

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2018

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38554

**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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input 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

As of August 1, 2018, the registrant had 31,048,086 shares of common stock, \$0.0001 par value per share, outstanding.

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### Where You Can Find More Information

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website ([ir.fortyseveninc.com/investor-relations](http://ir.fortyseveninc.com/investor-relations)), SEC filings, webcasts, press releases, and conference calls. We use these mediums, including our website, to communicate with our members and public about our company, our products, and other issues. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website.

## Item 1. Financial Statements.

**Forty Seven Inc.**  
**Condensed Balance Sheets**  
*(In thousands)*

	June 30, 2018 <u>(Unaudited)</u>	December 31, 2017 <u>(1)</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 13,114	\$ 24,417
Short-term investments	44,893	63,694
Prepaid expenses and other current assets	3,597	4,450
Total current assets	<u>61,604</u>	<u>92,561</u>
Property and equipment, net	1,165	1,358
Other assets	5,326	1,546
Total assets	<u>\$ 68,095</u>	<u>\$ 95,465</u>
<b>Liabilities, convertible preferred stock and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 3,102	\$ 3,705
Accrued liabilities	5,577	4,808
Deferred grant funding, current	5,565	2,759
Total current liabilities	<u>14,244</u>	<u>11,272</u>
Lease-related liabilities, noncurrent	413	476
Other long-term liabilities	171	255
Total liabilities	<u>14,828</u>	<u>12,003</u>
Commitments and Contingencies (Note 5)		
Convertible preferred stock	149,397	—
Stockholders' equity (deficit):		
Convertible preferred stock	—	149,397
Common stock	1	1
Additional paid-in capital	4,793	3,507
Accumulated other comprehensive loss	(28)	(44)
Accumulated deficit	(100,896)	(69,399)
Total stockholders' equity (deficit)	<u>(96,130)</u>	<u>83,462</u>
<b>Total liabilities, convertible preferred stock and stockholders' equity (deficit)</b>	<u>\$ 68,095</u>	<u>\$ 95,465</u>

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

(1) The balance sheet as of December 31, 2017 is derived from the audited financial statements as of that date.

**Forty Seven Inc.**  
**Condensed Statements of Operations and Comprehensive Loss**  
(Unaudited)  
(In thousands, except share and per share data)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Operating expenses:				
Research and development	\$ 13,596	\$ 9,189	\$ 24,749	\$ 18,370
General and administrative	3,362	1,697	7,205	3,458
Total operating expenses	<u>16,958</u>	<u>10,886</u>	<u>31,954</u>	<u>21,828</u>
Loss from operations	(16,958)	(10,886)	(31,954)	(21,828)
Interest and other income, net	236	59	457	93
Net loss	(16,722)	(10,827)	(31,497)	(21,735)
Unrealized gain (loss) on available-for-sale securities	43	(1)	16	(17)
Comprehensive loss	<u>\$ (16,679)</u>	<u>\$ (10,828)</u>	<u>\$ (31,481)</u>	<u>\$ (21,752)</u>
Net loss per share, basic and diluted	<u>\$ (2.52)</u>	<u>\$ (1.68)</u>	<u>\$ (4.76)</u>	<u>\$ (3.39)</u>
Shares used in computing net loss per share, basic and diluted	<u>6,636,862</u>	<u>6,431,534</u>	<u>6,618,736</u>	<u>6,404,423</u>

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

**Forty Seven, Inc.**  
**Condensed Statements of Cash Flows**  
(Unaudited)  
(In thousands)

	Six Months Ended June 30,	
	2018	2017
<b>Cash flows from operating activities:</b>		
Net loss	\$ (31,497)	\$ (21,735)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,047	202
Depreciation and amortization	193	183
Accretion of premium/discount on marketable securities	(180)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	853	1,062
Other assets	(1,412)	(251)
Accounts payable	(603)	(1,785)
Accrued liabilities	762	3,341
Deferred grant funding	2,806	3,338
Lease-related liabilities	(56)	(40)
Other long-term liabilities	—	(20)
Net cash used in operating activities	<u>(28,087)</u>	<u>(15,705)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	—	(43)
Purchases of available-for-sale securities	(16,368)	(26,998)
Proceeds from maturities of available-for-sale securities	35,365	4,000
Net cash provided by (used in) investing activities	<u>18,997</u>	<u>(23,041)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	40,377
Proceeds from issuance of common stock upon exercise of stock options	155	5
Payments of deferred offering costs	(2,368)	—
Net cash (used in) provided by financing activities	<u>(2,213)</u>	<u>40,382</u>
Net (decrease) increase in cash and cash equivalents	(11,303)	1,636
Cash and cash equivalents — beginning of period	24,417	9,742
Cash and cash equivalents — end of period	<u>\$ 13,114</u>	<u>\$ 11,378</u>
<b>Supplemental disclosures of cash flow information:</b>		
Deferred offering costs included in accounts payable and accrued liabilities	\$ 1,697	\$ —

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

**Forty Seven Inc.**  
**Notes to Condensed 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.

***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 \$58.0 million as of June 30, 2018. Since inception through June 30, 2018, the Company has incurred cumulative net losses of \$100.9 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 including the net proceeds received from its initial public offering will be sufficient to fund operating expenses and capital expenditure requirements for a period of at least one year from the date the unaudited financial statements are filed with the Securities and Exchange Commission (SEC).

***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.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The interim condensed balance sheet as of June 30, 2018, the condensed statements of operations and comprehensive loss for the three and six months ended June 30, 2018 and 2017, and the statements of cash flows for the six months ended June 30, 2018 and 2017 are unaudited. The unaudited interim condensed financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's financial position as of June 30, 2018, its results of operations for the three and six months ended June 30, 2018 and 2017, and cash flows for the six months ended June 30, 2018 and 2017. The financial data and the other financial information contained in these notes to the condensed financial statements related to the three month and six month periods are also unaudited. The results of operations for the three and six months ended June 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other future annual or interim period. The condensed balance sheet as of December 31, 2017 included herein was derived from the audited financial statements as of that date. These condensed financial statements should be read in conjunction with the Company's audited financial statements included in the prospectus dated June 27, 2018 ("Prospectus") that forms a part of the Company's Registration Statements on Form S-1 (File Nos. 333-2225390 and 333-225933), as filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424 promulgated under the Securities Act of 1933, as amended.

### ***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“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, 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.

### ***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.

### ***Deferred Offering Costs***

Offering costs, consisting of legal, accounting, printer and SEC and FINRA filing fees related to the initial public offering (“IPO”), were deferred and were offset against the offering proceeds upon the completion of the IPO. As of June 30, 2018, \$4.1 million of deferred offering costs have been capitalized, which is included in other assets in the accompanying condensed balance sheet. There were no deferred offering costs recorded as of December 31, 2017.

### ***Recent Accounting Pronouncements***

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases (ASU 2016-02)* which provides accounting guidance for both lessee and lessor accounting models. The principle of ASU 2016-02 is that a lessee should recognize the assets and liabilities that arise from leases. Lessees will need to recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability. For income statement purposes, ASU 2016-02 requires leases to be classified as either operating or finance. Operating leases will result in straight-line expense while finance leases will result in a front-loaded expense pattern. ASU 2016-02 is effective for years beginning after December 15, 2019. Early adoption is permitted. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements (“ASU No. 2018-11”)*. In issuing ASU No. 2018-11, the FASB is permitting another transition method for ASU 2016-02, which allows the 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 is currently evaluating the impact and materiality that this ASU will have on its condensed financial statements. However, the Company does expect an increase in its condensed assets and liabilities upon adoption of this standard.

## **3. Fair Value Measurements**

The Company measures and reports its cash equivalents and short-term investments 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

**Forty Seven Inc.**  
**Notes to Condensed Financial Statements**

investments held as of June 30, 2018 and December 31, 2017 had maturities of less than one year. There were no realized gains or losses on investments for the three and six months ended June 30, 2018 and 2017.

The fair value and amortized cost of cash equivalents and available-for-sale securities by major security type as of June 30, 2018 and December 31, 2017 are presented in the following tables:

	As of June 30, 2018				
	Fair Value Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Market Value
	(In thousands)				
Money market funds	Level 1	\$ 8,485	\$ —	\$ —	\$ 8,485
Commercial paper	Level 2	19,604	—	—	19,604
Corporate debt securities	Level 2	9,562	—	(16)	9,546
Asset-backed securities	Level 2	9,769	—	(8)	9,761
US government debt securities	Level 2	5,986	—	(4)	5,982
Total cash equivalents and available-for-sale securities		<u>\$ 53,406</u>	<u>\$ —</u>	<u>\$ (28)</u>	<u>\$ 53,378</u>

	As of December 31, 2017				
	Fair Value Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Market Value
	(In thousands)				
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>

#### 4. Balance Sheet Components

##### *Accrued Liabilities*

Accrued liabilities consist of the following:

	June 30, 2018	December 31, 2017
	(In thousands)	
Accrued research and development expenses	\$ 2,903	\$ 4,096
Accrued offering costs	1,343	—
Accrued bonus	748	—
Lease-related liabilities, current	140	133
Other	443	579
Total accrued liabilities	<u>\$ 5,577</u>	<u>\$ 4,808</u>

#### 5. 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 six months ended June 30, 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 June 30, 2018 and December 31, 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. As of June 30, 2018 and December 31, 2017, the Company had received \$1.6 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”). The LLS research grant stipulates various milestone-based payments with a total award of \$4.0 million through December 2019. As of June 30, 2018 and December 31, 2017, the Company had received \$3.8 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 recognizes research grants as a reduction of research and development expense when the eligible costs are incurred. For the three months ended June 30, 2018 and 2017, the Company recognized \$1.9 million and \$0.8 million as a reduction to research and development expenses for research grants. For the six months ended June 30, 2018 and 2017, the Company recognized \$3.4 million and \$1.4 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 June 30, 2018, the Company recorded a receivable \$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.

***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 to maintain the license and could be required to pay up to \$43.0 million in milestone payments in aggregate based on the achievement of certain development and regulatory approval milestones. No such milestone payments have been made as of June 30, 2018. In addition, the Company could be required to pay Blink a royalty of single digit percentage on net sales of licensed products, which is subject to two buy-out provisions for a one-time payment that can be exercised by the Company prior to certain development milestones being achieved. During the three and six months ended June 30, 2018, the Company recognized \$2.5 million in research and development expense related to the Blink asset purchase agreement.

## 6. Convertible Preferred Stock

Through December 31, 2017, the Company's convertible preferred stock was classified in permanent equity as redemption of the convertible preferred stock was in the control of the Company. However, changes to the Company's board composition during the first quarter of 2018, resulted in the convertible preferred stock being reclassified outside of stockholders' deficit because, in the event of certain "liquidation events" that are not solely within the Company's control (including merger, acquisition, or sale of all or substantially all of our assets), the shares could become redeemable at the option of the holders. As of June 30, 2018, shares of the convertible preferred stock were not redeemable and the Company did not adjust the carrying values of the convertible preferred stock to the deemed liquidation values of such shares since a liquidation event was not probable of occurring.

On the completion of the IPO on July 2, 2018, all outstanding shares of convertible preferred stock were automatically converted into 16,215,896 shares of common stock.

## 7. 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 June 30, 2018, there were 3,363,968 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.

The following summarizes option activity for the six months ended June 30, 2018:

	Shares Issuable Under Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contract Term  (In years)	Aggregate Intrinsic Value  (In thousands)
Balance, December 31, 2017	2,102,528	\$ 4.47	9.43	\$ 1,672
Options granted	1,323,138	8.89		
Options exercised	(28,630)	5.43		
Options forfeited	(22,718)	4.31		
Balance outstanding June 30, 2018	<u>3,374,318</u>	6.20	9.28	<u>33,067</u>
Exercisable, June 30, 2018	<u>1,982,455</u>	6.03	9.24	<u>19,773</u>
Vested and expected to vest, June 30, 2018	<u>3,374,318</u>	6.20	9.28	<u>33,067</u>

Total stock-based compensation was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Research and development	\$ 162	\$ 39	\$ 297	\$ 65
General and administrative	454	104	750	137
Total	<u>\$ 616</u>	<u>\$ 143</u>	<u>\$ 1,047</u>	<u>\$ 202</u>

**Restricted Stock**

As of June 30, 2018 and December 31, 2017, there was \$171,000 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:

	<b>Number of Restricted Shares Outstanding</b>
Unvested shares—December 31, 2017	156,988
Early exercised options	11,418
Restricted shares vested	(54,839)
Repurchased by the Company	(41,935)
Unvested shares—June 30, 2018	71,632

**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 25, 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. Total stock-based compensation related to the ESPP for the six months ended June 30, 2018 was immaterial to the condensed financial statements.

**8. Net Loss Per Share**

As discussed in Note 10, effective upon the closing of the Company’s IPO on July 2, 2018, all outstanding shares of convertible preferred stock were automatically converted into 16,215,896 shares of common stock. In addition, 8,090,250 shares of common stock were issued in the IPO. 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:

	<b>June 30,</b>	
	<b>2018</b>	<b>2017</b>
Convertible preferred stock	16,215,896	8,626,388
Stock options to purchase common stock	3,374,318	1,094,930
Restricted stock subject to future vesting	71,633	190,456
Total	19,661,847	9,911,774

**9. Income Taxes**

In December 2017, the Tax Cuts and Jobs Act of 2017 (the “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. However, since the Company established a valuation allowance to offset its deferred tax assets, there was no impact to the effective tax rate, as any changes to deferred taxes would be offset by the valuation allowance. The deferred tax remeasurement is provisional and is subject to revision as the Company completes its analysis of the Tax Act, collects and prepares necessary data and interprets any additional guidance issued by standard-setting bodies. The Company currently anticipates finalizing and recording any resulting adjustments related to the tax effects of the Tax Act in 2018.

**10. Subsequent Events**

***Initial Public Offering***

On July 2, 2018, the Company completed its 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 of \$9.1 million and offering expenses of \$4.1 million.

Upon the closing of the IPO on July 2, 2018, all outstanding shares of convertible preferred stock were automatically converted into 16,215,896 shares of common stock. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding. The condensed financial statements as of June 30, 2018, including share and per share amounts, do not give effect to the IPO, or the conversion of the convertible preferred stock, as the IPO and such conversions were completed subsequent to June 30, 2018.

The following table represents the unaudited pro forma Balance Sheet data as of June 30, 2018 and has been prepared assuming (1) the automatic conversion of all outstanding shares of convertible preferred stock into 16,215,896 shares of common stock upon the completion of the IPO, and (2) the issuance of common shares in the IPO including the exercise of the underwriters's over-allotment option.

	<b>As of June 30, 2018</b>	
	<b>Actual</b>	<b>Pro Forma</b>
	<b>(In thousands)</b>	
Cash, cash equivalents, and short-term investments	\$ 58,007	\$ 174,325
Total assets	68,095	180,348
Convertible preferred stock	149,397	—
Total stockholders' equity (deficit)	(96,130)	165,520

***Synthon License Agreement***

On July 16, 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 is 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 \$47.0 million 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. 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 addition, the Company 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. The Company has the right to buy out its royalty obligations for each licensed product in full by paying Synthon specified lump sum amounts prior to the occurrence of certain defined events. All payments under the settlement and license agreement are specified in Euros and have been converted into U.S. Dollars based on the exchange rate as of July 16, 2018.

## Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

*You should read the following discussion of our financial condition and results of operations in conjunction with our condensed financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act of 1933, as amended, dated June 27, 2018 (the “Prospectus”). In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled “Risk Factors” under Part II, Item 1A below. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “predict,” “should,” “will” or the negative of these terms or other similar expressions.*

*In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.*

### Overview

We are a clinical-stage immuno-oncology company focused on developing novel checkpoint 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, dosed as a monotherapy or in combination with marketed cancer therapies, can transform the treatment of cancer. 5F9 has demonstrated promising activity in five Phase 1b/2 clinical trials in which we have treated over 190 relapsed or refractory cancer patients with solid or hematologic tumors. 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 primarily 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 preferred stock and the receipt of government and private grants. We are eligible to receive up to \$19.2 million in grants from the California Institute for Regenerative Medicine, or CIRM, and the Leukemia and Lymphoma Society, or LLS, of which \$12.6 million has been received through June 30, 2018.

On June 27, 2018, our Registration Statements on Form S-1 (File No. 333-225390 and 333-225933) relating to our initial public offering, or 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. The sale and issuance of 7,035,000 shares in the IPO closed on July 2, 2018 and the sale and issuance of an additional 1,055,250 shares pursuant to the underwriters’ over-allotment option closed on July 27, 2018. Upon the closing of the IPO on July 2, 2018, all outstanding shares of convertible preferred stock automatically converted into 16,215,896 shares of common stock. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding.

We have incurred net losses in each year since inception. Our net losses were \$44.9 million and \$19.5 million for 2017 and 2016, respectively. Our net loss was \$31.5 million and \$21.7 million for the six months ended June 30, 2018 and 2017, respectively and \$16.7 million and \$10.8 million for the three months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, we had an accumulated deficit of \$100.9 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. 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 2017 and as of June 30, 2018 totaled \$5.9 million and \$12.6 million, respectively. No grants were received during 2016.

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 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

### Three Months Ended June 30, 2018 and 2017

	Three Months Ended June 30,		Increase/ (Decrease)
	2018	2017	
	(In thousands)		
Operating expenses:			
Research and development	\$ 13,596	\$ 9,189	\$ 4,407
General administrative	3,362	1,697	1,665
Total operating expenses	16,958	10,886	6,072
Loss from operations	(16,958)	(10,886)	(6,072)
Interest and other income, net	236	59	177
Net loss	<u>\$ (16,722)</u>	<u>\$ (10,827)</u>	<u>\$ (5,895)</u>

#### Research and Development Expenses

Research and development expenses increased by \$4.4 million, or 48%, to \$13.6 million for the three months ended June 30, 2018 from \$9.2 million for the three months ended June 30, 2017. The increase was primarily due to a \$4.0 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 \$1.4 million reduction related to grant funding recognized under the CIRM and LLS grants during the three months ended June 30, 2018. There was also a \$1.1 million increase in personnel-related costs, including stock-based compensation. In addition, there was a \$0.7 million increase in our other preclinical and discovery programs costs as we expanded our immuno-oncology efforts.

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

	Three Months Ended June 30,		Increase (Decrease)
	2018	2017	
	(In thousands)		
<i>Product-specific costs:</i>			
5F9	\$ 9,411	\$ 5,341	\$ 4,070
Grant funding reimbursement	(2,257)	(811)	(1,446)
<i>Non product-specific costs:</i>			
Stock-based compensation	162	39	123
Personnel-related	2,473	1,535	938
Other preclinical programs	3,807	3,085	722
Total research and development expenses	<u>\$ 13,596</u>	<u>\$ 9,189</u>	<u>\$ 4,407</u>

#### General and Administrative Expenses

General and administrative expenses increased by \$1.7 million, or 98%, to \$3.4 million for the three months ended June 30, 2018 from \$1.7 million for the three months ended June 30, 2017. The increase was primarily due to a \$1.2 million increase in personnel-related costs driven by an increase in headcount, a \$0.2 million increase in accounting and consulting expenses incurred in connection with our preparation to become a public company, and a \$0.1 million increase in rent expense.

#### Interest and Other Income, Net

Interest and other income, net increased by \$0.2 million to \$0.2 million for the three months ended June 30, 2018 from \$59,000 for the three months ended June 30, 2017. The increase was primarily due to interest income earned from the investment of the net proceeds from the issuance of preferred stock in financings completed during 2017.

## Six Months Ended June 30, 2018 and 2017

	Six Months Ended June 30,		Increase/ (Decrease)
	2018	2017	
	(In thousands)		
<b>Operating expenses:</b>			
Research and development	\$ 24,749	\$ 18,370	\$ 6,379
General administrative	7,205	3,458	3,747
Total operating expenses	31,954	21,828	10,126
Loss from operations	(31,954)	(21,828)	(10,126)
Interest and other income, net	457	93	364
Net loss	<u>\$ (31,497)</u>	<u>\$ (21,735)</u>	<u>\$ (9,762)</u>

### Research and Development Expenses

Research and development expenses increased by \$6.4 million, or 35%, to \$24.8 million for the six months ended June 30, 2018 from \$18.4 million for the six months ended June 30, 2017. The increase was primarily due to a \$6.6 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 \$2.5 million reduction related to grant funding recognized under the CIRM and LLS grants during the six months ended June 30, 2018. There was also a \$1.5 million increase in personnel-related costs, including stock-based compensation driven by increased headcount. In addition, there was a \$0.8 million increase in our other preclinical and discovery programs costs as we expanded our immuno-oncology efforts.

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

	Six Months Ended June 30,		Increase (Decrease)
	2018	2017	
	(In thousands)		
<b>Product-specific costs:</b>			
5F9	19,439	12,793	6,646
Grant funding reimbursement	(3,963)	(1,422)	(2,541)
<b>Non product-specific costs:</b>			
Stock-based compensation	297	65	232
Personnel-related	4,136	2,864	1,272
Other preclinical programs	4,840	4,070	770
Total research and development expenses	<u>24,749</u>	<u>18,370</u>	<u>6,379</u>

### General and Administrative Expenses

General and administrative expenses increased by \$3.7 million, or 108%, to \$7.2 million for the six months ended June 30, 2018 from \$3.5 million for the six months ended June 30, 2017. The increase was primarily due to a \$1.9 million increase in personnel-related costs driven by an increase in headcount, a \$1.2 million increase in accounting and consulting expenses incurred in connection with our preparation to become a public company, and a \$0.2 million increase in rent expense.

### Interest and Other Income, Net

Interest and other income, net increased by \$0.4 million to \$0.5 million for the six months ended June 30, 2018 from \$0.1 million for the six months ended June 30, 2017. The increase was primarily due to interest income earned from the investment of the net proceeds from the issuance of our 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. Prior to our IPO, our operations have been financed primarily by net proceeds from the sale and issuance of our preferred stock. As of June 30, 2018, we had \$58.0 million in cash, cash equivalents and short-term investments. 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 with our existing capital resources, including the net proceeds we received from our IPO, will enable us to fund our operating expenses and capital expenditure requirements into 2020. 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:

	Six Months Ended	
	June 30,	
	2018	2017
	(In thousands)	
Cash used in operating activities	\$ (28,087)	\$ (15,705)
Cash provided by (used in) investing activities	18,997	(23,041)
Cash (used in) provided by financing activities	(2,213)	40,382
Net (decrease) increase in cash and cash equivalents	\$ (11,303)	\$ 1,636

### ***Operating Activities***

During the six months ended June 30, 2018, cash used in operating activities of \$28.1 million was attributable to a net loss of \$31.5 million, partially offset by a net change of \$2.4 million in our net operating assets and liabilities and \$1.1 million in non-cash charges. The non-cash charges consisted primarily of stock-based compensation of \$1.0 million. The change in operating assets and liabilities was primarily due to a \$2.8 million increase in deferred grant funding due to research grant award payments received and a \$0.9 million decrease in prepaid expenses and other current assets resulting from the timing of prepayments made for research and development activities, partially offset by a \$1.4 million increase in other assets primarily resulting from deferred offering costs incurred but not paid.

During the six months ended June 30, 2017, cash used in operating activities of \$15.7 million was attributable to a net loss of \$21.7 million, partially offset by a net change of \$5.6 million in our net operating assets and liabilities and \$0.4 million in non-cash charges, which consisted of depreciation and amortization and stock-based compensation. The change in operating assets and liabilities was primarily due to a \$3.3 million increase in deferred grant funding due to research grant award payments received, a \$3.3 million increase accrued liabilities resulting primarily from increases in our research and development activities, and a \$1.1 million decrease in prepaid expenses and other current assets resulting from the timing of prepayments made for research and development activities. This was partially offset by a \$1.7 million decrease in accounts payable due to timing of payments and a \$0.3 million increase in other assets due to prepayments made for long-term research and development.

### ***Investing Activities***

During the six months ended June 30, 2018, cash provided by investing activities was \$19.0 million related to the maturity of investments of \$35.4 million, partially offset by the purchase of short-term investments of \$16.4 million.

During the six months ended June 30, 2017, cash used for investing activities was \$23.0 million related primarily to the purchase of short-term investments of \$27.0 million, partially offset by the maturity of investments of \$4.0 million.

### ***Financing Activities***

During the six months ended June 30, 2018, cash used in financing activities was \$2.2 million related primarily to payments of deferred offering costs.

During the six months ended June 30, 2017, cash provided by financing activities was \$40.4 million related to the net proceeds from the issuance of preferred stock.

### **Contractual Obligations and Commitments**

There have been no material changes to our contractual obligations as of June 30, 2018, as compared to those disclosed in the Prospectus as of December 31, 2017, except as discussed below.

#### ***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 Agreement**

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 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.

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 is subject to the satisfaction of specified conditions, including 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. Our obligation to withdraw such proceedings and the effectiveness of the release of claims by Synthon and us are subject to (i) SSB agreeing to release us from all claims and liabilities under the USPTO and EPO proceedings and (ii) SSB agreeing to grant us a direct license to the sublicensed patents in the event the license between SSB and Synthon is terminated.

Our sublicense will include the right to further sublicense the applicable patent rights to our collaborators, corporate partners and service providers and will cover one named product, which will be 5F9. We will 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 will retain 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, the Company agreed to pay Synthon an aggregate of up to approximately \$47.0 million 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. 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 addition, the Company 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. The Company has the right to buy out its royalty obligations for each licensed product in full by paying Synthon specified lump sum amounts prior to the occurrence of certain defined events. All payments under the settlement and license agreement are specified in Euros and have been converted into U.S. Dollars based on the exchange rate as of July 16, 2018.

## **Off-Balance Sheet Arrangements**

During 2017 and the six months ended June 30, 2018, 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 condensed 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.

We believe that the assumptions and estimates associated with accrued research and development expenditures and stock-based compensation have the most significant impact on our condensed financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

There have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in the section titled “Management’s Discussion and Analysis of Financial Condition and Operations” included in the Prospectus, except for the determination of the fair value of our common stock, which is used in estimating the fair value of stock-based awards at grant date. Prior to the IPO, our common stock was not publicly traded, therefore we estimated the fair value of our common stock as discussed in the Prospectus. Following our IPO, the closing sale price per share of our common stock as reported on the Nasdaq Global Select Market on the date of grant will be used to determine the exercise price per share of our share-based awards to purchase common stock.

### **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

### **Recent Accounting Pronouncements**

Please refer to Note 2 to our unaudited condensed consolidated financial statements appearing under Part 1, Item 1 for a discussion of new accounting standards updates that may impact us.

### **Item 3. 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 \$58.0 million and \$88.1 million as of June 30, 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 vendors for research and development services with payments denominated in foreign currencies, including the British Pound. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our financial statements and we have not had a formal hedging program with respect to foreign currency. A 10% increase or decrease in current exchange rates would not have a material effect on our financial results.

### **Item 4. Controls and Procedures.**

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized,

and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

### **Remediation Efforts on Previously Identified 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, creating a formal month-end close process, and establishing more robust processes supporting internal controls over financial reporting, including accounting policies and procedures. Our remediation efforts are ongoing. 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, 2017 in accordance with the provisions of the Sarbanes-Oxley 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.

### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Inherent Limitations on Effectiveness of Controls**

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, in designing and evaluating the disclosure controls and procedures, management recognizes that any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

## PART II-OTHER INFORMATION

### Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of 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 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q 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 Quarterly 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 \$31.5 million for 2016, 2017 and the six months ended June 30, 2018, respectively. As of June 30, 2018, we had an accumulated deficit of \$100.9 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 June 30, 2018, we had cash, cash equivalents and short-term investments of \$58.0 million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments, together with the net proceeds from our IPO, 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 Therapeutics, Inc., Surface Oncology, Inc., Novimmune SA, OSE Immunotherapeutics SA, Aurigene Discovery Technologies Ltd 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. If Lonza is unable to supply us with sufficient clinical and commercial grade quantities of 5F9, 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 June 30, 2018, the only patent applications solely owned by us are provisional patent applications and PCT applications, and we do not own any issued patents.

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.

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-SIRPα 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. On June 4, 2018, we acquired the opposition against this European patent from the original opponent. Pursuant to the agreement, we and Synthon Biopharmaceuticals B.V., or 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.

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, 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 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. Please see Part 1, Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations and Commitments – License Agreement” for further information regarding the settlement and license agreement.

We may need to obtain additional licenses to use our anti-SIRP $\alpha$  antibodies for the treatment of cancer or risk litigation in connection with our commercialization of anti-SIRP $\alpha$  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 expected 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 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 June 30, 2018, we had 48 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**

***We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.***

Prior to our initial public offering, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. In connection with the audit of our financial statements, we identified material weaknesses 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 financial statements will not be prevented or detected on a timely basis. The material weaknesses related to our accounting for complex transactions and the timing of our recognition of research and development expenses. We are implementing measures designed to improve our internal control over financial reporting to remediate these material weaknesses including, the engagement of technical accounting consulting resources, plans to hire additional finance department employees and the implementation of more formal policies and procedures related to the accounting for our procurement and vendor payment process.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

If we fail to remediate our existing material weaknesses or identify new material weaknesses in our internal controls over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to conclude that our internal controls over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting when we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

***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 shares are restricted from immediate resale but 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.

All shares of common stock not sold in our initial public offering will be available for sale in the public market beginning after the end of the 180th day after the date of our initial public offering following the expiration of lock-up agreements between our stockholders and certain of the underwriters for this offering, subject, in the case of our affiliates, to the conditions of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. Morgan Stanley & Co. LLC and Credit Suisse Securities (USA) LLC on behalf of the underwriters may release these stockholders from their lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market subject to the conditions of Rule 144 under the Securities Act.

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 June 30, 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.

***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. Our remediation efforts are ongoing. 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.

***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. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.***Sales of Unregistered Securities*

Since April 1, 2018 we have made sales of the following unregistered securities (share and per share amounts give effect to a 1-for-7.75 reverse stock split of our common stock and preferred stock effected on June 14, 2018):

(1) Between April 1, 2018 and June 30, 2018, we granted stock options or restricted stock awards under our 2015 Equity Incentive Plan and 2018 Equity Incentive Plan to purchase an aggregate of 1,209,493 shares of our common stock at exercise prices ranging between \$8.7575 and \$16.00 per share to a total of 58 employees, directors and consultants.

(2) Between April 1, 2018 and June 30, 2018, we issued and sold to our employees, directors and consultants an aggregate of 28,630 shares of our common stock upon the exercise of options for aggregate proceeds of \$155,391.

The issuances and sales of the securities listed in (1) and (2) above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act or Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions by an issuer not involving a public offering or transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701.

*Use of Proceeds from our Initial Public Offering of Common Stock*

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.

*Repurchase of Shares of Company Equity Securities.*

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

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 <a href="#">Exhibits 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
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			

\* The Certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Forty Seven, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Quarterly Report on Form 10-Q) irrespective of any general incorporation language contained in such filing.



**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: August 13, 2018

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

Date: August 13, 2018

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







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

In connection with the Quarterly Report of Forty Seven Inc. (the "Company") on Form 10-Q for the period ending June 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of her 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 result of operations of the Company.

Date: August 13, 2018

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