford in any such year following the first commercial sale of licensed products under the agreement. We are required to make milestone payments up to \$5.6 million in respect of the first three licensed products that successfully satisfy certain clinical and regulatory milestones in the United States, major European countries and Japan. The first clinical milestone payment of \$75,000 was paid to Stanford in February 2018, recognizing the initiation of the Phase 2 trial of 5F9 in NHL. We also agreed to pay Stanford tiered royalties on a specified percentage of net sales made by us, our affiliates and our sublicensees of licensed products at rates ranging from a low-to-high single digit percentage, subject to certain reductions and offsets, with the royalty rate on 5F9 reaching a high single digit percentage when its net sales exceed \$3 billion. To the extent we enter into any sublicensing agreements granting rights to any of the licensed patents to a third party, other than the right to make, have made, use or sell licensed products on behalf of us or our affiliates, we will be required to pay Stanford a low-to-mid double digit percentage of all non-royalty income received from such sublicensees, which decreases based on our level of investment in the licensed products or licensed services and their stage of development. Our license, on a product-by-product and country-by-country basis, shall become royalty-free and fully paid-up upon the later of (i) the date on which the last valid claim included in the licensed patents expires and (ii) the ten year anniversary of the first commercial sale of the licensed product.

We are obligated to use commercially reasonable efforts to commercialize the inventions covered by the licensed patent rights. We are also required to achieve certain specified milestones by specified times, provided that an extension of such timelines can be obtained upon mutual agreement by the parties.

Stanford retains sole responsibility for the prosecution and maintenance of certain patents relating to SIRPa, upon consultation with us. We are responsible for the prosecution and maintenance of the other licensed patents, at our expense and using commercially reasonable efforts, but Stanford retains final approval of such matters. Except for the patents prosecuted and maintained by Stanford, we have the first right to enforce the licensed patents, at our expense.

We may terminate the license at any time for any reason with at least 30 days' written notice to Stanford. Stanford may terminate the license if we enter into an insolvency-related event or in the event of our material breach of the agreement or other specified obligations therein, in each case, that remains uncured for 30 days after the date that we are provided with written notice of such breach by Stanford. In addition, if we fail to achieve any specified diligence milestone by the specified time, Stanford has the right to terminate our license solely with respect to the applicable licensed products for which the milestone was not achieved, which could include 5F9. Our obligations to pay royalties that are accrued or accruable will survive any termination.

#### ***Clinical Trial Collaboration and Supply Agreement with Merck KGaA***

In January 2018, we entered into a clinical trial collaboration agreement with Ares Trading S.A., a subsidiary of Merck KGaA, to evaluate the safety, tolerability and clinical activity of 5F9 combined with Merck KGaA's cancer immunotherapy, avelumab, a fully humanized monoclonal antibody targeting PD-L1, in a Phase 1b clinical trial in patients with ovarian cancer. Pursuant to the agreement, we will act as the sponsor of the study and will hold the regulatory filings relating to the study. We will supply 5F9 and Merck KGaA will supply avelumab for the study, and we and Merck KGaA will jointly pay for the cost of the study. We will conduct the study under the supervision of a joint combination study committee comprised of an equal number of representatives from each of Merck KGaA and us.

Under the terms of the agreement, we own the rights to any inventions or discoveries arising from the study that relate solely to 5F9. Merck KGaA owns the rights to any inventions or discoveries arising from the study that relate solely to avelumab. Both parties will jointly own the rights to inventions or discoveries relating to 5F9 and avelumab in combination. Each party has the sole right to prosecute and maintain patents relating to its solely owned inventions or discoveries, and we will be primarily responsible for, upon consultation with Merck KGaA, the prosecution, maintenance and defense of patents relating to jointly owned inventions or discoveries. We and Merck KGaA each have the first right to initiate legal action to enforce patents relating to jointly owned discoveries where the alleged infringement or misappropriation results from the development or sale of 5F9 or avelumab, respectively.

During the course of the agreement and for 90 days after our delivery of the final clinical study report to Merck KGaA, we agreed to work exclusively with Merck KGaA for any trials testing 5F9 in combination with an anti-PD-1 or anti-PD-L1 antibody in the specific field of ovarian cancer. In addition we have an option to initiate an additional study under the agreement to evaluate 5F9 and avelumab in combination in patients with a different cancer indication or another indication that may be agreed by the parties, which Merck may elect to co-fund at its discretion.

The agreement will expire after 90 days following our provision of the final clinical study report to Merck KGaA. We and Merck KGaA each have the right to terminate the agreement in the event of an uncured material breach of the agreement by the other party. In addition, each party may terminate the agreement upon its own reasonable good faith determination (i) that the study presents a safety risk or (ii) that it is required to be terminated for medical, scientific, legal or regulatory reasons, or if an applicable regulatory authority takes any action that prevents the supply of its respective compound for use in the study. If Merck KGaA terminates the agreement for medical, scientific, legal or regulatory reasons relating to avelumab, we will be able to continue any study that is ongoing as of the effective date of termination.

### ***Master Combination Study Agreement with Genentech, Inc.***

In November 2017, we entered into a master clinical trial collaboration agreement with Genentech to evaluate the safety, tolerability and clinical activity of 5F9 combined with Genentech's cancer immunotherapy, atezolizumab, a fully humanized monoclonal antibody targeting PD-L1, in two separate Phase 1b clinical trials (in patients with bladder cancer and AML, respectively). Pursuant to the agreement, we will supply 5F9 for the studies and will partially reimburse Genentech for its costs in connection with the bladder cancer study, and Genentech will supply atezolizumab for the studies and be solely responsible for all of its costs in connection with the AML study. Genentech will conduct the studies under the supervision of a joint development committee comprised of representatives of both parties.

Under the terms of the agreement, we own the rights to any inventions or discoveries arising from the study that relate solely to 5F9. Genentech owns the rights to any inventions or discoveries arising from the study that relate solely to atezolizumab. Both parties will jointly own the rights to inventions or discoveries relating to 5F9 and atezolizumab in combination, without the right to assign or license any patents that relate to such jointly owned rights to third parties unless necessary for the research, development or commercialization of products utilizing the combination of 5F9 and atezolizumab. Additionally, each party grants the other a non-exclusive, worldwide, fully-paid, perpetual, sublicenseable license to research, develop and commercialize combinations of 5F9 and atezolizumab. Genentech does not receive any rights from us to research, develop or commercialize 5F9 except in combination with atezolizumab and we do not receive any rights from Genentech to research, develop or commercialize atezolizumab except in combination with 5F9. Each party has the sole right to prosecute, maintain and enforce patents relating to its solely owned inventions or discoveries, and we and Genentech shall jointly prosecute, maintain and enforce patents relating to jointly owned inventions or discoveries.

As part of the agreement, we agreed to notify Genentech if we intend to commence discussions with a third party regarding an agreement to commercialize 5F9 in combination with a PD-L1 or PD-1 antagonist. Following such notice, we may not execute any such agreement until the earlier of 30 days following the date of such notice and Genentech's written confirmation that it does not intend to discuss with us a similar commercial arrangement.

The agreement shall expire after the later of (i) five years after its effective date and (ii) the expiration, termination or completion of all studies being performed under the agreement. We and Genentech each have the right to terminate the agreement in the event of a material breach of the agreement by the other party that remains uncured for 30 days after the date that such party is provided with written notice of such breach. In addition, subject to certain discussion obligations and limitations, each party may suspend or terminate a study under the agreement if, based on its review of the study data and other related information, such party determines that the study presents a safety risk or if an applicable regulatory authority withdraws authorization to conduct such study or takes any action that prevents the supply of 5F9 or atezolizumab for use in the study.

### ***Clinical Trial Collaboration and Supply Agreement with Eli Lilly and Company***

In August 2016, we entered into a clinical trial collaboration agreement with Eli Lilly and Company and its subsidiary ImClone LLC, collectively Lilly, to evaluate the safety, tolerability and clinical activity of 5F9 combined with Lilly's cancer immunotherapy, cetuximab, a chimeric monoclonal antibody targeting the epidermal growth factor receptor, in a Phase 1b/2 clinical trial in patients with solid tumors and CRC. Pursuant to the agreement, we will act as the sponsor of the study and will hold the applicable regulatory filings relating to the study. Lilly will supply cetuximab for the study at no cost to us, and we will supply 5F9 and bear all other costs of the study.

Under the terms of the agreement, we own the rights to any inventions or discoveries arising from the study that relate solely to 5F9. Lilly owns the rights to any inventions or discoveries arising from the study that relate solely to cetuximab. Both parties will jointly own the rights to inventions or discoveries relating to 5F9 and cetuximab in combination. Pursuant to the agreement, the prosecution, maintenance and defense of patents relating to jointly owned inventions or discoveries will be managed jointly by the parties. Each party has the first right to initiate legal action to enforce patents relating to jointly owned discoveries depending on whether the alleged infringement or misappropriation results from the development or sale of a biosimilar or interchangeable version of 5F9, in which case we will have the first right, or cetuximab, in which case Lilly will have the first right. Each party has the sole right to prosecute, maintain and enforce patents relating to its solely owned inventions or discoveries.

Unless earlier terminated, the agreement will expire after each party completes all of its obligations under the agreement. Each party may terminate the agreement for an uncured material breach by the other party, for certain violations of anti-corruption and other applicable laws by the other party, if such party determines in good faith that the continuation of the study presents an unreasonable safety risk to patients, or if an applicable regulatory authority takes any action that prevents the supply of its respective compound for use in the study. In addition, we can terminate the agreement if we discontinue the development of 5F9, and Lilly can terminate the agreement if cetuximab is no longer commercially available.

### **Sales and Marketing**

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We plan to build focused capabilities in the United States and European Union to commercialize our development programs focused on NHL, where we believe the patient populations and medical specialists for the indications we are targeting are sufficiently concentrated to allow us to effectively promote our product, if approved for commercial sale, with a targeted sales team. In other markets for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our drug candidates.

### **Manufacturing and Supply**

We currently do not own or operate any manufacturing facilities. We rely, and expect to continue to rely for the foreseeable future, on third party contract manufacturing organizations, or CMOs, including Lonza and Biotechpharma UAB, or BTPH, to produce our product candidates for preclinical and clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval. We require that our CMOs produce bulk drug substances and finished drug products in accordance with current cGMPs and all other applicable laws and regulations. We maintain agreements with our manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

We have engaged Lonza to manufacture 5F9 for preclinical and clinical use. Additional CMOs are used to label, package and distribute 5F9 for preclinical and clinical use. We obtain our supplies from these CMOs on a purchase order basis and do not have any long-term commercial supply arrangements in place. We do not currently have arrangements in place for redundant supply. For all of our product candidates, we intend to identify and qualify additional manufacturers to provide the active pharmaceutical ingredient and fill-and-finish services prior to seeking regulatory approval.

In August 2016 and December 2017, we entered into development and manufacturing agreements with Lonza relating to the manufacturing of 5F9-related products and preclinical testing. The August 2016 agreement was amended in November 2017 to provide for the manufacturing of our other preclinical program related products. In July 2018, we entered into development and manufacturing agreements with BTPH relating to the manufacturing of FSI-174 related products and preclinical testing. For additional details, please see “Management Discussion and Analysis—Contractual Obligations and Commitments” section.

### **Competition**

The pharmaceutical industry and the immuno-oncology subsector are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing treatments and new treatments that may become available in the future.

The key competitive factors affecting the success of 5F9, if approved, are likely to be its efficacy, safety, convenience, pricing and durability.

We are aware that Celgene Corporation, Trillium Therapeutics, ALX Oncology, Arch Oncology, Surface Oncology, Novimmune, OSE Immunotherapeutics, Innovent, I-MAB BIOPHARMA, Aurigene Discovery Technologies and others are developing drugs targeting the CD47 pathway that may have utility for the treatment of indications that we are targeting. We are also aware of competing cKIT antibodies being developed for conditioning treatments prior to transplantation by Magenta and Amgen/Stanford.

As noted above, there are existing treatment alternatives in each of the indications we are targeting, and we will face competition from the incumbent drug therapies in each of those markets.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, more convenient, less expensive or with a more favorable label than 5F9 or any other drug that we may develop. Our competitors also may obtain FDA or other regulatory approvals for their drugs more rapidly than we may obtain approval for our drug, 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 are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors will also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

## **Intellectual Property**

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our current and future product candidates, novel discoveries, product development technologies and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, copyright protection, know-how, continuing technological innovation and confidential information to develop and maintain our proprietary position.

Regardless of the coverage we seek under our existing patent applications, there is always a risk that an alteration to the product or process may provide sufficient basis for a competitor to avoid infringement claims. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued and courts can reinterpret patent scope after issuance. Moreover, many jurisdictions, including the United States, permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. Moreover, we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any current or future issued patents will adequately protect our intellectual property.

As of December 31, 2018, we own four U.S. provisional patent applications, three pending PCT applications and 14 pending foreign patent applications. Our portfolio of licensed patents, which we license from Stanford, includes approximately 102 issued patents (26 of which are in the United States) and approximately 124 pending patent applications (23 of which are in the United States). These licensed patents are expected to expire between 2029 and 2034 excluding any extension of patent term that may be available. For more information regarding our license agreement with Stanford, please see “Business—License and Collaboration Agreements.”

Our patent portfolio licensed from Stanford contains patent families directed to the 5F9 composition of matter and methods of using 5F9 as a monotherapy and in combination with certain other therapeutic compounds, which are comprised of 11 U.S. issued patents, four U.S. patent applications and two granted European patents which have each been validated as national patents in 12 different European countries. These patents are subject to retained rights by Stanford to allow academic and non-profit research institutions to practice the licensed technology and patents for non-commercial purposes. In addition, some of these patents are subject to certain pre-existing non-



exclusive rights that Stanford has granted to two third parties. In particular, a non-exclusive license to certain patents was granted to a third party in the field of research product sales and diagnostics for use in a flow cytometry platform. Another non-exclusive license to certain patents was granted to a different third party for the use of certain SIRPa proteins, SIRPa fragments and SIRPa fusion proteins as therapeutic agents for use in the therapeutics field. For clarity, we believe that these pre-existing non-exclusive licenses do not relate to 5F9 or our other product candidates or their use in the therapeutic field. These patents are expected to expire between 2029 and 2034 excluding any extension of patent term that may be available.

Provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, a patent term can be extended to recapture a portion of the delay by the USPTO, in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years, the total patent term including the restoration period must not exceed 14 years following FDA approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug or a method for using it may be extended. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. The actual protection afforded by a patent may vary on a product-by-product basis and from country to country and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our employees and consultants and any potential commercial partners and collaborators and invention assignment agreements with our employees. We also have implemented or intend to implement confidentiality agreements or invention assignment agreements with our selected consultants and any potential commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing upon, misappropriating or otherwise violating the intellectual or proprietary rights of third parties. The issuance of third-party patents could require us to alter our development or commercial strategies, change our products or processes, obtain licenses to additional third-party patents or other intellectual property or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future products may have an adverse impact on us. Given that patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially longer, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference, revocation, derivation, re-examination, post-grant review, *inter partes* review, or opposition proceedings brought by third parties or declared by the USPTO or an equivalent foreign body.

We have also obtained a sublicense to a family of patent and patent applications owned by Stichting Sanquin Bloedvoorziening, or SSB, and licensed to Synthon Biopharmaceuticals B. V., or Synthon, that encompass certain combination therapies for the treatment of cancer using anti-CD47 antibodies. This family of U.S. and foreign patents includes U.S. Patent No. 9,352,037, or the U.S. '037 Patent, the related European Patent No. EP 2 282 772, or the EP '772 Patent, and its UK counterpart EP (UK) 2 282 772, or the UK '772 Patent. These patents relate to the treatment of cancer with an anti-CD47 antibody or an anti-SIRPa antibody in combination with certain other antibodies, including rituximab or cetuximab.

We are also aware of an opposition filed by different third parties against European patent number EP 2 242 512, or the EP '512 Patent, a European patent that we exclusively in-licensed from Stanford. The EPO opposition proceeding may involve issues including, but not limited to, procedural formalities related to filing the European patent application, priority, and the patentability of the involved claims. The independent claims of EP '512 patent was maintained in the EPO Opposition Division on November 15, 2018. The opponents may appeal the EPO Opposition Division decision to the Technical Boards of Appeal at the EPO. The outcome at the Technical Boards of Appeal cannot be predicted. In addition, one or more of the third parties that have filed oppositions against the EP '512 Patent or other third parties may file future oppositions or other challenges, in Europe or other jurisdictions, against other patents that we in-license or own. The loss of priority for, or the loss of, the EP '512 Patent or our other patents could harm our business, financial condition, results of operations and prospects.

For more information regarding the risks related to our intellectual property, including the above referenced intellectual property proceedings, see “Risk Factors—Risks Related to Our Intellectual Property.”

## **Government Regulation**

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of products, such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates.

### ***United States Government Regulation***

In the United States, the FDA regulates pharmaceuticals under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and their implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign 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 after approval may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a pharmaceutical product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's GLP regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCP requirements to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of a BLA in the case of a biologic such as 5F9;

- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity; and
- FDA review and approval of the BLA.

### ***Preclinical Studies***

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even 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 clinical trial on a 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***

Clinical trials involve the administration of the investigational new drug to human patients under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research patients provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1 clinical trial: The drug is initially introduced into healthy human volunteers or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2 clinical trial: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3 clinical trial: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Each of Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research 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 has been associated with unexpected serious harm to patients.

### ***Marketing Approval***

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. In most cases, the submission of a BLA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard BLA to review and act on the submission. This review typically takes 12 months from the date the BLA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended and reauthorized, certain applications or supplements must contain data that are adequate to assess the safety and effectiveness 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, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all BLAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept a BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews a BLA to determine, among other things, whether the biologic is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application 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. Additionally, before approving a BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the application and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

### ***Post-Approval Requirements***

Pharmaceuticals manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an application. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, pharmaceutical manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

### ***Orphan Drug Designation in the United States***

Under the Orphan Drug Act of 1983, the FDA may grant orphan designation to a drug or biologic 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. Orphan drug designation must be requested before submitting a BLA or supplemental BLA. After the FDA grants orphan drug designation, the name of the sponsor, identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not shorten the duration of the regulatory review or approval process, but does provide certain advantages, such as a waiver of PDUFA, fees, enhanced access to FDA staff and potential waiver of pediatric research requirements.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application user fee. 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. In addition, 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 quantities of the product to meet the needs of patients with the rare disease or condition.

In August 2015, the FDA granted orphan drug designation in the United States for 5F9 for the treatment of AML. We intend to pursue orphan drug designation for 5F9 in additional indications, as well as for potential other future product candidates, in the United States and in the European Union as we deem it appropriate. Even if we obtain orphan drug designation for a product candidate, we may not obtain orphan exclusivity and that exclusivity may not effectively protect the drug or biologic from the competition of different drugs or biologics for the same condition, which could be approved during the exclusivity period.

### ***Expedited Development and Review Programs***

The FDA is required to facilitate the development and expedite the review of pharmaceutical products that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request the FDA to designate the product for a specific indication as a fast track product concurrent with or after the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for fast track designation within 60 days after receipt of the sponsor's request. In April 2018, the FDA granted Fast Track designations to 5F9 for the treatment of both relapsed and/or refractory DLBCL and relapsed and/or refractory FL.

In addition to other benefits, such as the ability to have more frequent interactions with the FDA, the agency may initiate review of sections of a fast track product's BLA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's PDUFA review period for a fast track application does not begin until the last section of the BLA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the agency believes that the designation is no longer supported by data emerging in the clinical trial process.

### ***Coverage and Reimbursement***

Sales of our drug candidates, if approved, will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have

continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any drug candidates that we develop will be made on a payor-by-payor basis. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates or a decision by a third-party payor to not cover our drug candidates could reduce physician usage of our drug candidates, once approved, and negatively impact our sales, results of operations and financial condition.

#### **Other Healthcare Laws**

Because of our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors, we will also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we will conduct our business, including our clinical research, proposed sales, marketing and educational programs. Failure to comply with these laws, where applicable, can result in the imposition of significant civil penalties, criminal penalties, or both. The U.S. laws that may affect our ability to operate, among others, include: HIPAA, as amended by HITECH, which is a federal law governing the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; certain state laws governing the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs; federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Current and future legislative proposals to further reform healthcare or reduce healthcare costs may result in lower reimbursement for our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our revenues from the sale of our products.

### ***Orphan Drug Designation in the European Union***

In accordance with Article 3 of Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, a medicinal product may be designated as an orphan medicinal product if: (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the incentives derived from orphan medicinal product status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition.

Products authorized in the European Union as orphan medicinal products are entitled to 10 years of market exclusivity. The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation. Additionally, marketing authorization may be granted to a similar product during the 10-year period of market exclusivity for the same therapeutic indication at any time if:

- the second applicant can establish in its application that its product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply enough orphan medicinal product.

In November 2015, the EMA granted orphan drug designation in the European Union for 5F9 for the treatment of AML.

### **U.S. Healthcare Reform**

Current and future legislative proposals to further reform healthcare or reduce healthcare costs may result in lower reimbursement for our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our revenues from the sale of our products.

For example, implementation of the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The Affordable Care Act, among other things, established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and congressional challenges to certain aspects of the Affordable Care Act. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The U.S. House of Representatives passed legislation known as the American Health Care Act of 2017 in May 2017. More recently, the Senate Republicans introduced and then updated a bill to replace the Affordable Care Act known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the Affordable Care Act without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. Each of these measures was rejected by the full Senate. Congress will likely consider other legislation to replace elements of the Affordable Care Act.



In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, then-President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2025 unless Congress takes additional action. Recently, 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 bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We expect that additional federal and state, as well as foreign, healthcare reform measures will be adopted in the future, any of which could result in reduced demand for our products or additional pricing pressure.

## **Employees**

As of December 31, 2018, we had 57 full-time employees, (i) 41 of whom were primarily engaged in research and development activities and (ii) 16 of whom had an M.D. or Ph.D. degree. None of our employees is represented by a labor union and we consider our employee relations to be good.

## **Facilities**

Our principal executive offices are located at 1490 O'Brien Drive, Suite A, Menlo Park, California, under a lease that expires in 2021. We believe that our facilities are adequate to meet our current needs but expect to need additional space to accommodate our anticipated growth.

## **Legal Proceedings**

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business.

## **Available Information**

We were incorporated in the State of Delaware in 2014 as CD47 Sciences, Inc. Our telephone number is +1 (650) 352 4150. Our website address is [www.fortyseveninc.com](http://www.fortyseveninc.com). Information found on, or accessible through, our website is not a part of, and is not incorporated into, this Annual Report on Form 10-K.

We file electronically with the U.S. Securities and Exchange Commission, or SEC, our 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 Securities Exchange Act of 1934, as amended. We make available on our website at [www.fortyseveninc.com](http://www.fortyseveninc.com), free of charge, copies of these reports as soon as reasonably practicable after filing these reports with, or furnishing them to, the SEC.

## **Item 1A. Risk Factors.**

### **RISK FACTORS**

*Our business involves significant risks, some of which are described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business*

operations. This report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report.

## **Risks Related to Our Financial Position and Need for Additional Capital**

*We have a limited operating history and have incurred significant losses since inception and we anticipate that we may continue to incur losses for the foreseeable future and may never achieve or maintain profitability.*

We are an immuno-oncology company with a limited operating history. Since inception in 2014, we have not generated any revenue and have incurred significant operating losses. Our net loss was \$19.5 million, \$44.9 million and \$70.4 million for 2016, 2017 and 2018, respectively. As of December 31, 2018, we had an accumulated deficit of \$139.8 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Since inception, we have devoted substantially all of our efforts to research and preclinical and clinical development of our product candidates, as well as to building out our management team and infrastructure. It could be several years, if ever, before we have a commercialized drug. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue to advance our research and clinical and preclinical development of our product candidates;
- scale up manufacturing to provide adequate drug substance for clinical trials and commercialization;
- initiate further clinical trials for our product candidates;
- seek to identify additional product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand, protect and enforce our intellectual property portfolio and obtain licenses to third-party intellectual property;
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel; and
- incur additional legal, accounting and other expenses in operating our business, including the additional costs associated with operating as a public company.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical products and development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase and profitability could be further delayed if we decide to or are required by the FDA or other regulatory authorities such as the European Medicines Agency, or EMA, or the U.K. Medicines & Healthcare Products Regulatory Agency, or MHRA, to perform studies or trials in addition to those currently expected, or if there are any delays in the development, or in the completion of any planned or future preclinical studies or clinical trials of our current and future product candidates. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing our current and future product candidates.

Even 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 will need substantial funding to pursue our business objectives. If we are unable to raise capital when needed or on terms favorable to us, we could be forced to delay, reduce or terminate our product development, other operations or commercialization efforts.*

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and begin selling any approved products. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue to develop our product candidates. Our expenses could increase beyond our current expectations if the FDA requires us to perform clinical trials and other studies in addition to those that we currently anticipate. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or terminate our research and development programs or future commercialization efforts.

As of December 31, 2018, we had cash, cash equivalents and short-term investments of \$139.0 million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will enable us to fund our cash and capital expenditure requirements through at least the next 12 months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the cost associated with commercializing any approved product candidates;
- the cost and timing of developing our ability to establish sales and marketing capabilities, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights, defending intellectual property-related claims and obtaining licenses to third-party intellectual property;
- the timing and amount of milestone and royalty payments we are required to make under our license agreements;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies and associated intellectual property.

We will require additional capital to complete our planned clinical development programs for our current product candidates to obtain regulatory approval. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved.

In addition, we cannot guarantee that future financing will be available on a timely basis, in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities by us, whether equity or debt, or the market perception that such issuances are likely to occur, could cause the market price of our common stock to decline. If we are unable to obtain funding on a timely basis on acceptable terms, we may be required to delay, reduce or terminate one or more of our research and development programs or the commercialization of any product candidates that may be approved.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

**Risks Related to the Development of Our Product Candidates**

***We depend primarily on the success of our lead product candidate, 5F9, which is in clinical development and which has not completed a pivotal trial. If we do not obtain regulatory approval for and successfully commercialize our lead product candidate in one or more indications or we experience significant delays in doing so, we may never generate any revenue or become profitable.***

We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of our lead product candidate, 5F9, in our six ongoing clinical trials, including trials in monotherapy and in combination with anti-cancer antibodies such as rituximab and cetuximab. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of 5F9 in one or more of these indications. We cannot be certain that 5F9 will receive regulatory approval or will be successfully commercialized even if it receives regulatory approval. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of 5F9 is, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates in the United States will prevent us from commercializing and marketing our product candidates. The success of 5F9 and any other product candidates will depend on several additional factors, including:

- completing clinical trials that demonstrate their efficacy and safety;
- receiving marketing approvals from applicable regulatory authorities;
- completing any post-marketing studies required by applicable regulatory authorities;
- establishing commercial manufacturing capabilities;
- launching commercial sales, marketing and distribution operations;
- the prevalence and severity of adverse events experienced with our product candidates;
- acceptance of our product candidates by patients, the medical community and third-party payors;
- a continued acceptable safety profile following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement for our product candidates;

- competing effectively with other therapies, including with respect to the sales and marketing of our product candidates, if approved; and
- qualifying for, maintaining, enforcing and defending our intellectual property rights and claims and obtaining licenses to any third party intellectual property we deem necessary or desirable.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates, which would materially harm our business, financial condition and results of operations.

In addition, the clinical trial requirements of the FDA, the EMA, the MHRA and other regulatory agencies and the criteria these regulators may use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

***Our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development.***

We have concentrated our product research and development efforts on our novel therapeutic approach, and our future success depends on the successful development of our lead product candidate, 5F9, and other product candidates. There can be no assurance that any development problems we experience in the future related to our novel therapy will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

***Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.***

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies or clinical trials for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. We have limited clinical data for each of our product candidates. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. For example, the favorable results of our ongoing trial of 5F9 in tumor targeting antibody combinations with rituximab may not be predictive of similar results in subsequent trials. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

***We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.***

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. Clinical trials are expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement or failing to agree on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites;
- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future drug sales and regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable drugs to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;

- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our drug development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA or an institutional review board may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our investigational new drug applications or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed or eliminated entirely.

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

Because we have limited financial and managerial resources, we focus on research programs that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial therapies or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.***

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. Other products focused on CD47 have had problems with toxicity. If one or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a "black box" warning or contraindication;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;

- commitment to expensive additional safety studies prior to approval or post-marketing studies required by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

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

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study 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;
- the size and health 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 drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in any future clinical trial.

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



***We have received Fast Track designations for 5F9 for the treatment of both relapsed and/or refractory DLBCL and relapsed and/or refractory FL, but such designations may not actually lead to a faster development or regulatory review or approval process.***

In April 2018, the FDA granted Fast Track designations to 5F9 for the treatment of both relapsed and/or refractory DLBCL and relapsed and/or refractory FL. If a drug is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for such condition, a drug sponsor may apply for FDA Fast Track designation. Even though we received Fast Track designations for 5F9 for the treatment of both relapsed and/or refractory DLBCL and relapsed and/or refractory FL, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

***We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.***

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. We currently have no products that have been approved for commercial sale. However, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. In addition, we have agreed to indemnify the licensors of the intellectual property related to our product candidates against certain intellectual property infringement claims. Any claims against us, or with respect to which we are obligated to provide indemnification, regardless of their merit, could be difficult and costly to defend or settle, and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

#### **Risks Related to Commercialization of Our Product Candidates**

***We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.***

We have never commercialized a product candidate. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We currently have no sales force, marketing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

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

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. There are other companies working to develop immunotherapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are developing our initial product candidates for the treatment of cancer and currently none of these therapies are approved. There are already a variety of available drug therapies marketed for cancer and some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

Competition may further increase as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. We are aware that Celgene Corporation, Trillium Therapeutics Inc., ALX Oncology Ltd, Arch Oncology, Inc., Surface Oncology, Inc., Novimmune SA, OSE Immunotherapeutics SA, Aurigene Discovery Technologies Ltd and Innovent and others are developing drugs targeting the CD47 pathway that may have utility for the treatment of indications that we are targeting. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

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

If 5F9 and any other future product candidates receive marketing approval, whether as a single agent or in combination with other therapies, they 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 5F9 and any other future product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of 5F9 and any future products, 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;
- sufficient third-party coverage or reimbursement, including of combination therapies;
- adoption of a companion diagnostic and/or complementary diagnostic; and
- the prevalence and severity of any side effects.

***The successful commercialization of certain of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.***

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford products such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates and attract additional collaboration partners to invest in the development of our product candidates. Coverage under certain government programs, such as Medicare, Medicaid and TRICARE, may not be available for certain of our product candidates. Assuming we obtain coverage 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. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. 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 applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

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

***Even if we receive marketing approval for any of our product candidates, we may not achieve market acceptance, which would limit the revenue that we can generate from sales of any of our approved product candidates.***

Even if the FDA approves the marketing of any product candidates that we develop, physicians, patients, third-party payors or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. Market acceptance of 5F9 and our other product candidates, if any are approved, will depend on a number of factors, including, among others:

- the ability of 5F9 and our other product candidates to treat cancer, as compared with other available drugs, treatments or therapies;
- the prevalence and severity of any adverse side effects associated with 5F9 and our other product candidates;
- limitations or warnings contained in the labeling approved for 5F9 or our other product candidates by the FDA;
- availability of alternative treatments;
- the size of the target patient population, and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity for our product candidates and competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our product candidates through marketing efforts;
- our ability to obtain sufficient third-party coverage or reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage; and
- the likelihood that the FDA may impose additional requirements that limit the promotion, advertising, distribution or sales of our product candidates.

The market acceptance of our product candidates also will depend in part on the market acceptance of other immunotherapies for the treatment of cancer. While a number of other cancer immunotherapies have received regulatory approval and are being commercialized, our approach to targeting the CD47 pathway is novel. Adverse events in clinical trials for 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 5F9 or any other product candidate 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 generally could also result in greater governmental regulation and stricter labeling requirements.

If any of our product candidates is approved but does not achieve an adequate level of acceptance by patients, physicians and third-party payors, we may not generate sufficient revenue to become or remain profitable and our business may be harmed.

***Even if we obtain regulatory approval for our product candidates, they will remain subject to ongoing regulatory oversight.***

Even if we obtain regulatory approval for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record-keeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMP, regulations and GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, 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.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include:

- issuing warning or untitled letters;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;
- suspension or imposition of restrictions on operations, including product manufacturing;
- seizure or detention of products, refusal to permit the import or export of products, or request that we initiate a product recall;
- suspension or withdrawal of our marketing authorizations;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to applications submitted by us; or
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could adversely affect our business, financial condition and results of operations.

***If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.***

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

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

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future product candidates;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

### **Risks Related to Our Dependence on Third Parties**

*We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of 5F9 and any future product candidate.*

We have limited experience in drug formulation and manufacturing and do not own or operate, and we do not expect to own or operate, facilities for drug manufacturing, storage, distribution, or testing. We have entered into a development and manufacturing agreement with Lonza, pursuant to which we agreed to purchase 5F9. Lonza is currently our sole supplier of 5F9. We have also entered into an agreement with BTPH as our sole supplier for our cKIT antibodies. If Lonza or BTPH are unable to supply us with sufficient clinical and commercial grade quantities of drug substance, and we are unable to timely establish an alternate supply from one or more third-party contract manufacturers, we could experience delays in our development efforts as we locate and qualify new manufacturers. Under such circumstances, we may be required to receive drug substance for use on a purchase order basis, and as such, there can be no assurance that we actually receive sufficient quantities.

Further, our reliance on third-party manufacturers exposes us to risks beyond our control, including the risk of:

- inability to meet our drug specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and drug quality issues, including related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for additional scale-up;
- failure to comply with cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for drug components, such that if we are unable to secure a sufficient supply of these drug components, we will be unable to manufacture and sell 5F9 or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of a FDA Form 483 notice or warning letter;

- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our drugs under specified storage conditions and in a timely manner.

Some of these events could be the basis for FDA action, including injunction, recall, seizure, or total or partial suspension of production. In addition, our third-party manufacturers and suppliers are subject to FDA inspection from time to time. Failure by our third-party manufacturers and suppliers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidate may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

In addition, our contract manufacturers are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or manufacturer's facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved.

As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates, which may include transferring production to new third-party suppliers or manufacturers. In order to conduct larger or late-stage scale clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our product candidates in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. These third-party contractors may not be able to successfully increase the manufacturing capacity for any such product candidates in a timely or cost-effective manner or at all. Significant scale up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and which the FDA and foreign regulatory authorities must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the active pharmaceutical ingredients or the finished product. If our third-party contractors are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects.

Any of these events could lead to clinical trial delays, failure to obtain regulatory approval or impact our ability to successfully commercialize any potential future product candidates.

***We rely on third parties to conduct our preclinical studies and clinical trials and if these third parties perform in an unsatisfactory manner, our business could be substantially harmed.***

We intend to conduct our future clinical trials using our own clinical resources while also leveraging expertise and assistance from CROs as appropriate. We do not currently have the ability to independently conduct large-scale clinical trials, such as a Phase 3 clinical trial, without outside assistance.



We have relied upon and plan to continue to rely upon medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or assist us in conducting GCP-compliant clinical trials on our product candidates properly and on time, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-party CROs, we will have only limited control over their actual performance of these activities.

We and our CROs and other vendors are required to comply with cGMP, GCP and good laboratory practices, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Union and any comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators, clinical trial sites and other contractors. Although we rely on CROs to conduct any current or planned GLP-compliant preclinical studies and GCP-compliant clinical trials and have limited influence over their actual performance, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA, MHRA or any comparable foreign regulatory agency may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory agency, such regulatory agency will determine that all of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP requirements. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process.

While we will have agreements governing their activities, our CROs will not be our employees, and we will not be able to control whether or not they devote sufficient time and resources to our future preclinical and clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. CROs also may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize or invalidate our proprietary information and intellectual property. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, the clinical data generated in our clinical trials may be deemed unreliable, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus, and could delay development and commercialization of our product candidates. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business and financial condition.

***If we are not able to maintain our current collaborations and establish further collaborations, we may have to alter some of our future development and commercialization plans.***

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital to fund expenses. We have entered into collaboration agreements with pharmaceutical and biotechnology companies for certain combination therapies with 5F9 and may decide to collaborate for the future development and potential commercialization of other product candidates. For example,

we have an ongoing combination clinical trial in ovarian cancer with Merck KGaA and combination clinical trials planned in AML and bladder cancer with Genentech. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we have entered into or will enter into.

We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial 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. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA, MHRA or similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, 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. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate further collaborations on a timely basis, on acceptable terms, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. Our existing collaboration partners may not prioritize our product candidates or otherwise not effectively pursue the development of our product candidates which may delay, reduce or terminate the development of such product candidate, reduce or delay its development program or delay its potential commercialization. Further if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to delay, reduce or terminate the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. Doing so will likely harm our ability to execute our business plans. 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.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual agreements with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

### **Risks Related to Regulatory Compliance**

***Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may charge for such product candidates.***

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and congressional challenges to certain aspects of the Affordable Care Act. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The U.S. House of Representatives passed legislation known as the American Health Care Act of 2017 in May 2017. More recently, the Senate Republicans introduced and then updated a bill to replace the Affordable Care Act known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the Affordable Care Act without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. Each of these measures was rejected by the full Senate. Congress will likely consider other legislation to replace elements of the Affordable Care Act. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, then-President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2025 unless Congress takes additional action. Recently, 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 bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

***Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

Although we do not currently have any products on the market, if we obtain FDA approval for our product candidates, and begin commercializing those products in the United States, our operations may be directly, or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, 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 U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the Final HIPAA Omnibus Rule, i.e. health plans, healthcare clearinghouses and healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state 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; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

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

We have obtained orphan drug designation in the United States and Europe for use of 5F9 in treating AML. We may seek orphan drug designation for other product candidates in the future. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product 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 in the United States.

Our orphan drug exclusivity for the use of 5F9 in treating AML is contingent upon a showing that 5F9 is clinically superior to existing treatments of AML. Clinical superiority may be demonstrated by showing that a drug has greater effectiveness than the approved drug, greater safety in a substantial portion of the target population, or

otherwise makes a major contribution to patient care. If we are unable to demonstrate that the use of 5F9 in treating AML is clinically superior to existing treatments, we will not be entitled to the benefits of orphan drug exclusivity, which could adversely affect our business and our ability to market and sell 5F9 if it is approved for sale.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for the same indication during that time period. The applicable period is seven years in the United States and ten years in the European Union. 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 so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA 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.

We cannot assure you that any future application for orphan drug designation with respect to any other product candidate will be granted. If we are unable to obtain orphan drug designation with respect to other product candidates in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even when we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a later 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.

### **Risks Related to Our Intellectual Property**

*If we are unable to obtain and maintain sufficient patent and other intellectual property protection for our product candidates and technology, we may not be able to compete effectively in our market.*

Our success depends in significant part on our ability and the ability of our licensors and collaborators to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to our product candidates and technology and to operate our business without infringing, misappropriating, or otherwise violating the intellectual property rights of others. We have licensed a patent estate from The Board of Trustees of the Leland Stanford Junior University, or Stanford. In addition, we have filed our own patent applications, and acquired patent applications from Blink Biomedical and as of December 31, 2018, the only patent applications solely owned by us are provisional patent applications, and PCT applications, and pending non-provisional patent applications in the United States and other countries. We do not own any issued patents. With regard to the provisional patent applications, they are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. Similarly, PCT applications are international applications that are not eligible to become issued patents in the member countries of the PCT until the PCT application is converted to national phase applications in the individual member countries or in regional patent offices such as the European Patent Office. If we do not timely file these national phase patent applications from the PCT application, we may lose our priority date for the PCT application and may lose any patent protection on the inventions disclosed in the PCT application. While we intend to timely file national phase applications from our PCT application, we cannot predict whether such national phase applications in the United States or other countries will result in the issuance of patents that provide us with any competitive advantage.

We have also licensed patent and other intellectual property rights to and from our partners. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, whereas other licenses may not give us such rights. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications or to maintain the patents covering technology that we license to or from our partners, and we may have to rely on our partners to fulfill these responsibilities.

Consequently, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent prosecution process is expensive and time-consuming. We and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors will fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's patent application may pose obstacles to our ability to obtain or limit the scope of patent protection we may obtain. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, 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 jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and is the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or which effectively exclude others from commercializing competitive technologies and products. The patent examination process may require us or our licensors to narrow the scope of the claims of our pending and future patent applications, and therefore, even if such patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover such technology. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

***The patent protection we obtain for our product candidates and technology may be challenged or not sufficient enough to provide us with any competitive advantage.***

Even if our owned or licensed patent applications issue as patents, the issuance of any such patents is not conclusive as to their inventorship, scope, validity, or enforceability, and such patents may be challenged, invalidated or held to be unenforceable, including in the courts or patent offices in the United States and abroad, or circumvented. We may be subject to a third party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or equivalent foreign bodies, or become involved in opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. For example, we are aware of an opposition proceeding filed in the European Patent Office, or the EPO, by different third parties against a European patent that we exclusively in-license from Stanford that relates to the treatment of cancer with certain anti-CD47 antibodies or anti-SIRP $\alpha$  antibodies. We are also aware of an opposition proceeding filed in the EPO by a third party against a different European patent that we exclusively in-license from Stanford that relates to hematopoietic stem cell transplantation with anti-cKIT antibodies. One or more

of the third parties that have filed oppositions against these patents or other third parties may file future oppositions or other challenges, in Europe or other jurisdictions, against other patents that we in-license or own. Such proceedings and any other patent challenges may result in loss of patent rights, loss of exclusivity, loss of priority, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

Furthermore, 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 owned and licensed patent portfolios may not provide us with adequate protection against third parties seeking to commercialize products similar or identical to ours. We expect to request extensions of patent terms to the extent available in countries where we obtain issued patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the expiration of the patent. However, there are no assurances that the FDA or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part. In such case, our competitors may launch their products earlier than might otherwise be anticipated. Moreover, some of our owned or 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 co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us.

In addition, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, our license to certain intellectual property owned by Stanford is subject to certain rights Stanford granted to third parties prior to our license agreement. In addition, the research resulting in certain of our owned and in-licensed patent rights and technology was funded in part by the U.S. federal or state governments, including our grants from the California Institute for Regenerative Medicine, or CIRM. As a result, the government may have certain rights, including march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties or allow third parties to use our licensed technology. The government can also 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 of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

***We are heavily dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business.***

We are heavily reliant upon licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development of our product candidates, including 5F9. For example, in November 2015 we entered into a license agreement with Stanford under which we are granted rights to intellectual property that are necessary to the development and commercialization of 5F9 and are otherwise important to our business. We may also need to obtain additional licenses to advance the development and commercialization of other product candidates we may develop. Our existing license agreement with Stanford imposes, and we expect that future license agreements will impose, upon us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy-related event, the licensor may have the right to terminate the license, in which event we would not be able to develop, market or otherwise commercialize products covered



by the license, including 5F9 if any of the foregoing were to occur with respect to our license with Stanford. Our business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and certain provisions in intellectual property license agreements may be susceptible to multiple interpretations. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign the license; and
- the effects of termination.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

For example, in December 2016 and April 2017, we filed third party observations in an opposition proceeding in the European Patent Office, or EPO, with respect to European Patent No. EP 2 282 772 and in January 2018, petitioned for inter partes review of U.S. Patent No. 9,352,037 in the U.S. Patent and Trademark Office, or USPTO, each of which is related to the treatment of cancer with an anti-CD47 antibody or an anti-SIRP $\alpha$  antibody in combination with certain other antibodies. The opposition proceeding was rejected by the EPO and the original opponent appealed the decision. In June, 2018, we acquired the opposition against this European patent from the original opponent. Subsequently, pursuant to a settlement and license agreement with Synthon Biopharmaceuticals B.V., or Synthon, the licensee of these patents, the inter partes review in the USPTO against U.S. Patent No. 9,352,037 was terminated, and the appeal in the opposition proceedings against European patent No. EP 2 282 772 was withdrawn, thereby terminating the opposition. The settlement agreement with Synthon is described briefly below.

In July 2018, we entered into a settlement and license agreement with Synthon. Under the agreement, we agreed to discontinue our ongoing oppositions and challenges at the EPO, and the USPTO, directed towards certain patents licensed by Synthon from Stichting Sanquin Bloedvoorziening, or SSB, including European Patent No. EP 2 282 772 and U.S. Patent No. 9,352,037, that relate to the use of anti-CD47 products in combination with other antibodies to treat cancer. Pursuant to this agreement, we withdrew our challenges to these patents in the USPTO and EPO. In return Synthon granted us a non-exclusive, worldwide sublicense to certain patents they have licensed from SSB, including the SSB patents we are opposing at the USPTO and EPO to commercialize a single anti-CD47 product (such as 5F9 or an alternate anti-CD47 product) to treat cancer in combination with other antibodies. Pursuant to the agreement, we and Synthon, have each released the other party (and we have released SSB) from all claims and liabilities relating to the USPTO and EPO proceedings. Please see Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments—License Agreements” for further information regarding the settlement and license agreement.

We may need to obtain additional licenses to use our anti-SIRP $\alpha$ , anti-CD47 and anti-cKIT antibodies for the treatment of cancer or risk litigation in connection with our commercialization of anti-SIRP $\alpha$  antibodies, anti-CD47 and anti-cKIT antibodies to treat cancer. Such licenses may not be available at all or may not be available on commercially reasonable terms such that we may be required to pay significant fees and royalties to secure licenses to the applicable patents. Moreover, such licenses, like our sublicense from Synthon, may only be non-exclusive, in which case our ability to stop others from using or commercializing technology and products similar or identical to ours may be limited. If we are unable to obtain and maintain such licenses, we may need to cease the commercialization of 5F9 and other anti-CD47 antibodies or anti-SIRP $\alpha$  antibodies or anti-cKIT antibodies in combination with other antibodies, to treat cancer. The existing and any potential future legal proceedings relating to these patents could cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. If we are unsuccessful in our challenges to these patents and become subject to litigation or are unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business, financial condition, results of operations and prospects.

We may enter into additional licenses to third-party intellectual property that are necessary or useful to our business. Our current licenses and any future licenses that we may enter into impose various royalty payment, milestone and other obligations on us. Under some license agreements, we may not control prosecution of the licensed intellectual property, or may not have the first right to enforce the intellectual property. In those cases, we may not be able to adequately influence patent prosecution or enforcement, or prevent inadvertent lapses of coverage due to failure to pay maintenance fees. If we fail to comply with any of our obligations under a current or future license agreement, the licensor may allege that we have breached our license agreement, and may accordingly seek to terminate our license. Termination of any of our current or future licenses could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects. Under some license agreements, termination may also result in the transfer or granting of rights under certain of our intellectual property and information related to the product candidate being developed under the license, such as regulatory information.

In addition, if our licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms, our business, competitive position, financial condition, results of operations and prospects could be materially harmed.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.***

Competitors and other third parties may infringe or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors. In addition, our patents or the patents of our licensors may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties.

If we were to initiate legal proceedings against a third party to enforce a patent directed to our product candidates, or one of our future product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written

description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the applicable product candidates or technology covered by the patent rendered invalid or unenforceable. Such a loss of patent protection would materially harm our business, financial condition, results of operations and prospects.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be materially harmed if the prevailing party does not offer us a license on commercially reasonable terms.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing events could harm our business, financial condition, results of operation and prospects.

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

Filing, prosecuting, maintaining, defending and enforcing patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. 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 drugs and may export otherwise infringing drugs to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These drugs may compete with our product candidates 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 some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or

interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, which could adversely affect our business, financial condition, results of operations and prospects.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates.***

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

***If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.***

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology, on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we fail to comply with our obligations under our license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our 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, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

Obtaining and enforcing patents in the pharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents, and interpretation thereof, could change in unpredictable ways that could weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing or future patents. For example, the Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Therefore, there is increased uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' 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 Leahy-Smith 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 Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also 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 USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor-to-file provisions. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could harm our business, financial condition, results of operations and prospects.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.***

Periodic maintenance and annuity fees on any issued patent are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we rely on our licensors to pay these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business, financial condition, results of operations and prospects.

***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 negatively impact the success of our business.***

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drugs and technology, including re-examination, interference, post-grant review, *inter partes* review or derivation proceedings before the USPTO or an equivalent foreign body. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. 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.

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable and infringed, which could

materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we could be required to obtain a license from such a third party in order to continue developing and marketing our products and 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 access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

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

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. 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 former employer. Litigation may be necessary to defend against these claims.

In addition, we or our licensors may be subject to claims that former employees, collaborators, or other third parties have an interest in our owned or in-licensed patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the 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 develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

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 technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

We rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. 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 inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

***Intellectual property rights do not necessarily address all potential threats.***

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

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our current or future licensors might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our current or future licensors might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;



- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could harm our business, financial condition, results of operations and prospects.

### **Risks Related to Our Business Operations, Employee Matters and Managing Growth**

***Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.***

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for our product candidates, sales and marketing personnel, is critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and could harm our business, prospects, financial condition and results of operations.

***We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

As of December 31, 2018, we had 57 employees. As our clinical development progresses, we expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of clinical operations, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA, the EMA, the MHRA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. 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. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation.

We have adopted a code of business conduct and ethics, 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 be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government 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 significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

***Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.***

Our business is subject to risks associated with conducting business internationally. Some of our suppliers, industry partners and clinical study centers are located outside of the United States. Furthermore, our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our product candidates in patient populations outside the United States. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;

- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

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

***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 CROs and other third parties on which we rely, are vulnerable to damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure or security breach to our knowledge 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, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of 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.

**Risks Related to Our Common Stock**

***If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.***

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of The Nasdaq Global Select Market. Section 302 of the Sarbanes-Oxley Act requires, among other things, that we report on the effectiveness of our disclosure controls and procedures in our quarterly and annual reports and, beginning with our annual report for the year ending 2019, Section 404 of the Sarbanes-Oxley Act requires that we perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year. We will incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts.

As a public company, we will be required to maintain internal control over financial reporting and to report any material weaknesses in those internal controls. We and our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting, for the year ended December 31,

2016, related to the accounting for complex transactions and the timing of expense recognition for research and development expenses. During 2017 and 2018, management has hired key accounting personnel, created a formal month-end close process, and established more robust processes supporting internal controls over financial reporting, including accounting policies and procedures and the material weakness was fully remediated as of September 30, 2018. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by The Nasdaq Global Select Market, the SEC or other regulatory authorities. In addition, our common stock may not be able to remain listed on The Nasdaq Global Select Market or any other securities exchange.

***The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.***

Our stock price may be volatile. The stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- adverse regulatory decisions;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;

- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the United States or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

***A significant portion of our total outstanding may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to the restrictions and limitations described below. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market following this offering, the market price of our common stock could decline significantly.

In addition, we filed a registration statement on Form S-8 registering the issuance of approximately 6.8 million shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144.

Additionally, certain holders of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market without limitation. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

***Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.***

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third-party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by our stockholders.

Our charter documents will also contain other provisions that could have an anti-takeover effect, such as:

- establishing a classified board of directors so that not all members of our board of directors are elected at one time;
- permitting the board of directors to establish the number of directors and fill any vacancies and newly created directorships;
- providing that directors may only be removed for cause and by a two-thirds majority vote of the stockholders;
- prohibiting cumulative voting for directors;

- requiring super-majority voting to amend some provisions in our certificate of incorporation and bylaws;
- authorizing the issuance of “blank check” preferred stock that our board of directors could use to implement a stockholder rights plan;
- eliminating the ability of stockholders to call special meetings of stockholders; and
- prohibiting stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibit a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Any provision in our certificate of incorporation or our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

***Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.***

Based upon our common stock outstanding as of December 31, 2018, our executive officers, directors and current beneficial owners of 5% or more of our common stock will, in the aggregate, beneficially own a significant amount of our outstanding common stock. These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

***We will incur costs and demands upon our management as a result of complying with the laws and regulations affecting public companies in the United States, which may harm our business.***

As a public company listed in the United States, we incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the Securities and Exchange Commission, or SEC, and The Nasdaq Global Select Market may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from regular business activities to compliance activities. If, notwithstanding our efforts, we fail to comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

***We are an “emerging growth company,” and as a result of the reduced reporting requirements applicable to “emerging growth companies” our common stock may be less attractive to investors.***

We are an “emerging growth company,” as defined in 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, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As an “emerging growth company,” we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an “emerging growth company.” We could be an “emerging growth company” for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common stock held by non-affiliates exceeds \$700 million as of any June 30 (the end of our second quarter) before that time, in which case we would no longer be an “emerging growth company” as of the following December 31 (our year-end). 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 the price of our common stock may be more volatile.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.***

We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any existing or future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be 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 or our directors, officers or employees.***

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees. The Delaware Chancery Court recently issued an opinion invalidating provisions in the certificates of incorporation of Delaware companies that purport to limit to federal court the forum in which a stockholder could bring a claim under the Securities Act. The Chancery Court held that a Delaware corporation can only use its governing documents to bind a plaintiff to a particular forum where the claim involves rights or relationships established by or under Delaware’s corporate law. This case has been appealed to the Delaware Supreme Court. In light of this decision, we do not currently intend to enforce the foregoing federal forum selection provision unless the Delaware Supreme Court reverses the decision. If the Delaware Supreme Court affirms the Chancery Court’s decision, we will seek approval by our stockholders, at our next regularly scheduled annual meeting of stockholders, to amend the Charter to remove such provision. If a court were to find either choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

Our headquarters are located at 1490 O'Brien Drive, Suite A, Menlo Park, California 94025 under a lease that expires in August 2021. We believe that our existing facilities are adequate for our current needs but expect to need additional space to accommodate our anticipated growth. We believe that suitable additional or alternative space would be available as required in the future on commercially reasonable terms

**Item 3. Legal Proceedings.**

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

**Item 4. Mine Safety Disclosures.**

None.



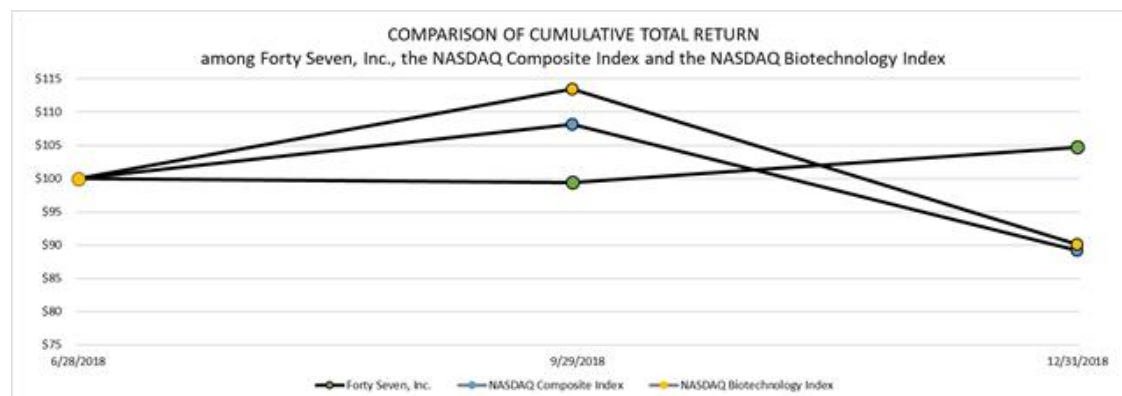
## Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

## Holders of Common Stock

As of March 15, 2019, there were approximately 86 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial owners of our common stock represented by these record holders.

## Stock Price Performance Graph

The following stock performance graph compares our total stock return for (i) the Nasdaq Composite Index and (ii) the Nasdaq Biotechnology Index for the period from June 28, 2018 (the date our common stock commenced trading on the Nasdaq Global Select Market) through December 31, 2018. The figures represented below assume an investment of \$100 in our common stock at the closing price on June 28, 2018 and in the Nasdaq Composite Index and the Nasdaq Biotechnology Index on June 28, 2018 and the reinvestment of dividends into shares of common stock. However, no dividends have been declared on our common stock to date. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.



\$100 investment in stock or index	Ticker	June 28, 2018	December 31, 2018
Forty Seven Inc.	FTSV	\$ 100.00	\$ 104.73
Nasdaq Composite Index	IXIC	100.00	89.21
Nasdaq Biotechnology Index	NBI	100.00	90.08

*This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.*

**Dividend Policy**

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. We do not intend to declare or pay cash dividends on common stock in the foreseeable future.

**Use of Proceeds from Registered Securities**

On June 27, 2018, our Registration Statements on Form S-1 (No. 333-225390 and 333-225933) were declared effective by the SEC pursuant to which, we issued and sold an aggregate of 8,090,250 shares of common stock (inclusive of 1,055,250 shares pursuant to the underwriters' option to purchase additional shares) at a price of \$16.00 per share for aggregate cash proceeds of \$116.3 million, net of underwriting discounts and commissions and estimated offering costs. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates.

The sale and issuance of 7,035,000 shares in the IPO closed on July 2, 2018 and the sale of 1,055,250 additional shares pursuant to the underwriters' over-allotment option closed on July 27, 2018. Morgan Stanley & Co. LLC and Credit Suisse Securities (USA) LLC acted as lead book-running managers for the offering. Canaccord Genuity LLC acted as lead manager and BTIG, LLC and Oppenheimer & Co. Inc. acted as co-managers for the offering.

There has been no material change in the planned use of proceeds from our IPO from that described in the Prospectus.

**Issuer Purchases of Equity Securities**

None.

**Item 6.****Selected Financial Data.**

The statements of operations data for the years ended December 31, 2018, 2017 and 2016 and the balance sheet data as of December 31, 2018 and 2017 are derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected balance sheet data as of December 31, 2016 is derived from our audited financial statements which are not included in this Annual Report on Form 10-K.

Our historical results are not necessarily indicative of the results to be expected in the future. You should read the selected financial data below in conjunction with the section of this report entitled "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included in this Annual Report on Form 10-K.

	Year Ended December 31,		
	2018	2017	2016
(in thousands, except per share data)			
<b>Statements of Operations Data:</b>			
Operating expenses:			
Research and development	\$ 56,673	\$ 37,174	\$ 14,464
General and administrative	15,432	8,130	5,153
Total operating expenses	<u>72,105</u>	<u>45,304</u>	<u>19,617</u>
Loss from operations	(72,105)	(45,304)	(19,617)
Interest and other income, net	1,735	406	78
Net loss	<u>\$ (70,370)</u>	<u>\$ (44,898)</u>	<u>\$ (19,539)</u>
Net loss per share, basic and diluted	<u>\$ (3.75)</u>	<u>\$ (6.94)</u>	<u>\$ (3.15)</u>
Shares used in computing net loss per share, basic and diluted	<u>18,768,868</u>	<u>6,468,634</u>	<u>6,197,195</u>
As of December 31,			
	2018	2017	2016
(in thousands)			
<b>Balance Sheet Data:</b>			
Cash, cash equivalents and short-term investments	\$ 139,023	\$ 88,111	\$ 9,742
Total assets	149,437	95,465	16,988
Working capital	130,449	81,289	9,692
Total liabilities	16,216	12,003	4,754
Convertible preferred stock	—	149,397	34,245
Accumulated deficit	(139,769)	(69,399)	(24,501)
Total stockholders' equity	133,221	83,462	12,234

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

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and related notes included in Part II, Item 8 of this Annual Report on Form 10-K.*

*This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Exchange Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended (“the Exchange Act”). Forward-looking statements are identified by words such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” “predict,” “could,” “potentially” or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other “forward-looking” information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part I, Item 1A — “Risk Factors,” and elsewhere in this report. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.*

### Overview

We are a clinical-stage immuno-oncology company focused on developing novel therapies to activate macrophages in the fight against cancer. We founded Forty Seven based on the insight that blocking CD47, a key signaling molecule that is overexpressed on cancer cells, renders tumors susceptible to macrophages. By harnessing macrophages, we believe that our lead product candidate, 5F9, can transform the treatment of cancer. 5F9 has demonstrated promising activity in six Phase 1b/2 clinical trials in which we have treated over 290 relapsed or refractory cancer patients with solid or hematologic tumors. In addition, we have two additional product candidates in preclinical development; FSI-189 an anti-SIRPα antibody and FSI-174 an anti-cKIT antibody. We hold worldwide rights to all of our product candidates.

We focus our efforts on targeting the CD47 pathway as a way to engage macrophages in fighting tumors. Macrophages function as first responders, swallowing foreign and abnormal cells, including cancer cells, and mobilizing other components of the immune system including T cells and antibodies. Cancer cells use CD47, a “don’t eat me” signal, in order to evade detection by the immune system and subsequent destruction by macrophages. Overexpression of CD47 is common to nearly all types of tumors and is also correlated with poor prognosis in multiple cancers including acute myelogenous leukemia, or AML, colorectal cancer, or CRC, gastric cancer, lung cancer, Non-Hodgkin’s lymphoma, or NHL, and ovarian cancer. Despite the central role of macrophages as cell-eating scavengers and first responders, the pharmaceutical industry is only beginning to bring this key group of cells into the fight against cancer.

Since our inception in 2014, we have devoted most of our resources to identifying and developing 5F9, advancing our preclinical programs, conducting clinical trials and providing general and administrative support for these operations. We have not recorded revenue from product sales or collaboration activities, or any other source. We have funded our operations to date primarily from the issuance and sale of our common stock in our initial public offering (IPO), the issuance and sale of our preferred stock and the receipt of government and private grants. We are eligible to receive up to \$17.6 million in grants from the California Institute for Regenerative Medicine, or CIRM, and the Leukemia and Lymphoma Society, or LLS, of which \$13.5 million has been received through December 31, 2018.

On June 27, 2018, our Registration Statements on Form S-1 (File No. 333-225390 and 333-225933) relating to our IPO, were declared effective by the Securities Exchange Commission, or SEC. Pursuant to the Registration Statements, we issued and sold an aggregate of 8,090,250 shares of common stock (inclusive of 1,055,250 shares pursuant to the underwriters’ over-allotment option) at a price of \$16.00 per share for aggregate cash proceeds of \$116.3 million, net of underwriting discounts and commissions and estimated offering costs.

We have incurred net losses in each year since inception. Our net losses were \$70.4 million, \$44.9 million and \$19.5 million for 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of \$139.8 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance product candidates through clinical trials;
- pursue regulatory approval of product candidates;
- operate as a public company;
- continue our preclinical programs and clinical development efforts;
- continue research activities for the discovery of new product candidates; and
- manufacture supplies for our preclinical studies and clinical trials.

## **Components of Results of Operations**

### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred for the development of our lead product candidate, 5F9, which include:

- expenses incurred under agreements with third-party contract organizations, investigative clinical trial sites that conduct research and development activities on our behalf, and consultants;
- costs related to production of clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical and clinical trials;
- employee-related expenses, which include salaries, benefits and stock-based compensation; and
- facilities and other expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, collaborators and third-party service providers. The cost of intangible assets that are purchased from others for a particular research and development project and that have no alternative future uses are considered research and development costs and are expensed as incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and as services are performed.

The largest component of our operating expenses has historically been our investment in research and development activities related to the clinical development of our lead product candidate, 5F9. We recognize the funds from research and development grants as a reduction of research and development expense when the related eligible research costs are incurred. Research and development grants received during 2018 and 2017 totaled \$7.6 million and \$5.9 million, respectively. In January 2018, we entered into a clinical trial collaboration and supply agreement with Ares Trading S.A, a subsidiary of Merck KGaA. Reimbursement under this collaboration agreement is recorded as a reduction to research and development expense. For the year ended December 31, 2018, we recognized \$1.2 million as a reduction to research and development expenses under this collaboration agreement.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, and as we begin to conduct larger clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming,

and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of personnel-related costs, facilities costs, depreciation and amortization expenses and professional services expenses, including legal, human resources, audit and accounting services. Personnel-related costs consist of salaries, benefits and stock-based compensation. Facilities costs consist of rent and maintenance of facilities. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in headcount to advance our product candidates and as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, the Nasdaq Global Select Market, additional insurance expenses, investor relations activities and other administrative and professional services.

### ***Interest and Other Income, Net***

Interest and other income, net consists of interest earned on our cash equivalents and short-term investments and foreign currency transaction gains and losses incurred during the period.

## **Results of Operations**

### **Years Ended December 31, 2018 and 2017**

	Year Ended December 31,		Increase/ (Decrease)
	2018	2017	
	(in thousands)		
Operating expenses:			
Research and development	\$ 56,673	\$ 37,174	\$ 19,499
General and administrative	15,432	8,130	7,302
Total operating expenses	<u>72,105</u>	<u>45,304</u>	<u>26,801</u>
Loss from operations	(72,105)	(45,304)	(26,801)
Interest and other income, net	1,735	406	1,329
Net loss	<u>\$ (70,370)</u>	<u>\$ (44,898)</u>	<u>\$ (25,472)</u>

## Research and Development Expenses

The following tables summarize the period-over-period changes in research and development expenses for the periods indicated:

	Year Ended December 31,		Increase/ (Decrease)
	2018	2017	
	(in thousands)		
<i>Product-specific costs:</i>			
5F9	\$ 40,449	\$ 27,873	\$ 12,576
Grant funding and cost share reimbursement	(9,179)	(3,861)	(5,318)
<i>Non product-specific costs:</i>			
Stock-based compensation	1,193	206	987
Personnel-related	8,224	6,258	1,966
Other preclinical programs	7,162	6,698	464
License fees	8,824	—	8,824
Total research and development expenses	<u>\$ 56,673</u>	<u>\$ 37,174</u>	<u>\$ 19,499</u>

Research and development expenses increased by \$19.5 million, or 52%, to \$56.7 million in 2018 from \$37.2 million in 2017. The increase was primarily due to a \$12.6 million increase in third party costs related to advancing our current clinical programs focused on CRC and NHL with our lead product candidate, 5F9, and associated contract manufacturing costs, partially offset by a \$5.3 million reduction related to grant funding and cost sharing recognized under the CIRM and LLS grants and the Merck collaboration agreement during 2018. There was a total upfront license fee of \$8.8 million increase related to the BliNK asset purchase and Synthon license agreement. In addition, personnel-related costs, including stock-based compensation, increased by \$3.0 million as a result of increased headcount.

## General and Administrative Expenses

General and administrative expenses increased by \$7.3 million, or 90%, to \$15.4 million in 2018 from \$8.1 million in 2017. The increase was primarily due to a \$4.0 million increase in personnel-related costs driven by an increase in headcount, a \$1.9 million increase in accounting and consulting expenses incurred in connection with becoming a public company, a \$0.5 million increase in insurance related expenses, a \$0.5 million increase in other administrative and services costs, and a \$0.3 million increase in facilities related expenses.

### *Interest and Other Income, Net*

Interest and other income, net increased by \$1.3 million to \$1.7 million in 2018 from \$0.4 million in 2017. The increase was primarily due to a \$1.9 million increase in interest income from the investment of the net proceeds of the IPO completed during 2018, offset by a \$0.3 million increase in other expenses due to the change in fair value of the embedded derivative, and a \$0.2 million increase in losses on foreign currency transactions.

### **Years Ended December 31, 2017 and 2016**

	Year Ended December 31,		Increase/ (Decrease)
	2017	2016	
	(in thousands)		
Operating expenses:			
Research and development	\$ 37,174	\$ 14,464	\$ 22,710
General and administrative	8,130	5,153	2,977
Total operating expenses	45,304	19,617	25,687
Loss from operations	(45,304)	(19,617)	(25,687)
Interest and other income, net	406	78	328
Net loss	\$ (44,898)	\$ (19,539)	\$ (25,359)

### *Research and Development Expenses*

The following tables summarize the period-over-period changes in research and development expenses for the periods indicated:

	Year Ended December 31,		Increase (Decrease)
	2017	2016	
	(in thousands)		
<i>Product-specific costs:</i>			
5F9	\$ 27,873	\$ 8,838	\$ 19,035
Grant funding and cost share reimbursement	(3,861)	—	(3,861)
<i>Non product-specific costs:</i>			
Stock-based compensation	206	93	113
Personnel-related	6,258	3,368	2,890
Other preclinical programs	6,698	2,165	4,533
Total research and development expenses	\$ 37,174	\$ 14,464	\$ 22,710

Research and development expenses increased by \$22.7 million, or 157%, to \$37.2 million in 2017 from \$14.5 million in 2016. The increase was primarily due to a \$19.0 million increase in third party costs related to advancing our current clinical programs focused on CRC and NHL with our lead product candidate, 5F9, and associated contract manufacturing costs, partially offset by a \$3.9 million reduction related to grant funding recognized under the CIRM and LLS grants during 2017. There was also a \$4.5 million increase in our other preclinical and discovery programs costs as we expanded our immuno-oncology efforts. In addition, personnel-related costs, including stock-based compensation, increased by \$3.0 million as a result of increased headcount.

### *General and Administrative Expenses*

General and administrative expenses increased by \$3.0 million, or 58%, to \$8.1 million in 2017 from \$5.2 million in 2016. The increase was primarily due to a \$1.4 million increase in accounting and consulting expenses, and a \$1.3 million increase in personnel-related costs driven by an increase in headcount.



### ***Interest and Other Income, Net***

Interest and other income, net increased by \$0.3 million to \$0.4 million in 2017 from \$0.1 million in 2016. The increase was primarily due to \$0.3 million in interest income from the investment of the net proceeds from the issuance of our Series A-2 and Series B preferred stock financings completed during 2017.

### **Liquidity, Capital Resources and Plan of Operations**

To date, we have incurred significant net losses and negative cash flows from operations. As of December 31, 2018, we had \$139.0 million in cash, cash equivalents and short-term investments. Prior to our IPO, our operations have been financed primarily by net proceeds from the sale and issuance of our preferred stock. In connection with our IPO, we issued and sold an aggregate of 8,090,250 shares of common stock (inclusive of 1,055,250 shares of common stock from the exercise of the over-allotment option granted to the underwriters) at a price of \$16.00 per share. We received proceeds of \$116.3 million, net of underwriting discounts and commissions and estimated offering costs.

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to our lead product candidate, 5F9, preclinical and discovery programs, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Based upon our current operating plan, we believe that our existing capital resources will enable us to fund our operating expenses and capital expenditure requirements for a period of at least one year from the date the audited financial statements are filed with the Securities and Exchange Commission ("SEC"). We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms, or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings and collaborations or licensing arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we 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 raise capital, we will need to delay, reduce or terminate planned activities to reduce costs. Doing so will likely harm our ability to execute our business plans.

## Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Cash used in operating activities	\$ (66,017)	\$ (36,937)	\$ (21,815)
Cash used in investing activities	(64,189)	(63,852)	(1,103)
Cash provided by financing activities	116,626	115,464	5,026
Net (decrease) increase in cash and cash equivalents	<u>\$ (13,580)</u>	<u>\$ 14,675</u>	<u>\$ (17,892)</u>

### Operating Activities

In 2018, cash used in operating activities of \$66.0 million was attributable to a net loss of \$70.4 million, partially offset by a net change of \$1.0 million in net operating assets and liabilities, and a net change of \$3.4 million in non-cash charges. The non-cash charges consisted primarily of stock-based compensation of \$3.4 million, depreciation and amortization of \$0.4 million, a change in fair value of the embedded derivative of \$0.3 million, offset by the net accretion of discount on marketable securities of \$0.7 million. The change in operating assets and liabilities was primarily due to a \$5.1 million increase in accounts payable and accrued liabilities resulting from increases in our research and development activities and accrued compensation. This was partially offset by a \$2.4 million increase in prepaid expense and other current assets and a \$0.7 million increase in other assets, driven by the timing of prepayments made for research and development activities, and a \$1.0 million decrease in deferred grant funding due to research grant awards being recognized as eligible research costs were incurred.

In 2017, cash used in operating activities of \$36.9 million was attributable to a net loss of \$44.9 million partially offset by \$1.1 million in non-cash charges and a net change of \$6.9 million in our net operating assets and liabilities. The non-cash charges consisted of stock-based compensation of \$0.7 million and depreciation and amortization of \$0.4 million. The change in operating assets and liabilities was primarily due to \$4.6 million increase in accounts payable and accrued liabilities resulting from increases in our operating activities, primarily in research and development, and a \$2.8 million increase in deferred grant funding due to research grant award payments received. This was partially offset by a \$0.6 million decrease in prepaid expenses and other current assets resulting from the timing of prepayments made for research and development activities.

In 2016, cash used in operating activities of \$21.8 million was attributable to a net loss of \$19.5 million and a net change of \$2.7 million in our net operating assets and liabilities, partially offset by \$0.4 million in non-cash charges. The non-cash charges consisted of stock-based compensation of \$0.3 million and depreciation and amortization of \$0.1 million. The change in operating assets and liabilities was primarily due to a \$3.9 million decrease in prepaid expenses and a \$1.7 million decrease in other assets resulting from the timing of prepayments made for research and development activities, partially offset by a \$2.8 million increase in accounts payable and accrued liabilities primarily driven by increases in accrued compensation and our research and development activities.

### Investing Activities

In 2018, cash used in investing activities was \$64.2 million related to the purchase of short-term investments of \$142.0 million, partially offset by the maturity of investments of \$78.2 million.

In 2017, cash used for investing activities was \$63.9 million related primarily to the purchase of short-term investments of \$79.7 million from the cash proceeds received from our preferred stock issuance, partially offset by the maturity of investments of \$16.0 million.

In 2016, cash used for investing activities was \$1.1 million related to capital expenditures on the purchase of property and equipment.

In 2018, cash provided by financing activities was \$116.6 million related to the net proceeds of \$116.3 million received from the initial public offering and \$0.3 million from the issuance of common stock in connection with stock option exercises.

In 2017, cash provided by financing activities was \$115.5 million related to net proceeds of \$115.2 million from the issuance of preferred stock and \$0.3 million from the issuance of common stock in connection with stock option exercises.

In 2016, cash provided by financing activities was \$5.0 million related to net proceeds of \$4.6 million from the issuance of preferred stock and \$0.4 million from the issuance of common stock in connection with stock option exercises.

### Contractual Obligations and Commitments

The following table summarizes our commitments to settle contractual obligations as of December 31, 2018:

	Payments Due By Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
(in thousands)					
<b>Financial Assets</b>					
Operating lease obligation	\$ 3,096	\$ 1,134	\$ 1,962	\$ —	\$ —
Contract manufacturing obligations	29,847	14,447	15,400	—	—
Total	<u>\$ 32,943</u>	<u>\$ 15,581</u>	<u>\$ 17,362</u>	<u>\$ —</u>	<u>\$ —</u>

We enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for preclinical studies and other services and products for operating purposes which are cancelable at any time by us, generally upon 30 days prior written notice. These payments are not included in this table of contractual obligations.

In addition, we have not included the potential contingent payment obligations from the following agreements described below in this table of contractual obligations because the timing and likelihood of such payments is not known. These payments generally become due and payable only upon achievement of certain development, regulatory or commercial milestones.

#### Contract Manufacturing Agreement

In August 2016 and December 2017, we entered into development and manufacturing agreements with Lonza relating to the manufacturing of 5F9-related products. The August 2016 agreement was amended in November 2017 to provide for the manufacturing of our other preclinical program related products. The August 2016 agreement was further amended in November and December 2018 as it related to the scope of manufacturing services.

Under the 2016 agreement, as amended, we were required to pay an annual suite reservation fee in each contract year, with the final annual suite reservation fee becoming payable in December 2018. We are required to pay the costs of ingredients, solvents and other components of 5F9 and our preclinical program-related products related to binding purchase commitments. There were no binding purchase commitments under the 2016 agreement as of December 31, 2018.

Our payment obligations under the 2017 agreement begin in January 2019 and run through the expiration of the agreement, which is expected in December 2021, unless the agreement is extended for at least an additional year. Under the 2017 agreement, we must also pay an annual suite reservation fee in each contract year and the costs of ingredients, solvents and other components of 5F9-related products required for the performance of the manufacturing process or services. Our contractual payment obligations under the 2016 and 2017 agreements are included in the table of contractual obligations above.

## ***Asset Purchase Agreement***

In June 2018, we entered into an asset purchase agreement with BliNK Biomedical SAS, or BliNK, pursuant to which we acquired all of BliNK's assets relating to its research and development program for antibodies directed against CD47. These assets predominately consist of certain patents and patent applications of BliNK and BliNK's opposition at the EPO against the third-party patent European Patent No. EP 2 282 772 as an acquired business asset. We paid BliNK an initial upfront payment of \$2.0 million and an additional \$1.0 million upon the completion of certain agreed activities by BliNK relating to the transfer of the assets to us. For each product incorporating a program antibody that satisfies certain clinical and commercial milestones in the United States, the European Union and Japan, we will be required to make milestone payments of up to \$43.0 million. Until we receive marketing approval for the first product, or for so long as we continue development of product candidates related to the acquired intellectual property, we will pay BliNK a minimum annual fee of \$0.3 million. In addition, we will pay BliNK a royalty of a tiered single digit percentage on net sales of any approved products. We have the right to buy out our royalty obligations in full by paying BliNK an agreed lump sum amount prior to the occurrence of certain defined events.

## ***License Agreements***

In July 2018, we entered into a settlement and license agreement with Synthon Biopharmaceuticals B.V., or Synthon. Under the agreement, we agreed to discontinue our ongoing oppositions and challenges at the European Patent Office, or EPO, and the U.S. Patent and Trademark Office, or USPTO, directed towards certain patents licensed by Synthon from Stichting Sanquin Bloedvoorziening, or SSB, that relate to the use of anti-CD47 products in combination with other antibodies to treat cancer. We also agreed to request the withdrawal of such proceedings with the USPTO and EPO. In return Synthon agreed to grant us a non-exclusive, worldwide sublicense to certain patents they have licensed from SSB, including the SSB patents we were opposing at the USPTO and EPO to commercialize a single anti-CD47 product (such as 5F9 or an alternate anti-CD47 product) to treat cancer in combination with other antibodies.

In December 2016 and April 2017, we filed third party observations in an opposition proceeding in the EPO with respect to European Patent No. EP 2 282 772 and in January 2018, petitioned for inter partes review of U.S. Patent No. 9,352,037 in the USPTO, each of which is related to the treatment of cancer with an anti-CD47 antibody or an anti-SIRP $\alpha$  antibody in combination with certain other antibodies. The opposition proceeding was rejected by the EPO and the original opponent appealed the decision. On June 4, 2018, we acquired the opposition against this European patent from the original opponent. Pursuant to the agreement, we and Synthon have each agreed to release the other party (and we have agreed to release SSB) from all claims and liabilities relating to the USPTO and EPO proceedings.

The sublicense grant was subject to specified conditions, which have now been met. These conditions included our withdrawal of the proceedings opposing the above-mentioned SSB U. S. and European patents and the termination of these proceedings by the USPTO and the EPO. In connection with the release of claims by Synthon and us, SSB agreed to release us from all claims and liabilities under the USPTO and EPO proceedings and to grant us a direct license to the sublicensed patents in the event the license between SSB and Synthon is terminated.

Our sublicense includes the right to further sublicense the applicable patent rights to our collaborators, corporate partners and service providers and covers one named product, which is 5F9. In addition, we have the right to replace 5F9 with a different anti-CD47 product in the event of a development failure of 5F9. We will also have an option to expand our rights to cover a follow-on anti-CD47 product in exchange for a specified option exercise fee. Synthon retains the right to use the licensed patents and to grant other third parties the right to do so.

In exchange, for these sublicenses and option rights, we agreed to pay Synthon an aggregate of up to approximately 40.0 million Euros comprising an upfront payment upon the grant of the sublicense and the achievement of future regulatory and commercial milestones which comprise the significant majority of the aggregate payments. If we exercise our option right, we will pay Synthon additional amounts upon the achievement of certain regulatory and commercial milestones related to such follow-on anti-CD47 product. In addition, we will be required to pay Synthon an annual license fee and a royalty of a tiered, low single digit percentage on net sales of any approved licensed products. We have the right to buy out our royalty obligations for each licensed product in full by paying Synthon specified lump sum amounts prior to the occurrence of certain defined events.

## *License and Collaboration Agreements*

In January 2018, we entered into a clinical trial collaboration and supply agreement with Merck, to evaluate 5F9 combined with Merck's cancer immunotherapy, avelumab, in a Phase 1b clinical trial in patients with ovarian cancer. Pursuant to the agreement, the parties will jointly pay for the cost of the study. As of December 31, 2018, we recorded a receivable of \$0.6 million from Merck for reimbursement of research and development costs incurred.

In March 2017, we entered into an agreement with LLS regarding our NHL rituximab combination clinical trial and amended the agreement to include an additional study in June 2018. The LLS research grant stipulates various milestone-based payments with a total award of \$4.2 million through December 2019. As of December 31, 2018, we had received \$3.9 million under the award. We are required to pay LLS certain development and regulatory approval milestone payments, as well as a low single digit percentage royalty on net sales, up to a maximum of \$15 million in total. The contingent milestone payments in our agreement with LLS were concluded to be an embedded derivative and we recorded a liability for the derivative of approximately \$0.3 million, as part of other long-term liabilities as of December 31, 2018.

In January 2017, we were awarded a research grant from CIRM supporting our CRC trial. The CIRM grant stipulates various milestone-based payments to us with the total award of \$10.2 million over a period of four years. As of December 31, 2018, we had received \$7.2 million under the award. In November 2017, we were awarded a second research grant from CIRM for a separate clinical trial study in AML. The total amount of the research grant awarded was \$5.0 million in various milestone-based payments over a period of five years. During 2018, the award was amended to \$3.2 million in various-milestone payments over a period of five years, as was provided for under the terms of the original award because we opted not to expand the patient population participating in the study. As of December 31, 2018, we had received \$2.4 million under the award. Under the terms of the CIRM grants, we are obligated to pay royalties and licensing fees based on a low single digit royalty percentage on net sales of CIRM-funded product candidates or CIRM-funded technology. We have the option to decline any and all amounts awarded by CIRM. As an alternative to revenue sharing, we have the option to convert each award to a loan, which option must be exercised on or before ten business days after the FDA notifies us that it has accepted our application for marketing authorization. In the event we exercise our right to convert an award to a loan, we will be obligated to repay the loan within ten business days of making such election, including interest at the rate equal to the three-month LIBOR rate (2.8% as of December 31, 2018) plus zero to 30% per annum that varies depending on the stage of the research and the stage of development at the time the election is made. In the event that we terminate a CIRM-funded clinical trial, we will be obligated to repay the remaining CIRM funds on hand.

In September 2016, we entered into a collaboration agreement with The University of Texas MD Anderson Cancer Center that grants us access to their immunotherapy platform. The platform provides instrumentation and technical support for cellular and molecular analysis of experimental therapies effects on the immune system in order to gain insight into mechanisms of action and to discover biomarkers to identify patients who are likely to respond to or develop adverse reactions to therapies. Pursuant to the terms of the collaboration agreement, we are required to make quarterly payments of \$250,000 for three years, subject to our right to cancel the agreement at any time with 45 days' notice.

In November 2015, we entered into a technology license agreement with Stanford under which Stanford granted us exclusive licenses under certain patents and other intellectual property rights relating to our current product candidates, including 5F9 and non-exclusive licenses under certain other patents and other intellectual property rights to develop, manufacture and commercialize products for use in certain licensed fields, including oncology. We are required to make milestone payments up to \$5.6 million in respect of the first three licensed products that successfully satisfy certain clinical and regulatory milestones in the United States, major European countries and Japan. The first such milestone payment of \$75,000 was paid to Stanford in February 2018. In addition, we are required to pay Stanford a minimum annual fee and a royalty of a tiered single digit percentage on net sales of licensed products, reimburse patent-related expenses and share any non-royalty sublicensing income received related to the licensed technology.

## Off-Balance Sheet Arrangements

During 2018, 2017 and 2016, we did not have any off-balance sheet arrangements as defined in Item 303 of Regulation S-K.

## Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our 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. Actual results may differ from these estimates under different assumptions or conditions.

### *Accrued Research and Development Expenditures*

We record accrued expenses for estimated preclinical study and clinical trial expenses. Estimates are based on the services performed pursuant to contracts with research institutions and contract research organizations and clinical manufacturing organizations that conduct and manage preclinical studies and clinical trials on our behalf based on actual time and expenses incurred by them. Further, we accrue expenses related to clinical trials based on the level of patient enrollment and activity according to the related agreement. We monitor patient enrollment levels and related activity to the extent reasonably possible and make judgments and estimates in determining the accrued balance in each reporting period. If we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not experienced significant changes in our estimates of preclinical studies and clinical trial accruals.

### *Stock-Based Compensation*

We recognize compensation costs related to stock-based awards granted, including stock options and employee stock purchase plan, based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to determine the fair value of stock-based awards. These assumptions include:

- *Expected Term*—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method, as we do not have sufficient historical data to use any other method to estimate expected term. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.
- *Expected Volatility*—Since we have limited trading history for our common stock due to our short trading history, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.
- *Expected Dividend*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

We will continue to use judgment in evaluating the expected volatility and expected term utilized for our stock-based compensation calculations on a prospective basis.

### **Recent Accounting Pronouncements Not Yet Adopted**

Please refer to Note 2 to our financial statements appearing under Part 2, Item 8 for a discussion of new accounting standards updates that may impact us.

### **Emerging Growth Company Status**

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise 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.

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

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rate and currency exchange rate fluctuations.

***Interest Rate Risk***

Our cash, cash equivalents and short-term investments of \$139.0 million and \$88.1 million as of December 31, 2018 and December 31, 2017, consist of bank deposits, money market funds and available-for-sale securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. Due to the short-term maturities of our cash equivalents and marketable securities, and the low risk profile of our marketable securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities.

***Foreign Currency Risk***

Our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with licensors and vendors for research and development services with payments denominated in foreign currencies, including the British Pound and Euro. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. We recognized \$0.2 million in foreign currency losses for the year ended December 31, 2018. Foreign currency transaction gains and losses were not significant to the financial statements for the years ended December 31, 2017 and 2016. We have not had a hedging program with respect to foreign currency.

Our primary foreign currency exposure relates to our manufacturing commitments with Lonza for the manufacturing of 5F9-related products. Under the Lonza agreements, the Company is required to pay Lonza fixed fees based on manufacturing services performed. The fees payable under Lonza agreements are denominated in British Pounds. Our future minimum payments under the Lonza development and manufacturing agreements are converted into U.S. Dollars based on current exchange rates and are included in note 5 to our financial statements.



FORTY SEVEN, INC.  
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To the Stockholders and the Board of Directors of

Forty Seven, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Forty Seven, Inc. (the Company) as of December 31, 2018 and 2017, and the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at 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 U.S. generally accepted accounting principles.

**Basis for Opinion**

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017

San Jose, California

March 28, 2019

**FORTY SEVEN, INC.**

**Balance Sheets**

*(in thousands, except share and per share amounts)*

	December 31,	
	2018	2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 10,837	\$ 24,417
Short-term investments	128,186	63,694
Prepaid expenses and other current assets	6,835	4,450
Total current assets	145,858	92,561
Property and equipment, net	1,360	1,358
Other assets	2,219	1,546
Total assets	<u>\$ 149,437</u>	<u>\$ 95,465</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 4,621	\$ 3,705
Accrued liabilities	9,044	4,808
Deferred grant funding, current	1,744	2,759
Total current liabilities	15,409	11,272
Lease-related liabilities, noncurrent	331	476
Other long-term liabilities	476	255
Total liabilities	16,216	12,003
Commitments and Contingencies (Note 5)		
Stockholders' equity:		
Convertible preferred stock, \$0.0001 par value; nil and 16,215,944 shares authorized as of December 31, 2018 and 2017; nil and 16,215,896 shares issued and outstanding as of December 31, 2018 and 2017	—	149,397
Common stock, \$0.0001 par value: 200,000,000 shares authorized; 31,079,150 and 6,751,157 shares issued and outstanding at December 31, 2018 and 2017	3	1
Additional paid-in capital	273,069	3,507
Accumulated other comprehensive loss	(82)	(44)
Accumulated deficit	(139,769)	(69,399)
Total stockholders' equity	133,221	83,462
<b>Total liabilities and stockholders' equity</b>	<u>\$ 149,437</u>	<u>\$ 95,465</u>

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

**FORTY SEVEN, INC.**

**Statements of Operations and Comprehensive Loss**  
*(in thousands, except share and per share amounts)*

	Year Ended December 31,		
	2018	2017	2016
Operating expenses:			
Research and development	\$ 56,673	\$ 37,174	\$ 14,464
General and administrative	15,432	8,130	5,153
Total operating expenses	<u>72,105</u>	<u>45,304</u>	<u>19,617</u>
Loss from operations	(72,105)	(45,304)	(19,617)
Interest and other income, net	1,735	406	78
Net loss	(70,370)	(44,898)	(19,539)
Unrealized loss on available-for-sale securities	(38)	(44)	—
Comprehensive loss	<u>\$ (70,408)</u>	<u>\$ (44,942)</u>	<u>\$ (19,539)</u>
Net loss per share, basic and diluted	<u>(3.75)</u>	<u>\$ (6.94)</u>	<u>\$ (3.15)</u>
Shares used in computing net loss per share, basic and diluted	<u>18,768,868</u>	<u>6,468,634</u>	<u>6,197,195</u>

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

**FORTY SEVEN, INC.**

**Statements of Stockholders' Equity**  
(in thousands, except share amounts)

	<u>Convertible Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Other Comprehensive Loss</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Balance—January 1, 2016	3,845,145	\$ 29,655	5,427,087	\$ 1	\$ 2,039	\$ —	\$ (4,962)	\$ 26,733
Issuance of Series A-1 convertible preferred shares at \$7.75 per share, net of issuance costs of \$10	593,546	4,590	—	—	—	—	—	4,590
Issuance of common stock related to Stanford license agreement	—	—	1,000,160	—	—	—	—	—
Issuance of common stock for exercise of stock options	—	—	216,127	—	203	—	—	203
Vesting of restricted common stock	—	—	—	—	2	—	—	2
Stock-based compensation	—	—	—	—	245	—	—	245
Net loss	—	—	—	—	—	—	(19,539)	(19,539)
Balance—December 31, 2016	4,438,691	34,245	6,643,374	1	2,489	—	(24,501)	12,234
Issuance of Series A-2 convertible preferred shares at \$9.6472 per share, net of issuance costs of \$23	4,187,682	40,377	—	—	—	—	—	40,377
Issuance of Series B convertible preferred shares at \$9.8820 per share, net of issuance costs of \$225	7,589,523	74,775	—	—	—	—	—	74,775
Issuance of common stock for exercise of stock options	—	—	107,783	—	155	—	—	155
Vesting of restricted common stock	—	—	—	—	2	—	—	2
Vesting of early exercised stock options	—	—	—	—	137	—	—	137
Stock-based compensation	—	—	—	—	724	—	—	724
Net loss	—	—	—	—	—	—	(44,898)	(44,898)
Unrealized loss on available-for-sale securities	—	—	—	—	—	(44)	—	(44)
Balance—December 31, 2017	16,215,896	149,397	6,751,157	1	3,507	(44)	(69,399)	83,462
Conversion of preferred stock into common stock upon completion of the initial public offering	(16,215,896)	(149,397)	16,215,896	1	149,396	—	—	—
Issuance of common stock in connection with the initial public offering, net of issuance costs of \$4,047	—	—	8,090,250	1	116,335	—	—	116,336
Repurchase of fractional shares resulting from reverse stock split	—	—	(83)	—	(1)	—	—	(1)
Issuance of common stock for exercise of stock options	—	—	63,865	—	191	—	—	191
Vesting of restricted common stock	—	—	—	—	1	—	—	1
Vesting of early exercised stock options	—	—	—	—	209	—	—	209
Repurchase of unvested common stock	—	—	(41,935)	—	—	—	—	—
Stock-based compensation	—	—	—	—	3,431	—	—	3,431
Net loss	—	—	—	—	—	—	(70,370)	(70,370)
Unrealized loss on available-for-sale securities	—	—	—	—	—	(38)	—	(38)
Balance—December 31, 2018	—	\$ —	31,079,150	3	\$ 273,069	\$ (82)	\$ (139,769)	\$ 133,221

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

**FORTY SEVEN, INC.**  
**Statements of Cash Flows**  
*(in thousands)*

	Year Ended December 31,		
	2018	2017	2016
<b>Cash flows from operating activities:</b>			
Net loss	\$ (70,370)	\$ (44,898)	\$ (19,539)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	3,431	724	245
Depreciation and amortization	401	371	134
Accretion of discounts on marketable securities	(744)	—	—
Change in fair value of embedded derivative	331	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(2,385)	(568)	(3,881)
Other assets	(673)	205	(1,691)
Accounts payable	916	1,221	1,995
Accrued liabilities	4,214	3,356	853
Deferred grant funding	(1,015)	2,759	—
Lease-related liabilities	(123)	(90)	53
Other long-term liabilities	—	(17)	16
Net cash used in operating activities	<u>(66,017)</u>	<u>(36,937)</u>	<u>(21,815)</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(403)	(114)	(1,103)
Purchases of available-for-sale securities	(142,027)	(79,738)	(4,000)
Proceeds from maturities of available-for-sale securities	78,241	16,000	4,000
Net cash used in investing activities	<u>(64,189)</u>	<u>(63,852)</u>	<u>(1,103)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	115,152	4,590
Proceeds from issuance of common stock upon exercise of stock options	291	312	436
Proceeds from initial public offering, net of issuance costs	116,336	—	—
Repurchase of fractional common stock upon reverse stock split	(1)	—	—
Net cash provided by financing activities	<u>116,626</u>	<u>115,464</u>	<u>5,026</u>
Net (decrease) increase in cash and cash equivalents	(13,580)	14,675	(17,892)
Cash and cash equivalents — beginning of period	24,417	9,742	27,634
Cash and cash equivalents — end of period	<u>\$ 10,837</u>	<u>\$ 24,417</u>	<u>\$ 9,742</u>
<b>Supplemental disclosures of cash flow information:</b>			
Purchases of property and equipment through accounts payable and accrued liabilities	\$ —	\$ 10	\$ —
Conversion of convertible preferred stock to common stock at close of initial public offering	\$ 149,397	\$ —	\$ —

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

## Notes to the Financial Statements

**1. Description of Business**

The Company is a clinical-stage immuno-oncology company focused on developing novel checkpoint therapies to activate macrophages in the fight against cancer. Forty Seven was founded based on the insight that blocking CD47, a key signaling molecule that is over-expressed on cancer cells, renders tumors susceptible to macrophages and the innate immune system. By harnessing macrophages, the Company believes that its lead product candidate, 5F9, dosed as a monotherapy and in combination with marketed cancer therapies, can transform the treatment of cancer.

***Initial Public Offering***

On July 2, 2018, the Company completed its initial public offering (“IPO”) of 7,035,000 shares of common stock, and subsequently on July 27, 2018, the Company issued and sold an additional 1,055,250 shares upon the exercise of the underwriters’ over-allotment option. In connection with the IPO, including the over-allotment option, the Company issued and sold an aggregate of 8,090,250 shares of common stock at \$16.00 per share, raising \$116.3 million in proceeds, net of underwriting discounts and commissions, and offering expenses of \$13.2 million. Upon the closing of the IPO, all outstanding shares of convertible preferred stock were automatically converted into 16,215,896 shares of common stock.

***Reverse Stock Split***

In June 2018, the Company’s board of directors approved an amended and restated certificate of incorporation to effect a reverse split of shares of the Company’s common stock and convertible preferred stock on a 1-for-7.75 basis (the “Reverse Stock Split”). The par values of the common stock and convertible preferred stock were not adjusted as a result of the Reverse Stock Split. All references to common stock, options to purchase common stock, restricted stock, share data, per share data, convertible preferred stock and related information contained in the financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. The Reverse Stock Split was effected on June 14, 2018.

***Liquidity***

In the course of its development activities, the Company has sustained operating losses and expects to continue to generate operating losses for the foreseeable future. The Company’s ultimate success depends on the outcome of its research and development activities. The Company had cash, cash equivalents and short-term investments of \$139.0 million as of December 31, 2018. Since inception through December 31, 2018, the Company has incurred cumulative net losses of \$139.8 million. Management expects to incur additional losses in the future to conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

The Company intends to raise such capital through the issuance of additional equity financing and/or third-party collaboration funding. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its products. The Company expects that its cash, cash equivalents and short-term investments will be sufficient to fund operating expenses and capital expenditure requirements for a period of at least one year from the date the audited financial statements are filed with the Securities and Exchange Commission (“SEC”).

## 2. Summary of Significant Accounting Policies

### *Basis of Presentation*

The accompanying financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”).

### *Use of Estimates*

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying financial statements include but are not limited to the fair value of common stock prior to the IPO, the fair value of stock options, income tax uncertainties, and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

### *Cash and Cash Equivalents*

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts.

### *Investments*

Investments have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in debt securities at the time of purchase. Investments with original maturities beyond three months at the date of purchase and which mature at, or less than twelve months from the balance sheet date are classified as current.

Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company’s ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on marketable securities are included in interest and other income, net. The cost of investments sold is based on the specific-identification method. There were no realized gains or losses on investments for the years ended December 31, 2018, 2017 and 2016. Interest on marketable securities is included in interest income.

### *Concentration of Credit Risk and Other Risks and Uncertainties*

Financial instruments that potentially subject the Company to concentrations of risk consist of cash, cash equivalents, and short-term investments. The Company’s cash, cash equivalents and short-term investments are held by one financial institution in the United States, which management believes to be of high credit quality. Deposits in this financial institution may at times exceed federally insured limits. The Company has not experienced any losses on its deposits of cash, cash equivalents, or short-term investments.



## Notes to the Financial Statements

***Fair Value Measurement***

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability 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. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active;

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

***Property and Equipment, Net***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed on a straight-line basis over the estimated useful lives of the related assets, generally three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the assets' estimated useful lives or the remaining term of the lease. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations.

***Impairment of Long-Lived Assets***

Long-lived assets are reviewed for indications of possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amounts to the future undiscounted cash flows attributable to these assets. An impairment loss is recognized to the extent an asset group is not recoverable, and the carrying amount exceeds the projected discounted future cash flows arising from these assets. There were no impairments of long-lived assets for any of the periods presented.

***Research and Development Expenditures***

Research and development expenses consist of costs incurred for the Company's own and for sponsored and collaborative research and development activities. Research and development costs are expensed as incurred. Research and development costs consist of salaries and benefits, including associated stock-based compensation, and laboratory supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities on the Company's behalf. The Company estimates preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and contract research organizations, or CROs, and clinical manufacturing organizations, or CMOs, that conduct and manage preclinical studies and clinical trials on the Company's behalf based on actual time and expenses incurred by them. Further, the Company accrues expenses related to clinical trials based on the level of patient enrollment and activity according to the related agreement. The Company monitors patient enrollment levels and related activity to the extent reasonably possible and adjust estimates accordingly. If the Company does not identify costs that have begun to be incurred or if the Company underestimates or overestimates the level of services performed or the costs of these services, actual expenses could differ from the Company's estimates. To date, the Company has not experienced significant changes in its estimates of preclinical studies and clinical trial accruals.

**Notes to the Financial Statements**

The Company expenses payments for the acquisition and development of technology as research and development costs if, at the time of payment, the technology is under development; is not approved by the U.S. Food and Drug Administration or other regulatory agencies for marketing; has not reached technical feasibility; or otherwise has no foreseeable alternative future use. In addition, funding from research grants is offset against the related qualified research and development costs incurred.

***Stock-Based Compensation***

The Company measures its stock-based awards granted to employees and directors based on the estimated fair values of the awards and recognizes the compensation over the requisite service period. The Company uses the Black-Scholes option-pricing model to estimate the fair value of its stock-based awards and employee stock purchase plan ("ESPP") purchases. Stock-based compensation is recognized using the straight-line method.

***Defined Contribution Plan***

The Company has a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code ("IRC"). This plan allows eligible employees to defer a portion of their annual compensation on a pre-tax or after-tax basis. The Company may make discretionary matching contributions. During 2018, 2017 and 2016, the Company made matching contributions on up to 3% of an employee's eligible compensation deferred. The Company recognized expense related to its contributions to the plan of \$281,000, \$211,000 and \$107,000 for the years ended December 31, 2018, 2017 and 2016.

***Income Taxes***

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Management makes an assessment of the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Changes in recognition or measurement are reflected in the period in which judgment occurs. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of provision for income taxes.

***Foreign Currency Transactions***

Gains or losses from foreign currency transactions are included in interest and other income, net, in the statements of operations and comprehensive loss. The Company recognized \$0.2 million in foreign currency losses for the year ended December 31, 2018. Foreign currency transaction gains and losses were not material for the years ended December 31, 2017 and 2016.

***Comprehensive Loss***

The Company's comprehensive loss is comprised of changes in unrealized losses on available-for-sale securities.

## Notes to the Financial Statements

***Net Loss per Share***

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive. Shares of common stock subject to repurchase are excluded from the weighted-average shares.

***Segment Reporting***

The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of allocating resources.

***Recently Issued and Adopted Accounting Pronouncements***

In June 2018, the FASB issued Accounting Standards Update No. 2018-07, *Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share-based payments. ASU 2018-07 expands the scope of Topic 718, Compensation-Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The Company adopted this guidance for the year ended December 31, 2018. The adoption of this guidance during the year ended December 31, 2018 did not have a material impact on the Company's financial statements.

***Recent Accounting Pronouncements Not Yet Adopted***

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2016-02, *Leases* (Topic 842). The principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from leases and provide enhanced disclosures. In July 2018, the FASB issued guidance to permit an alternative transition method for Topic 842, which allows transition to the new lease standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company expects to adopt Topic 842 as of January 1, 2019 under this new alternative transition method. The Company will elect 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. In addition, as a practical expedient relating to its property lease, the Company will not separate lease components from nonlease components. The Company will not elect the hindsight practical expedient permitted under the transition guidance within the new lease standard. The Company has substantially completed an assessment of the new standard's impact, and while the Company does not expect a material impact from adoption on its statements of operations or comprehensive loss, the Company does expect to record a material increase in its assets and liabilities on the balance sheet upon adoption of this standard. Upon adoption, the Company expects to recognize a right-of-use asset in the range of \$2.2 million to \$2.4 million and a lease liability in the range of \$2.7 million to \$2.9 million for the headquarters property lease.

**3. Fair Value Measurements**

The Company measures and reports its cash equivalents, short-term investments, and embedded derivative at fair value.

Money market funds are measured at fair value on a recurring basis using quoted prices and are classified as a Level 1 input. Short-term investments are measured at fair value based on inputs other than quoted prices that are derived from observable market data and are classified as Level 2 inputs. There were no transfers between Levels 1, 2 or 3 for any of the periods presented. All of the investments held as of December 31, 2018 and 2017 had maturities of less than one year. There were no realized gains or losses on investments for the years ended December 31, 2018, 2017 and 2016. Any unrealized losses were deemed to be temporary. The Company does not intend to sell its

Notes to the Financial Statements

securities that are in an unrealized loss position, and it is unlikely that the Company will be required to sell its securities before recovery of their amortized cost basis, which may be maturity.

The fair value and amortized cost of cash equivalents and available-for-sale securities by major security type as of December 31, 2018 and 2017 are presented in the following tables:

	As of December 31, 2018				
	Fair Value Hierarchy	Amortized Cost	Unrealized Gains (in thousands)	Unrealized Losses	Market Value
Money market funds	Level 1	\$ 7,959	\$ —	\$ —	\$ 7,959
Commercial paper	Level 2	43,277	—	—	43,277
Corporate debt securities	Level 2	46,186	—	(54)	46,132
Asset-backed securities	Level 2	22,842	—	(27)	22,815
US government debt securities	Level 2	15,963	—	(1)	15,962
Total cash equivalents and available-for-sale securities		<u>\$ 136,227</u>	<u>\$ —</u>	<u>\$ (82)</u>	<u>\$ 136,145</u>

	As of December 31, 2017				
	Fair Value Hierarchy	Amortized Cost	Unrealized Gains (in thousands)	Unrealized Losses	Market Value
Money market funds	Level 1	\$ 19,052	\$ —	\$ —	\$ 19,052
Commercial paper	Level 2	31,467	—	—	31,467
Corporate debt securities	Level 2	24,556	—	(35)	24,521
Asset-backed securities	Level 2	7,717	—	(7)	7,710
US government debt securities	Level 2	1,993	—	(2)	1,991
Total cash equivalents and available-for-sale securities		<u>\$ 84,785</u>	<u>\$ —</u>	<u>\$ (44)</u>	<u>\$ 84,741</u>

The Company's contingent milestone payments in its agreement with the Leukemia & Lymphoma Society, Inc. were concluded to be an embedded derivative. The embedded derivative contains unobservable inputs that are supported by little or no market activity at the measurement date. Accordingly, the Company's embedded derivative is measured at fair value on a recurring basis using unobservable inputs that are classified as level 3 inputs. Refer to Note 6 for the valuation techniques and assumptions used in estimating the fair value of the embedded derivative.

4. Balance Sheet Components

*Property and Equipment, Net*

Property and equipment, net consists of the following:

	December 31,	
	2018	2017
	(in thousands)	
Furniture and fixtures	\$ 108	\$ 14
Laboratory equipment	1,297	988
Computer equipment and software	91	91
Leasehold improvements	770	770
	<u>2,266</u>	<u>1,863</u>
Less: Accumulated depreciation and amortization	(906)	(505)
Total property and equipment, net	<u>\$ 1,360</u>	<u>\$ 1,358</u>

Notes to the Financial Statements

Depreciation and amortization expense for property and equipment amounted to \$401,000, \$371,000 and \$134,000 for the years ended December 31, 2018, 2017 and 2016.

**Accrued Liabilities**

Accrued liabilities consist of the following:

	December 31,	
	2018	2017
	(in thousands)	
Accrued research and development expenses	\$ 5,870	\$ 4,096
Accrued bonus	1,602	—
Lease-related liabilities, current	155	133
Other	1,417	579
Total accrued liabilities	<u>\$ 9,044</u>	<u>\$ 4,808</u>

**5. Commitments and Contingencies**

**Leases**

In August 2016, the Company entered into an operating lease agreement for its headquarters in Menlo Park, California. The lease term is for 60 months. The lease rental payments are on a graduated scale; however, rent expense is recognized on a straight-line basis over the lease term. The landlord provided the Company with a tenant improvement allowance of up to \$646,000. The allowance is amortized as an offset to rent expense over the lease term. Rent expense for the years ended December 31, 2018, 2017 and 2016 was \$1,071,000, \$993,000 and \$587,000. At December 31, 2018 and 2017, \$142,000 and \$135,000 was accrued as deferred rent expense.

Effective September 2016, the Company entered into a sublease agreement to lease a portion of the Menlo Park facility to a tenant. Sublease income was \$0, \$124,000 and \$62,000 for the years ended December 31, 2018, 2017 and 2016 and was recorded as an offset to rent expense.

In conjunction with the lease agreement, the Company paid a security deposit of \$265,000 included in prepaid expenses and other current assets and other assets as of December 31, 2017. The security deposit was reduced to \$176,000, included in prepaid expenses and other current assets and other assets as of December 31, 2018.

At December 31, 2018, future minimum payments are as follows (in thousands):

2019	\$	1,134
2020		1,168
2021		794
Total future minimum lease payments	<u>\$</u>	<u>3,096</u>

**Manufacturing Commitment**

In August 2016, the Company entered into a development and manufacturing agreement with Lonza Sales AG and, in December 2017, the Company entered into a second manufacturing agreement with Lonza Biologics Tuas Pte Ltd, each relating to the manufacturing of 5F9-related products.

The August 2016 agreement was amended by the Company in November 2017 as relating to the manufacturing of the Company's other preclinical program related products and in November and December 2018 as relating to the scope of manufacturing services. Under the agreements, the Company is required to pay Lonza fixed fees based on manufacturing services performed on the Company's behalf. Payments were due beginning in January 2018 through to the expiration of the agreements in December 2021. The fees payable under the August 2016 agreement and as

**Notes to the Financial Statements**

amended in November 2017 and November and December 2018, are specified in Great British Pounds and are converted into U.S. Dollars based on current exchange rates.

At December 31, 2018, future minimum payments under the Lonza development and manufacturing agreements are as follows (in thousands):

2019	\$	14,447
2020		10,250
2021		5,150
Total future minimum payments	\$	<u>29,847</u>

**6. Research and License Agreements**

***Stanford License Agreement***

In November 2015, the Company entered into a technology license agreement with The Board of Trustees of the Leland Stanford Junior University (“Stanford”) under which Stanford granted to the Company exclusive licenses under certain patents and other intellectual property rights relating to the Company’s current product candidates and non-exclusive licenses under certain other patents and intellectual property rights to develop, manufacture and commercialize products for use in certain licensed fields, the scope of which would include the application of the licensed intellectual property in oncology. With respect to these licenses, the Company could be required to pay Stanford up to \$5.6 million in milestone payments based on the achievement of certain development and regulatory approval milestones. The first such milestone payment of \$75,000 was paid to Stanford in February 2018 and included in research and development expense for the year ended December 31, 2018. In addition, the Company is required to pay Stanford a minimum annual fee and a royalty of single digit percentage on net sales of licensed products, reimburse patent-related expenses, share any non-royalty sublicensing income received related to the licensed technology, and pay a change of control fee.

***California Institute of Regenerative Medicine (CIRM) Grants***

In January 2017, the Company was awarded a research grant from CIRM. The CIRM grant stipulates various milestone-based payments to the Company with the total award of \$10.2 million over a period of four years. As of December 31, 2018 and 2017, the Company had received \$7.2 million and \$3.8 million under the award.

In November 2017, the Company was awarded a second research grant from CIRM for a separate clinical trial study. The total amount of the research grant awarded was \$5.0 million in various milestone-based payments over a period of five years. During 2018, the award was amended to \$3.2 million in various-milestone payments over a period of five years, as was provided for under the terms of the original award because the Company opted not to expand the patient population participating in the study. As of December 31, 2018 and 2017, the Company had received \$2.4 million and \$1.1 million under the award. Under the terms of the CIRM grants, the Company is obligated to pay royalties and licensing fees based on a low single digit royalty percentage on net sales of CIRM-funded product candidates or CIRM-funded technology. The Company has the option to decline any and all amounts awarded by CIRM. As an alternative to revenue sharing, the Company has the option to convert the award to a loan. No such election has been made as of the date of the issuance of these financial statements. In the event that the Company terminates a CIRM-funded clinical trial, it will be obligated to repay the remaining CIRM funds on hand.

***Leukemia & Lymphoma Society Grant***

In March 2017, the Company entered into an agreement with the Leukemia & Lymphoma Society, Inc. (“LLS”) and amended the agreement to include an additional study in June 2018. The LLS research grant stipulates various milestone-based payments with a total award of \$4.2 million through December 2019. As of December 31, 2018 and 2017, the Company had received \$3.9 million and \$1.0 million under the award. The Company could be required in the future to pay amounts to LLS upon reaching certain development and regulatory approval milestones as well as a low single digit percentage royalty rate on net sales, up to a maximum of \$15 million in total. The Company

**Notes to the Financial Statements**

concluded that the contingent milestone payments were an embedded derivative and the Company recorded a liability for the derivative of approximately \$0.3 million, as part of other long-term liabilities as of December 31, 2018. The liability for the derivative was not material to the financial statements as of December 31, 2017. The value of the embedded derivative was estimated using the probability-adjusted and discounted future milestone payments. The Company recorded the \$0.3 million increase in the fair value of the embedded derivative in the statement of operations as Interest and other income, net.

The Company recognizes research grants as a reduction of research and development expense when the eligible costs are incurred. For the years ended December 31, 2018 and 2017, the Company recognized \$8.0 million and \$3.9 million as a reduction to research and development expenses for research grants.

***Merck Collaboration Agreement***

In January 2018, the Company entered into a clinical trial collaboration and supply agreement with Ares Trading S.A, a subsidiary of Merck KGaA (“Merck”), to evaluate 5F9 combined with Merck’s cancer immunotherapy, avelumab, in a Phase 1b clinical trial in patients with ovarian cancer. Pursuant to the agreement, the parties will jointly pay for the cost of the study. As of December 31, 2018, the Company recorded a receivable of \$0.6 million from Merck for reimbursement of research and development costs incurred. Reimbursement under this collaboration agreement is recorded as a reduction to research and development expense. For the year ended December 31, 2018, the Company recognized \$1.2 million as a reduction to research and development expenses under this collaboration agreement.

***BliNK Purchase Agreement***

In June 2018, the Company entered into an asset purchase agreement with BliNK Biomedical SAS (“Blink”), under which Blink transferred its patents, intellectual property rights and know-how, and materials related to its CD47 antibody program to the Company. Under the agreement, the Company paid an initial upfront fee of \$2.5 million in June 2018, including \$0.5 million upon the completion of the transfer of intellectual property rights and know-how. An additional \$0.5 million was paid in July 2018 upon completion of material transfers related to its CD47 antibody program to the Company. Additionally, the Company is required to make annual payments of \$0.3 million until it receives marketing approval for the first product. The Company could also be required to pay up to \$43.0 million in milestone payments in aggregate per product based on the achievement of certain development and regulatory approval milestones. No such milestone payments have been made as of December 31, 2018. In addition, the Company could be required to pay Blink a royalty of single digit percentage on net sales of approved products, which is subject to buy-out provisions for a one-time payment that can be exercised by the Company prior to certain development milestones being achieved. During the year ended December 31, 2018, the Company recognized \$3.0 million in research and development expense related to the Blink asset purchase agreement.

***Synthon License Agreement***

In July 2018, the Company entered into a settlement and license agreement with Synthon Biopharmaceuticals B.V. (“Synthon”). Under the agreement, the Company agreed to discontinue its ongoing oppositions and challenges at the European Patent Office (“EPO”) and the U.S. Patent and Trademark Office (“USPTO”) directed towards certain patents licensed by Synthon from Stichting Sanquin Bloedvoorziening (“SSB”) that relate to the use of anti-CD47 products in combination with other antibodies to treat cancer. The Company also agreed to request the withdrawal of such proceedings with the USPTO and EPO. In return Synthon agreed to grant the Company a non-exclusive, worldwide sublicense to certain patents Synthon have licensed from SSB, including the SSB patents the Company was opposing at the USPTO and EPO to commercialize a single anti-CD47 product (such as 5F9 or an alternate anti-CD47 product) to treat cancer in combination with other antibodies.

In exchange, for these sublicenses and option rights, the Company agreed to pay Synthon an aggregate of up to approximately 40.0 million Euros (approximately \$46 million US Dollar based on the exchange rate at December 31, 2018) comprising an upfront payment upon grant of sublicense and the achievement of future regulatory and commercial milestones which comprise the significant majority of the aggregate payments. The Company also has an option to expand its rights to cover a follow-on anti-CD47 product in exchange for a specified option exercise fee. If the Company exercises its option right, the Company will pay Synthon additional amounts upon the achievement of certain regulatory and commercial milestones related to such follow-on anti-CD47 product. In

**Notes to the Financial Statements**

addition, the Company will be required to pay Synthron an annual license fee and a royalty of a tiered, low single digit percentage on net sales of any approved licensed products. The Company has the right to buy out its royalty obligations for each licensed product in full by paying Synthron specified lump sum amounts prior to the occurrence of certain defined events.

**7. Convertible Preferred Stock**

On the completion of the IPO (see Note 1) on July 2, 2018, all outstanding shares of convertible preferred stock were automatically converted into 16,215,896 shares of common stock and the related carrying value was reclassified to common stock and additional paid-in capital. Accordingly, there were no shares of convertible preferred stock outstanding as of December 31, 2018. The convertible preferred stock as of December 31, 2017 consisted of the following:

	December 31, 2017		
	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value
	(in thousands, except share data)		
Series A-1	4,438,709	4,438,691	\$ 34,245
Series A-2	4,187,698	4,187,682	40,377
Series B	7,589,537	7,589,523	74,775
	16,215,944	16,215,896	\$ 149,397

**8. Stock-Based Compensation**

*2015 and 2018 Equity Incentive Plans*

In November 2015, the Company adopted the 2015 Equity Incentive Plan (“2015 Plan”). The 2015 Plan provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company under terms and provisions established by the board of directors. As of December 31, 2018, there were 3,291,597 shares of the Company’s common stock reserved for future issuance under the 2015 Plan upon the exercise of outstanding stock options.

In June 2018, the Company adopted the 2018 Equity Incentive Plan (“2018 Plan”), which became effective upon the execution of the underwriting agreement related to the IPO. As a result, the Company will not grant any additional awards under the 2015 Plan. The terms of the 2015 Plan and applicable award agreements will continue to govern any outstanding awards thereunder. The Company has initially reserved 3,000,000 shares of common stock for issuance under the 2018 Plan. In addition, the number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on the first day of January for a period of up to ten years, commencing on January 1, 2019, in an amount equal to 5% of the total number of shares of the Company’s capital stock outstanding on the last day of the preceding year, or a lesser number of shares determined by the Company’s board of directors. As of December 31, 2018, there were 2,886,650 shares available for future grants under the 2018 Plan.



Notes to the Financial Statements

A summary of option activity under the 2015 Plan and 2018 Plan is as follows:

	Shares Issuable Under Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contract Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2016	624,177	\$ 2.02	9.35	\$ 1,790
Options granted	1,756,056	5.08		
Options exercised	(107,783)	2.90		
Options forfeited	(169,922)	2.71		
Balance, December 31, 2017	2,102,528	\$ 4.47	9.43	\$ 1,672
Options granted	1,426,038	9.44		
Options exercised	(63,865)	4.56		
Options forfeited	(59,854)	4.96		
Balance outstanding December 31, 2018	<u>3,404,847</u>	\$ 6.55	8.82	\$ 31,388
Exercisable, December 31, 2018	<u>2,167,142</u>	\$ 6.18	8.75	\$ 20,771
Vested and expected to vest, December 31, 2018	<u>3,404,847</u>	\$ 6.55	8.82	\$ 31,388

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money.

The intrinsic value of options exercised for the years ended December 31, 2018, 2017 and 2016 was \$554,000, \$226,000 and \$0, respectively.

During the years ended December 31, 2018, 2017 and 2016, the estimated total grant-date fair value of the options vested was \$2.3 million, \$3.7 million and \$1.1 million and the estimated weighted-average grant-date fair value of employee options granted was \$6.14, \$3.39 and \$1.33 per share, respectively. As of December 31, 2018, there was \$11.4 million of unrecognized stock-based compensation related to unvested stock options that is expected to be recognized over a weighted-average period of 3.3 years.

**Employees Share Purchase Plan (ESPP)**

In June 2018, the Company adopted the 2018 Employee Stock Purchase Plan ("ESPP"), which became effective upon the execution of the underwriting agreement related to the IPO. The Company has initially reserved 450,000 shares of common stock for purchase under the ESPP. The initial offering period began June 27, 2018 and will end on August 15, 2020 with purchase dates of February 15, 2019, August 15, 2019, February 15, 2020, and August 15, 2020. Each subsequent offering will be approximately 24 months long and will consist of four purchase periods with purchase dates occurring on February 15 and August 15 of each year. On each purchase date, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date.

**Stock-Based Compensation**

The Company uses the grant date fair value of its common stock to value options when granted. The Company measures its stock-based awards granted to employees and directors based on the estimated fair values of the awards and recognizes the compensation over the requisite service period. In determining the fair value of the stock-based awards, the Company uses the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and its determination generally requires significant judgment.

*Expected term*—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method, as we do not have sufficient

**Notes to the Financial Statements**

historical data to use any other method to estimate expected term. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the stock-based awards.

*Expected volatility*—Since the Company has limited trading history for its common stock due to its short trading history, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.

*Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

*Dividend yield*—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

The fair value of employee and director stock option awards was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2018	2017	2016
Expected term (years)	5.48 - 6.44	6.0	6.0
Expected volatility	65.8% - 70.8%	75.5%	75%
Weighted average risk-free interest rate	2.51% - 3.10%	1.77% - 2.21%	1.25% - 2.08%
Dividend yield	0%	0%	0%

The fair value of the ESPP is estimated using the Black-Scholes option pricing model. For the year ended December 31, 2018, the weighted average grant date fair value per share for the ESPP was \$6.95. Stock-based compensation expense for the ESPP was \$423,000 for the year ended December 31, 2018.

For the year ended December 31, 2018, the fair value of ESPP was estimated using the following assumptions:

	Year Ended December 31,
	2018
Expected term (years)	0.58 - 2.08
Expected volatility	66% - 68%
Weighted average risk-free interest rate	2.14% - 2.53%
Dividend yield	0%

The ESPP commenced in June 2018. No shares of common stock were purchased pursuant to the ESPP in 2018. Cash received from payroll deductions pursuant to the ESPP in 2018 was \$473,000.

Total stock-based compensation was as follows:

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Research and development	\$ 1,193	\$ 206	\$ 93
General and administrative	2,238	518	152
Total	<u>\$ 3,431</u>	<u>\$ 724</u>	<u>\$ 245</u>

**Restricted Stock**

The Company typically allows its employees and directors to exercise options granted under the 2015 Plan prior to vesting. The Company also has issued restricted stock purchase awards to employees and directors under the

**Notes to the Financial Statements**

2015 Plan. The shares related to early exercised stock options and restricted stock purchase awards are subject to the Company's lapsing repurchase right upon termination of employment at the original purchase price. In order to vest, the holders are required to provide continued service to the Company. The proceeds are initially recorded in other long-term liabilities and are reclassified to common stock and paid-in capital as the repurchase right lapses. As of December 31, 2018 and 2017, there was \$144,000 and \$255,000 recorded in other long-term liabilities related to shares held by employees and directors that were subject to repurchase.

A summary of restricted stock activity follows for the years ended December 31, 2017 and 2018:

	<u>Number of Restricted Shares Outstanding</u>
Unvested shares—December 31, 2016	299,327
Early exercised options	32,258
Restricted shares vested	<u>(174,596)</u>
Unvested shares—December 31, 2017	156,989
Early exercised options	11,418
Restricted shares vested	(77,420)
Repurchased by the Company	<u>(41,935)</u>
Unvested shares—December 31, 2018	<u><u>49,052</u></u>

**9. Net Loss Per Share**

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	<u>December 31,</u>		
	<u>2018</u>	<u>2017</u>	<u>2016</u>
Convertible preferred stock	—	16,215,896	4,438,691
Stock options to purchase common stock	3,404,847	2,102,528	624,177
Restricted stock subject to future vesting	49,052	156,988	299,327
Shares committed under ESPP	35,383	—	—
Total	<u><u>3,489,282</u></u>	<u><u>18,475,412</u></u>	<u><u>5,362,195</u></u>

**10. Income Taxes**

The provision for income taxes for the years ended December 31, 2018, 2017 and 2016 was an immaterial amount. The Company has incurred net operating losses for all the periods presented. The Company has not reflected any benefit of such net operating loss carryforwards in the financial statements. The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

**Notes to the Financial Statements**

A reconciliation of total provision for income taxes and the amount computed by applying the federal statutory income tax rate of 21% to loss before provision from income taxes is as follows:

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Computed expected tax benefit	\$ (14,778)	\$ (9,428)	\$ (6,540)
State taxes (net of federal tax benefits)	(1,621)	(3,119)	(1,111)
Increase in valuation allowance	17,992	10,185	7,685
Other	481	(65)	89
R&D tax credits	(2,074)	(326)	(123)
Federal rate change (pursuant to the Tax Act)	—	2,753	—
Total provision for income taxes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

The components of the deferred tax assets and liabilities are as follows:

	December 31,	
	2018	2017
	(in thousands)	
Net operating loss carryforwards	\$ 19,748	\$ 4,309
Capitalized R&D	10,673	13,537
Stock-based compensation	583	122
Intangibles	2,891	896
Tax credits	2,711	637
Accruals and other	1,067	180
Total deferred tax assets	<u>37,673</u>	<u>19,681</u>
Less: valuation allowance	<u>(37,673)</u>	<u>(19,681)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Due to the lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately \$18.0 million, \$10.2 million and \$7.7 million during the years ended December 31, 2018, 2017 and 2016.

The Company has net operating carryforwards for federal and California income tax purposes of approximately \$76.4 million and \$53.4 million, respectively, as of December 31, 2018. As of December 31, 2017, we had federal and California net operating loss carryforwards of approximately \$16.5 million and \$16.6 million, respectively. The federal net operating loss carryforwards, if not utilized, will expire beginning in 2035. The state net operating loss carryforwards, if not utilized, will expire beginning in 2035. Under the U.S. Tax Cuts & Jobs Act, passed into law in December 2017, effective January 1, 2018, net operating losses generated after December 31, 2017 will be carried forward indefinitely with the yearly net operating loss utilization limited to 80 percent of taxable income.

The Company has federal and California research credit carryforwards of approximately \$2.1 million and \$1.5 million, respectively, as of December 31, 2018. As of December 31, 2017, we had federal and California research credit carryforwards of approximately \$0.4 million and \$0.6 million, respectively. The Company also has Federal Orphan Drug credits of approximately \$0.2 million as of December 31, 2018. The federal credits will begin to expire in 2035 while the California research credits have no expiration date.

Federal and California tax laws impose significant restrictions on the utilization of net operating loss carryforwards in the event of a change in ownership of the Company, as defined by Internal Revenue Code Section 382 (“Section 382”). A formal Section 382 study has not been completed to determine if an ownership change has occurred and if its net operating losses are subject to an annual limitation. Such annual limitations could affect the utilization of NOL and tax credit carryforwards in the future.

**Notes to the Financial Statements**

No liability related to uncertain tax positions is recorded on the financial statements related to uncertain tax positions. It is the Company's policy to include penalties and interest expense related to income taxes as a component of interest and other income, net, as necessary.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Balance at beginning of year	\$ 283	\$ 93	\$ —
Increases related to current year tax positions	553	190	93
Balance at end of year	<u>\$ 836</u>	<u>\$ 283</u>	<u>\$ 93</u>

Although it is reasonably possible that certain unrecognized tax benefits may increase or decrease within the next twelve months due to tax examination changes, settlement activities, expirations of statute of limitations, or the impact on recognition and measurement considerations related to the results of published tax cases or other similar activities, the Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months.

Income tax returns are filed in the U.S. and California. The years 2015 through 2018 remain open to examination by the domestic taxing jurisdictions to which the Company is subject. Net operating losses generated on a tax return basis by the Company for 2015 through 2018 remain open to examination by the domestic taxing jurisdictions.

In December 2017, the Tax Cuts and Jobs Act of 2017 ("Tax Act") was signed into law. The Tax Act, among other changes, lowers the Company's federal tax rate from 34% to 21%. Based on provisions of the Tax Act, the Company remeasured its deferred tax assets and liabilities as of December 31, 2017 to reflect the lower statutory tax rate. The Company completed its accounting for the income tax effects of the Tax Act in 2018, and no material adjustments were required to the provisional amounts initially recorded.

**11. Related-Party Relationship**

Dr. Weissman and Dr. Majeti, co-founders and members of the Company's board of directors, are professors at Stanford. While employed by Stanford, Dr. Weissman and Dr. Majeti are co-inventors of some of the patents that the Company licenses under the Stanford License Agreement. Under Stanford's policies, as co-inventors Dr. Weissman and Dr. Majeti are entitled to receive a share of any royalties that the Company pays to Stanford under the agreement with respect to the covered intellectual property. No royalty payments have been made to date. In addition, under Stanford's policies, as co-inventors Dr. Weissman and Dr. Majeti are entitled to receive a share of the annual license fees that the Company pays to Stanford with respect to the covered intellectual property.

**12. Selected Quarterly Financial Data (Unaudited)**

Selected quarterly results from operations for the years ended December 31, 2018 and 2017 are as follows:

	Three Months Ended,			
	December 31,	September 30,	June 30,	March 31,
	(in thousands, except per share data)			
<b>2018</b>				
Loss from operations	(17,784)	(22,367)	(16,958)	(14,996)
Net loss	(17,214)	(21,659)	(16,722)	(14,775)
Net loss per share, basic and diluted	\$ (0.56)	\$ (0.71)	\$ (2.52)	\$ (2.24)
<b>2017</b>				
Loss from operations	(12,583)	(10,893)	(10,886)	(10,942)
Net loss	(12,330)	(10,833)	(10,827)	(10,908)
Net loss per share, basic and diluted	\$ (1.88)	\$ (1.67)	\$ (1.68)	\$ (1.71)

**FORTY SEVEN, INC.**  
**Notes to the Financial Statements**

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

None.

**Item 9A. Controls and Procedures.**

**Evaluation of Disclosure Controls and Procedures**

As of December 31, 2018, management, with the participation of our Chief Executive Officer and our Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2018, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

**Remediation Efforts of Previously Reported Material Weakness**

During the audit of our financial statements for the year ended December 31, 2016, a material weakness was identified in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls. The material weakness that was identified related to the accounting for complex transactions and the timing of expense recognition for research and development expenses.

We have implemented measures designed to improve our disclosure controls and procedures and internal control over financial reporting to address the underlying causes of this material weakness, including hiring key accounting personnel, engaging technical accounting consulting resources, establishing more formal controls for the review and documentation of the accounting for complex non-routine transactions, establishing more formal policies and procedures related to the accounting for our procurement and vendor payment process, and creating a formal month-end close process.

Our management believes that these and other actions taken to remediate this material weakness were fully implemented as of September 30, 2018 and that the previously reported material weakness had been remediated. However, we cannot assure you that the measures we have taken to date, and are continuing to implement, or any measures we may take in the future, will be sufficient to identify or prevent future material weaknesses. We, and our independent registered public accounting firm, were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2018 in accordance with the provisions of the Sarbanes-Oxley Act, and will not be required to attest formally to the effectiveness of our internal controls over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an "emerging growth company" as defined in the JOBS Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required by reporting requirements under Section 404 of the Sarbanes-Oxley Act. If other material weaknesses or other deficiencies occur, or currently exist, our ability to accurately and timely report our financial position could be impaired, which could result in a misstatement of our financial statements that would not be prevented or detected on a timely basis.

**Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting during the quarter ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Attestation Report of Registered Public Accounting Firm**

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting pursuant to SEC rules that permit us to provide only management's report in this Annual Report.

**Item 9B. Other Information.**

None.



## PART III

### **Item 10. Directors, Executive Officers and Corporate Governance.**

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2019 Annual Meeting of Stockholders, or the Proxy Statement, which is expected to be filed not later than 120 days after the end of our year ended December 31, 2018, under the headings “Executive Officers,” “Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance,” and “Section 16(a) Beneficial Ownership Reporting Compliance,” and is incorporated herein by reference.

We have adopted a Code of Conduct that applies to our officers, directors, employees and independent contractors, which is available on our website at [www.fortyseveninc.com](http://www.fortyseveninc.com). The Code of Conduct is intended to qualify as a “code of ethics” within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Conduct that applies to a director, executive officer or senior financial officer and (2) the nature of any waiver, including an implicit waiver, from a provision of our Code of Conduct that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

### **Item 11. Executive Compensation.**

The information required by this item regarding executive compensation is incorporated by reference to the information set forth in the sections titled “Executive Compensation” in our Proxy Statement.

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

The information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement.

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

The information required by this item regarding certain relationships and related transactions and director independence is incorporated by reference to the information set forth in the sections titled “Transactions with Related Parties” and “Election of Directors– Independence of the Board of Directors,” respectively, in our Proxy Statement.

### **Item 14. Principal Accounting Fees and Services.**

The information required by this item regarding principal accountant fees and services is incorporated by reference to the information set forth in the section titled “Principal Accountant Fees and Services” in our Proxy Statement.

**Item 15. Exhibits, Financial Statement Schedules.**

(a) The following documents are filed as part of this report:

1. Financial Statements

See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

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

3. Exhibits

**Exhibit Index**

Exhibit Number	Description	Incorporation By Reference		
		Form	SEC File No.	Exhibit
3.1	<a href="#">Amended and Restated Certificate of Incorporation of Forty Seven, Inc.</a>	8-K	001-38554	3.1
3.2	<a href="#">Amended and Restated Bylaws of Forty Seven, Inc.</a>	S-1	333-225390	3.4
4.1	Reference is made to Exhibits <a href="#">3.1</a> through <a href="#">3.2</a> .			
4.2	<a href="#">Form of Common Stock Certificate.</a>	S-1	333-225390	4.1
10.1	<a href="#">Amended and Restated Investor Rights Agreement, by and among Forty Seven, Inc. and the investors listed on Exhibit A thereto, dated October 17, 2017.</a>	S-1	333-225390	10.1
10.2+	<a href="#">Forty Seven, Inc. 2015 Equity Incentive Plan, as amended.</a>	S-1	333-225390	10.2
10.3+	<a href="#">Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the 2015 Equity Incentive Plan.</a>	S-1	333-225390	10.3
10.4+	<a href="#">Forty Seven, Inc. 2018 Equity Incentive Plan, as amended.</a>	S-1	333-225390	10.4
10.5+	<a href="#">Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the 2018 Equity Incentive Plan.</a>	S-1	333-225390	10.5
10.6+	<a href="#">Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2018 Equity Incentive Plan.</a>	S-1	333-225390	10.6
10.7+	<a href="#">Forty Seven, Inc. 2018 Employee Stock Purchase Plan.</a>	S-1	333-225390	10.7
10.8+	<a href="#">Form of Indemnification Agreement, by and between Forty Seven, Inc. and each of its directors and executive officers.</a>	S-1	333-225390	10.8
10.9+	<a href="#">Offer Letter, by and between Forty Seven, Inc. and Mark McCamish, dated November 10, 2016.</a>	S-1	333-225390	10.9
10.10+	<a href="#">Executive Employment Agreement, by and between Forty Seven, Inc. and Chris Takimoto, effective as of January 7, 2016.</a>	S-1	333-225390	10.10
10.11	<a href="#">Lease Agreement, by and between Forty Seven, Inc. and MENLO PREHC I, LLC, dated as of April 13, 2016.</a>	S-1	333-225390	10.11
10.12**	<a href="#">Exclusive (Equity) Agreement, by and between Forty Seven, Inc. and The Board of Trustees of the Leland Stanford Junior University, dated November 19, 2015, as amended by Amendment No. 1 to Exclusive (Equity) Agreement, by and between Forty Seven, Inc. and The Board of Trustees of the Leland Stanford Junior University, dated April 19, 2017.</a>	S-1	333-225390	10.12
10.13**	<a href="#">Assigned Capacity and Manufacturing Agreement, by and between Forty Seven, Inc. and Lonza Sales AG, dated August 30, 2016.</a>	S-1	333-225390	10.13

10.14**	<a href="#">Amendment to the Assigned Capacity and Manufacturing Agreement, by and between Forty Seven, Inc. and Lonza Sales AG, dated June 9, 2017.</a>	S-1	333-225390	10.14
10.15**	<a href="#">Assigned Capacity and Manufacturing Agreement for 2000 L Scale, by and between Forty Seven, Inc. and Lonza Biologics Tuas Pte Ltd, dated December 21, 2017.</a>	S-1	333-225390	10.15
10.16+	<a href="#">Forty Seven, Inc. Executive Severance and Change in Control Plan.</a>	S-1	333-225390	10.16
10.17**	<a href="#">Settlement and License Agreement, by and between Forty Seven, Inc. and Synthon Biopharmaceuticals B.V. dated July 16, 2018.</a>	10-Q	001-38554	10.1
10.18+	<a href="#">Amended and Restated Annual Bonus Plan</a>	8-K	001-38554	10.1
16.1	<a href="#">Letter from PricewaterhouseCoopers LLP to the Securities and Exchange Commission, dated March 23, 2018.</a>	S-1	333-225390	16.1
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm</a>			
31.1	<a href="#">Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) of the Securities and Exchange Act of 1934, as amended.</a>			
31.2	<a href="#">Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) of the Securities and Exchange Act of 1934, as amended.</a>			
32.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Rule 13a-14(b) of the Securities and Exchange Act, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>			
32.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Rule 13a-14(b) of the Securities and Exchange Act, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>			
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			

\* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certification furnished in Exhibit 32.1 hereto is deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

+ Indicates management contract or compensatory plan or arrangement.

\*\* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Forty Seven, Inc.

Date: March 28, 2019

By: /s/ MARK A. MCCAMISH  
Mark A. McCamish, M.D.  
President and Chief Executive Officer  
*(Principal Executive Officer)*

Date: March 28, 2019

By: /s/ ANN D. RHOADS  
Ann D. Rhoads  
Chief Financial Officer  
*(Principal Financial and Accounting Officer)*

**POWER OF ATTORNEY**

Each person whose individual signature appears below hereby authorizes and appoints Mark A. McCamish and Ann D. Rhoads, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual 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/ Mark A. McCamish Mark A. McCamish, M.D.	President, Chief Executive Officer <i>(Principal Executive Officer)</i>	March 28, 2019
/s/ Ann D. Rhoads Ann D. Rhoads	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	March 28, 2019
/s/ Kristine M. Ball Kristine M. Ball	Director	March 28, 2019
/s/ Jeffrey W. Bird Jeffrey W. Bird, M.D.	Director	March 28, 2019
/s/ Ian T. Clark Ian T. Clark	Director	March 28, 2019
/s/ Dennis J. Henner Dennis J. Henner, Ph.D.	Director	March 28, 2019
/s/ Ravindra Majeti Ravindra Majeti, M.D.	Director	March 28, 2019
/s/ Irving L. Weissman Irving L. Weissman, M.D.	Director	March 28, 2019

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-225958) of Forty Seven, Inc. of our report dated March 28, 2019, with respect to the financial statements of Forty Seven, Inc. included in this Annual Report (Form 10-K) of Forty Seven, Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP

San Jose, California

March 28, 2019



## CERTIFICATION

I, Mark A. McCamish, certify that:

1. I have reviewed this Annual Report on Form 10-K of Forty Seven, 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(s) 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) 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
  - (c) 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(s) 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 28, 2019

By: \_\_\_\_\_ /s/ Mark A. McCamish

**Mark A. McCamish, M.D.**  
**President and Chief Executive Officer**  
*(Principal Executive Officer)*

## CERTIFICATION

I, Ann D. Rhoads, certify that:

1. I have reviewed this Annual Report on Form 10-K of Forty Seven, 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(s) 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) 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
  - (c) 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(s) 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 28, 2019

By: \_\_\_\_\_ /s/ Ann D. Rhoads

**Ann D. Rhoads**  
**Chief Financial Officer**  
**(Principal Financial Officer)**

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Forty Seven, Inc. (the "Company") on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark A. McCamish, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2019

By: \_\_\_\_\_  
/s/ Mark A. McCamish  
**Mark A. McCamish, M.D.**  
**President and Chief Executive Officer**  
*(Principal Executive Officer)*

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Forty Seven, Inc. (the "Company") on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ann D. Rhoads, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2019

By: \_\_\_\_\_ /s/ Ann D. Rhoads  
**Ann D. Rhoads**  
**Chief Financial Officer**  
*(Principal Financial Officer)*