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, 2019

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	**47-4065674**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1490 O'Brien Drive, Suite A Menlo Park, California 94025	**94025**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	Ticker Symbol	Name of each exchange on which registered
Common Stock, $0.0001 par value	FTSV	The Nasdaq Global Select Market

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

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

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

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

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

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

As of August 6, 2019, the registrant had 42,215,143 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), SEC filings, webcasts, press releases, and conference calls. We use these mediums, including our website, to communicate with our stockholders and the 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, 2019 (Unaudited)	December 31, 2018 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 17,849	$ 10,837
Short-term investments	81,158	128,186
Prepaid expenses and other current assets	11,861	6,835
Total current assets	110,868	145,858
Property and equipment, net	1,288	1,360
Operating lease right-of-use assets	2,579	—
Other assets	1,067	2,219
Total assets	$ 115,802	$ 149,437
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 8,499	$ 4,621
Accrued liabilities	9,719	9,044
Lease liabilities, current	1,397	—
Deferred grant funding, current	2,742	1,744
Total current liabilities	22,357	15,409
Lease liabilities, noncurrent	1,600	—
Deferred rent, noncurrent	—	331
Other long-term liabilities	361	476
Total liabilities	24,318	16,216
Commitments and Contingencies		
Stockholders' equity:		
Common stock	3	3
Additional paid-in capital	277,413	273,069
Accumulated other comprehensive income (loss)	59	(82)
Accumulated deficit	(185,991)	(139,769)
Total stockholders' equity	91,484	133,221
Total liabilities and stockholders' equity	$ 115,802	$ 149,437

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

(1) The balance sheet as of December 31, 2018 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 18,829	$ 13,596	$ 37,955	$ 24,749
General and administrative	5,057	3,362	9,641	7,205
Total operating expenses	23,886	16,958	47,596	31,954
Loss from operations	(23,886)	(16,958)	(47,596)	(31,954)
Interest and other income, net	680	236	1,374	457
Net loss	(23,206)	(16,722)	(46,222)	(31,497)
Unrealized gains on available-for-sale securities	41	43	141	16
Comprehensive loss	$ (23,165)	$ (16,679)	$ (46,081)	$ (31,481)
Net loss per share, basic and diluted	$ (0.74)	$ (2.52)	$ (1.48)	$ (4.76)
Shares used in computing net loss per share, basic and diluted	31,355,135	6,636,862	31,261,182	6,618,736

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

Forty Seven Inc.
Condensed Statements of Stockholders' Equity
For the Three and Six Months Ended June 30, 2019 and 2018
(Unaudited)
(In thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	(Loss)	Deficit	Equity
Balance at December 31, 2018	—	$ —	31,079,150	$ 3	$ 273,069	$ (82)	$ (139,769)	$ 133,221
Issuance of common stock for exercise of stock options	—	—	174,793	—	789	—	—	789
Issuance of common stock pursuant to the ESPP	—	—	44,656	—	588	—	—	588
Vesting of early exercised stock options	—	—	—	—	113	—	—	113
Stock-based compensation	—	—	—	—	1,104	—	—	1,104
Net loss	—	—	—	—	—	—	(23,016)	(23,016)
Other comprehensive income	—	—	—	—	—	100	—	100
Balance at March 31, 2019	—	—	31,298,599	3	275,663	18	(162,785)	112,899
Issuance of common stock for exercise of stock options	—	—	133,723	—	$ 612	—	—	612
Vesting of early exercised stock options	—	—	—	—	13	—	—	13
Stock-based compensation	—	—	—	—	1,125	—	—	1,125
Net loss	—	—	—	—	—	—	(23,206)	(23,206)
Other comprehensive income	—	—	—	—	—	41	—	41
Balance at June 30, 2019	—	$ —	31,432,322	$ 3	$ 277,413	$ 59	$ (185,991)	$ 91,484

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Comprehensive Loss	Deficit	Equity
Balance at December 31, 2017	16,215,896	$ 149,397	6,751,157	$ 1	$ 3,507	$ (44)	$ (69,399)	$ 83,462
Settlement of fractional shares from reverse stock split	—	—	(15)	—	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	13	—	—	13
Stock-based compensation	—	—	—	—	431	—	—	431
Repurchase of shares	—	—	(41,935)	—	—	—	—	—
Net loss	—	—	—	—	—	—	(14,775)	(14,775)
Other comprehensive loss	—	—	—	—	—	(27)	—	(27)
Balance at March 31, 2018	16,215,896	149,397	6,709,207	1	3,951	(71)	(84,174)	69,104
Issuance of common stock for exercise of stock options	—	—	28,630	—	55	—	—	55
Vesting of early exercised stock options	—	—	—	—	171	—	—	171
Stock-based compensation	—	—	—	—	616	—	—	616
Net loss	—	—	—	—	—	—	(16,722)	(16,722)
Other comprehensive income	—	—	—	—	—	43	—	43
Balance at June 30, 2018	16,215,896	$ 149,397	6,737,837	$ 1	$ 4,793	$ (28)	$ (100,896)	$ 53,267

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,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (46,222)	$ (31,497)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,229	1,047
Depreciation and amortization	233	193
Amortization of right-of-use assets	461	—
Accretion of discounts on marketable securities	(730)	(180)
Realized gain on sale of available-for-sale securities	(4)	—
Change in fair value of embedded derivative	12	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,026)	853
Other assets	1,620	(1,412)
Accounts payable	3,720	(603)
Accrued liabilities	571	762
Deferred grant funding	997	2,806
Lease related liabilities	(530)	(56)
Net cash used in operating activities	(42,669)	(28,087)
Cash flows from investing activities:		
Purchases of property and equipment	(70)	—
Purchases of available-for-sale securities	(68,819)	(16,368)
Proceeds from sales of available-for-sale securities	3,996	—
Proceeds from maturities of available-for-sale securities	112,727	35,365
Net cash provided by investing activities	47,834	18,997
Cash flows from financing activities:		
Payments of deferred offering costs	(143)	(2,368)
Proceeds from issuance of common stock upon ESPP purchase	588	—
Proceeds from issuance of common stock upon exercise of stock options	1,402	155
Net cash provided by (used in) financing activities	1,847	(2,213)
Net increase (decrease) in cash and cash equivalents	7,012	(11,303)
Cash and cash equivalents — beginning of period	10,837	24,417
Cash and cash equivalents — end of period	$ 17,849	$ 13,114
Supplemental disclosures of cash flow information:		
Noncash investing and financing activities:		
Purchase of property and equipment through accounts payable and accruals	$ 91	$ —
Deferred offering costs included in accounts payable and accrued liabilities	$ 326	$ 1,697
Lease liability obtained in exchange for right-of-use asset	$ 712	$ —

The accompanying notes are an integral part of these unaudited 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 $99.0 million as of June 30, 2019. Since inception through June 30, 2019, the Company has incurred cumulative net losses of $186.0 million. Management expects to incur additional losses in the future to conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The interim condensed financial statements 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, results of operations and cash flows for the periods presented. The results of operations for the three and six months ended June 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. The condensed balance sheet as of December 31, 2018 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 and related notes as set forth in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, as filed with the SEC on March 28, 2019.

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, the fair value of investments, income tax uncertainties, lease liability, 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.

Leases

The Company adopted Accounting Standards Update (ASU) No. 2016-02, *Leases* on January 1, 2019 using the modified retrospective method. For its operating leases in excess of 12 months, the Company recognizes a right-of-use asset and a lease liability on its balance sheet. The lease liability is determined as the present value of future lease payments using an estimated rate of interest that the Company would pay to borrow equivalent funds on a collateralized basis at the adoption date for the existing lease and at lease commencement date for new leases. The right-of-use asset is based on the liability adjusted for any prepaid or deferred rent, and lease incentives, as applicable. The lease term at the commencement date is determined by considering whether renewal options and termination options are reasonably assured of exercise.

Rent expense for the operating leases is recognized on a straight-line basis over the lease term and is included in operating expenses on the statements of operations and comprehensive loss. Variable lease payments include lease operating expenses.

The accompanying condensed financial statements as of and for the three and six months ended June 30, 2019 are presented under Topic 842. The prior periods continue to be reported in accordance with previous lease guidance, ASC Topic 840, *Leases*. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows the Company to carry forward the historical lease classification of the leases in place as of January 1, 2019. As allowed under Topic 842, the Company has elected to not separate lease and nonlease components. The Company has also elected to not apply the recognition requirement of Topic 842 to leases with a term of 12 months or less.

The impact of the adoption of Topic 842 on the accompanying condensed balance sheet as of January 1, 2019 was as follows:

	December 31, 2018	Adjustments due to the adoption of Topic 842	January 1, 2019
		(In thousands)	
Assets			
Operating lease right-of-use asset	$ —	$ 2,328	$ 2,328
Liabilities and stockholders' equity			
Deferred rent classified as accrued liabilities	$ 155	$ (155)	$ —
Lease liability, current	$ —	$ 968	$ 968
Lease liability, noncurrent	$ —	$ 1,847	$ 1,847
Deferred rent, noncurrent	$ 331	$ (331)	$ —

The adjustments due to the adoption of Topic 842 related to the recognition of an operating lease right-of-use asset and lease liability for the Company's existing property operating lease and the derecognition of the deferred rent recognized under Topic 840. There was no impact on the Company’s statement of operations and comprehensive loss from the adoption and no cumulative-effect adjustment to the beginning accumulated deficit.

3. Fair Value Measurements

The Company measures and records 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 investments held as of June 30, 2019 and December 31, 2018 had maturities of less than one year. There were no significant realized gains or losses on investments for the three and six months ended June 30, 2019 and 2018. Any identified unrealized losses were deemed to be temporary. The Company does not intend to sell its securities that are in an unrealized loss position, if any, and it is unlikely that the Company will be required to sell its securities before recovery of their amortized cost basis, which may be maturity.

The fair value and amortized cost of cash equivalents and available-for-sale securities by major security type as of June 30, 2019 and December 31, 2018 are presented in the following tables:

	As of June 30, 2019				
	Fair Value Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Market Value
		(In thousands)			
Money market funds	Level 1	$ 15,670	$ —	$ —	$ 15,670
Commercial paper	Level 2	24,271	—	—	24,271
Corporate debt securities	Level 2	20,453	24	—	20,477
Asset-backed securities	Level 2	16,470	11	—	16,481
US government debt securities	Level 2	19,905	24	—	19,929
Total cash equivalents and available-for-sale securities		$ 96,769	$ 59	$ —	$ 96,828

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

The Company's contingent milestone payments in its agreement with the Leukemia & Lymphoma Society, Inc. ("LLS") were concluded to be an embedded derivative. The embedded derivative contains unobservable inputs that are supported by little or no market activity at the measurement date. Accordingly, the Company's embedded derivative is measured at fair value on a recurring basis using unobservable inputs that are classified as Level 3 inputs. The Company recorded a liability for the derivative of approximately $0.3 million, as part of other long-term liabilities as of June 30, 2019 and December 31, 2018. Refer to Note 5 for the valuation techniques and assumptions used in estimating the fair value of the embedded derivative.

The change in fair value of the embedded derivative is presented in the following table:

	Six Months Ended June 30, 2019
	(In thousands)
Beginning balance	$ 331
Change in fair value of embedded derivative	12
Ending balance	$ 343

4. Balance Sheet Components

Accrued Liabilities

Accrued liabilities consist of the following:

	June 30, 2019	December 31, 2018
	(In thousands)	
Accrued research and development expenses	$ 6,338	$ 5,870
Accrued bonuses	1,379	1,602
Deferred rent, current	—	155
Other	2,002	1,417
Total accrued liabilities	$ 9,719	$ 9,044

5. Research and License Agreements

California Institute of Regenerative Medicine Grants

In January 2017, the Company was awarded a research grant from the California Institute of Regenerative Medicine ("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. During the three and six months ended June 30, 2019, the Company received $2.0 million related to this grant. As of June 30, 2019 and December 31, 2018, the Company had received $9.2 million and $7.2 million under the award, respectively.

In November 2017, the Company was awarded a second research grant from CIRM for a separate clinical trial study. The total amount of the research grant awarded was $5.0 million in various milestone-based payments over a period of five years. During 2018, the award was amended to $3.2 million in various-milestone payments over a period of five years, as was provided for under the terms of the original award because the Company opted not to expand the patient population participating in the study. During the three and six months ended June 30, 2019, the Company received $0.7 million related to this grant. As of June 30, 2019 and December 31, 2018, the Company had received $3.1 million and $2.4 million under the award, respectively. 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 royalty payments, 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 LLS and amended the agreement to include an additional study in June 2018. The LLS research grant stipulates various milestone-based payments with a total award of $4.2 million through December 2019. During the three and six months ended June 30, 2019, the Company did not receive any payments related to this grant. As of June 30, 2019 and December 31, 2018, the Company had received $3.9 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 $15.0 million in total. The Company concluded that the contingent milestone payments were an embedded derivative and the Company recorded a liability for the derivative of approximately $0.3 million, as part of other long-term liabilities as of June 30, 2019 and December 31, 2018. The value of the embedded derivative was estimated using the probability-adjusted and discounted future milestone payments.

In July 2019, the Company entered into an amendment of its agreement with LLS to further advance the treatment of myelodysplastic syndromes ("MDS"). Under the collaboration, the Company is eligible for up to $3.0 million in additional milestone payments from LLS upon the achievement of certain clinical or regulatory milestones in addition to the $4.2 million award that the Company is eligible for pursuant to the March 2017 agreement. Pursuant to the amendment, potential future payments by the Company to LLS upon reaching certain development and regulatory approval milestones on the additional funding could be up to $6.0 million in total.

The Company recognizes research grants as a reduction of research and development expense when the eligible costs are incurred. Under both CIRM and LLS grants, the Company recognized a total of $0.9 million and $1.9 million as a reduction to research and development expenses for research grants for the three months ended June 30, 2019 and 2018, respectively. The Company recognized a total of $2.0 million and $3.4 million as a reduction to research and development expenses for research grants for the six months ended June 30, 2019 and 2018, respectively.

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, 2019, the Company recorded a receivable of $0.9 million from Merck for reimbursement of research and development costs incurred. Reimbursement under this collaboration agreement is recorded as a reduction to research and development expense. For the three months ended June 30, 2019 and 2018, the Company recognized $0.3 million and $0.4 million, respectively, as a reduction to research and development expenses under this collaboration agreement. For the six months ended June 30, 2019 and 2018, the Company recognized $0.9 million and $0.6 million, respectively, as a reduction to research and development expenses under this collaboration agreement.

6. Leases

The Company leases office property and laboratory space at its headquarters in Menlo Park (the "Menlo Park Lease") through August 2021. The lease requires monthly lease payments subject to annual increases throughout the lease term and includes a renewal option at the election of the Company to extend the lease for an additional five years. The landlord provided the Company with a tenant improvement allowance of $646,000.

In April 2019, the Company entered into a sublease (the "Sublease") to obtain 6,230 rentable square feet to expand its current headquarters through February 2021. The lease requires monthly lease payments subject to annual increases throughout the lease term.

In April 2019, the Company also entered into an amendment of Menlo Park Lease to add additional space to its headquarter lease upon the expiration of the Sublease in February 2021. Under the terms of the lease amendment, the lease for the additional space will commence on March 1, 2021 and the base rent for the additional space will be approximately $36,000 per month.

As of June 30, 2019, the weighted average remaining lease term was 2.1 years and the weighted average incremental borrowing rate used to determine the operating lease liabilities was 7.0%.

The undiscounted future non-cancellable lease payments under the Company's operating leases are as follows:

	June 30, 2019
	(In thousands)
Years	
Remaining 2019	$ 777
2020	1,584
2021	864
Thereafter	—
Total undiscounted lease payments	3,225
Present value adjustment for minimum lease commitments	(228)
Lease liabilities	$ 2,997

As of June 30, 2019, the current and noncurrent portion of the lease liabilities was $1.4 million and $1.6 million. Rent expense for the operating leases was $0.3 million for the three months ended June 30, 2019 and 2018, and $0.6 million for the six months ended June 30, 2019 and 2018. Variable lease payments for operating expenses were $0.1 million for the three months ended June 30, 2019 and 2018. Variable lease payments for operating expenses were $0.3 million and $0.2 million for the six months ended June 30, 2019 and 2018, respectively.

7. Stockholders' Equity

2015 and 2018 Equity Incentive Plans

The following summarizes option activity for the six months ended June 30, 2019:

	Shares Issuable Under Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term	Aggregate Intrinsic Value
			(In years)	(In thousands)
Balance, December 31, 2018	3,404,847	$ 6.55	8.82	$ 31,388
Options granted	186,652	14.57		
Options exercised	(308,516)	4.54		
Options forfeited	(101,845)	7.02		
Balance outstanding June 30, 2019	3,181,138	$ 7.20	8.45	$ 12,331
Exercisable, June 30, 2019	2,071,836	$ 6.46	8.32	$ 8,906
Vested and expected to vest, June 30, 2019	3,181,138	$ 7.20	8.45	$ 12,331

Total stock-based compensation was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Research and development	$ 431	$ 162	$ 886	$ 297
General and administrative	694	454	1,343	750
Total	$ 1,125	$ 616	$ 2,229	$ 1,047

Restricted Stock

As of June 30, 2019 and December 31, 2018, there was $18,000 and $144,000, respectively, 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:

	Number of Restricted Shares Outstanding
Unvested shares—December 31, 2018	49,052
Restricted shares vested	(33,999)
Unvested shares—June 30, 2019	15,053

Employee 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 initial offering period began June 27, 2018 and will end on August 15, 2020 with purchase dates of February 15, 2019, August 15, 2019, February 15, 2020, and August 15, 2020. Each subsequent offering will be approximately 24 months long and will consist of four purchase periods with purchase dates occurring on February 15 and August 15 of each year. On each purchase date, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date. Total stock-based compensation related to the ESPP for the three and six months ended June 30, 2019 was $187,000 and $415,000, respectively. Total stock-based compensation related to the ESPP for the three and six months ended June 30, 2018 was immaterial to the condensed financial statements.

A total of 44,656 shares of common stock were purchased pursuant to the ESPP during the six months ended June 30, 2019 for total proceeds of $588,000.

Convertible preferred stock

The convertible preferred stock was temporarily reclassified to mezzanine equity as of June 30, 2018 before converting into common stock and permanent equity upon the closing of Company's initial public offering in July 2018.

8. Net Loss Per Share

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

	As of June 30,	
	2019	**2018**
Convertible preferred stock	—	16,215,896
Stock options to purchase common stock	3,181,138	3,374,318
Restricted stock subject to future vesting	15,053	71,633
Shares committed under ESPP	41,500	—
Total	3,237,691	19,661,847

9. Subsequent Events

Registration Statement on Form S-3

In July 2019, the Company filed a Registration Statement on Form S-3, as amended (file no. 333-232498), declared effective by the SEC on July 12, 2019 (the "Shelf Registration Statement"), covering the offering of up to $250 million of common stock, preferred stock, debt securities and warrants. The Company may use the Shelf Registration Statement at any time or from time to time to offer, in one or more offerings, common stock, preferred stock, debt securities and warrants. The Shelf Registration Statement included a prospectus covering the offering, issuance and sale of up to $60.0 million of shares of the Company's common stock from time to time in "at-the-market offerings" pursuant to a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") entered into with Cantor Fitzgerald & Co. (the "Sales Agent") on July 1, 2019. As of August 13, 2019, the Company had not sold any securities pursuant to the Sales Agreement.

Ono License and Collaboration Agreement

In July 2019, the Company entered into an exclusive license and collaboration agreement with Ono Pharmaceutical Co., Ltd., ("Ono"). Under the agreement, the Company granted Ono an exclusive license to develop, manufacture and commercialize 5F9, the Company's monoclonal antibody against CD47, as well as other anti-CD47 antibodies controlled by the Company in Japan, South Korea, Taiwan and the ASEAN countries(the "Ono Territory"). The Company retains all rights to 5F9 and other licensed antibodies outside of the Ono Territory.

Under the agreement, the parties will collaborate on the development, manufacturing and commercialization of 5F9 and other licensed antibodies. Each party will be responsible for conducting development and commercialization of licensed antibodies in its respective territory at its own cost. Further, each party will have the right to participate, at its cost, in global clinical studies of 5F9 and other licensed antibodies conducted by the other party.

The Company will receive a one-time upfront payment from Ono of 1.7 billion Japanese Yen (approximately $15.7 million US Dollar based on the exchange rate at July 10, 2019) and will be eligible to receive up to an additional 11.2 billion Japanese Yen (approximately $103.3 million US Dollar based on the exchange rate at July 10, 2019) if specified future development and commercial milestones are achieved by Ono. The Company is also eligible to receive tiered percentage royalties spanning from the mid-teens to the low-twenties on future net sales of 5F9 and other licensed antibodies in the Ono Territory, subject to certain offsets.

Public Offering

In July 2019, pursuant to the Shelf Registration Statement the Company completed an underwritten public offering of 10,781,250 shares of its common stock, including 1,406,250 shares sold pursuant to the underwriters' exercise of their option to purchase additional shares at a public offering price of $8.00 per share. The gross proceeds from the offering to the Company, before underwriting discounts and commissions and offering expenses, were approximately $86.3 million.

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 audited financial statements and related notes in the Annual Report on Form 10-K for the year ended December 31, 2018. 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 therapies to activate macrophages in the fight against cancer. We founded Forty Seven based on the insight that blocking CD47, a key signaling molecule that is overexpressed on cancer cells, renders tumors susceptible to macrophages. By harnessing macrophages, we believe that our lead product candidate, 5F9, can transform the treatment of cancer. 5F9 has demonstrated promising activity in multiple Phase 1b/2 clinical trials in which we have treated over 290 cancer patients with solid or hematologic tumors. In addition, we have two additional product candidates in preclinical development; FSI-189, an anti-SIRPα antibody, and FSI-174, an anti-cKIT antibody.

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

Our company was founded by leading scientists at Stanford University who uncovered the fundamental role of CD47 in cancer evasion. Preclinical work performed in the laboratory of our co-founder, Irving L. Weissman, at Stanford University and at Forty Seven demonstrated that:

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

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

The targeting of CD47 to make cancer cells susceptible to macrophages, a component of the innate immune system, is analogous to the approach that has been applied with checkpoint inhibitors and T cells, a component of the adaptive immune system. Since their introduction in 2011, T cell checkpoint inhibitors have become frontline therapies for certain cancers and we estimate that they generated over $17 billion in sales in 2018. Despite the success of T cell checkpoint inhibitors, these therapies have been shown to be effective only in a subset of tumors, highlighting the need for additional therapies. Similar to the way cancer cells overexpress programmed death-ligand 1, or PD-L1, to avoid attack by T cells, cancer cells overexpress CD47 as a way to avoid destruction by macrophages. We believe targeting CD47 represents a compelling and analogous approach.

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 sales of our capital stock and the receipt of government and private grants. We are eligible to receive up to $17.6 million in grants from the California Institute for Regenerative Medicine, or CIRM, and the Leukemia and Lymphoma Society, or LLS, of which $16.2 million has been received through June 30, 2019. In July 2019, we entered into an amendment of our agreement with LLS for up to an additional $3.0 million in grants upon the achievement of certain clinical or regulatory milestones.

We have incurred net losses in each year since inception. Our net losses were $23.2 million and $16.7 million for the three months ended June 30, 2019 and 2018, respectively, and $46.2 million and $31.5 million for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, we had an accumulated deficit of $186.0 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.

Our Development Pipeline

We are conducting clinical trials using 5F9 as monotherapy and in combination with other approved cancer therapies. As summarized in the following figure, our clinical trials are investigating multiple types of CD47 combination therapies: 5F9 with chemotherapeutic agents, 5F9 with tumor targeting antibodies and 5F9 with T cell checkpoint inhibitors, in a wide variety of tumors, including both solid and hematological cancers. We have treated over 290 relapsed or refractory cancer patients with 5F9 both as a monotherapy and in combination with tumor targeting antibodies such as rituximab and cetuximab. While the primary goal of our trials has been to demonstrate safety, we have also observed early signs of clinical activity in multiple tumor types. These signs include patients with partial and complete responses, as well as patients with “stable disease.” We use standard clinical assessment criteria to evaluate the growth or reduction in existing tumor size, within set parameters, as well as growth of new tumors and metabolic activity. Broadly stated, “stable disease” indicates a growth or reduction in tumor size that is insufficient to meet the definitions of either progressive disease or partial or complete response. In contrast, patients with partial or complete responses have substantial reductions in tumor size.

5F9 Monotherapy

In our ongoing monotherapy trials, 5F9 treatment has demonstrated biological responses including a confirmed objective response and multiple cases of stable disease in Phase 1 patients with refractory AML, as of April 2018. In biologic responders, defined as a reduction in bone marrow blasts, we confirmed the presence of macrophages in tumor tissues and we observed that other components of the immune system, including T cells, had been recruited.

We are also investigating 5F9 as a monotherapy in ovarian cancer and other solid tumors. In a Phase 1 trial of 5F9, we observed confirmed partial responses in 2 out of 21 evaluable patients in a cohort with ovarian cancer receiving either 20 mg/kg or higher doses of 5F9, as of April 2018. Both were heavily pre-treated patients failing seven or more previous treatment regimens. One of these patients had a durable partial response of more than six months in duration.

We believe the signals from these monotherapy trials have been encouraging; however, we have determined that the limited responses in these late stage patients are not adequate for us to initiate a trial of 5F9 as a single agent aimed at supporting registration by the FDA and we are now focused on combination approaches that have a strong scientific rationale and that are backed by preclinical data.

5F9 in Combination with Tumor Targeting Antibodies

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

5F9 in Combination with Chemotherapeutic Agents

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

5F9 Combinations with Checkpoint Inhibitors

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

In early 2018, we announced clinical trial collaboration and supply agreements with two pharmaceutical companies to combine 5F9 with PD-L1 checkpoint inhibitors, while retaining full economic rights to our products. Pursuant to these agreements, we are conducting clinical trials with Merck KGaA on the combination of 5F9 with BAVENCIO (avelumab) in ovarian cancer patients; and with Genentech, Inc., a member of the Roche Group, on the combination of 5F9 and TECENTRIQ (atezolizumab) in patients with bladder cancer and in patients with AML. In April 2019, we announced an extension of our clinical trial collaboration agreement with Genentech to also evaluate 5F9 in combination with rituximab and TECENTRIQ in patients with DLBCL. We will supply 5F9, and Merck KGaA and Genentech will supply their respective drug products for these trials.

Recent Developments

5F9 for the Treatment of MDS

Clinical Trial Update

In June 2019, we announced results from our Phase 1b trial designed to evaluate 5F9 as a monotherapy in patients with relapsed or refractory, or r/r, MDS or AML, and 5F9 in combination with azacitidine in higher-risk MDS patients and untreated, induction chemotherapy-ineligible AML patients. All patients received a 1 mg/kg priming dose of 5F9, coupled with intrapatient dose escalation, to mitigate on-target anemia. Patients in the combination cohort were then treated with full doses of azacitidine and a 5F9 maintenance dose of 30 mg/kg once weekly.

As of the data cutoff of May 10, 2019, 46 patients had been treated in the Phase 1b portion of the trial, including 10 r/r MDS or AML patients who received monotherapy 5F9, and 36 untreated higher-risk MDS patients or untreated AML patients ineligible for induction chemotherapy, who received 5F9 in combination with azacitidine.

Safety data are available for 5F9 in 10 patients treated with monotherapy and for 36 patients treated in combination with azacitidine. In both groups, 5F9 treatments were well-tolerated, and in the combination there was no evidence of increased toxicities compared to azacitidine alone. The number and type of adverse events, or AEs, observed were generally consistent with what has been previously seen with 5F9, and no significant cytopenias or autoimmune-related AEs were observed in patients treated with monotherapy 5F9. Overall, the most commonly reported treatment-related AEs were expected CD47-mechanism-based effects on red blood cells, which led to a temporary and reversible anemia with the initial dose. After the first few doses many patients in the combination cohort experienced a hemoglobin improvement over the course of their treatment with a decrease in transfusions. Importantly, no treatment-related infections were observed, and only one patient out of 36 treated with the combination experienced neutropenic fever (3%). No deaths were observed in the first 60 days on combination treatment. Only one patient out of 46 (2%) discontinued treatment due to a treatment-related AE.

Thirty-five patients were evaluable for response assessment, including 25 patients with untreated higher-risk MDS or AML who were treated with 5F9 and azacitidine (11 patients with higher-risk MDS and 14 patients with untreated AML) and 10 patients with r/r MDS or AML who were treated with monotherapy 5F9.

- In higher-risk MDS, the overall response rate, or ORR, for the combination was 100%, with six patients (55%) achieving a complete response, or CR, four patients (36%) achieving a marrow CR and one patient (9%) achieving hematologic improvement.
- In untreated AML, the ORR for the combination was 64%, with five patients (36%) achieving a CR, two patients (14%) achieving a complete response with incomplete blood count recovery, or CRi, and two patients (14%) achieving a morphologic leukemia-free state, or MLFS. Additionally, five patients (36%) achieved stable disease, or SD.
- In r/r MDS or AML treated with monotherapy 5F9, the ORR was 10%, consisting of one patient who achieved a MLFS. Additionally, seven patients (70%) achieved SD.
- The median time to response among MDS and AML patients treated with the combination was 1.9 months.
- Six patients (30% of responders) receiving the combination who had an objective response have experienced deepening responses over time resulting in complete remissions. Five patients (25% of responders) have also successfully received allogeneic stem cell transplants.
- Historical response rates for single-agent azacitidine show CR rates of approximately 15-20% in higher-risk MDS and untreated AML patients, with initial responses generally occurring after 4-6 months in most patients who respond.

Based on the favorable safety profile and encouraging clinical activity observed in this Phase 1b clinical trial to-date, expansion cohorts have been initiated in patients with both higher-risk MDS and untreated AML with 5F9 in combination with azacitidine.

Registration Strategy Update

Based on feedback from a Type B meeting with the FDA we believe a single-arm trial design may be sufficient to support the approval of 5F9 in combination with azacitidine for the treatment of naïve (1st line) intermediate to very high risk MDS patients. We plan to finalize the key parameters with the FDA on the trial elements through a Special Protocol Assessment.

The primary endpoint of this single-arm study is expected to be a durable objective response consisting of both complete and partial responses. We believe approximately 91 patients with six months of efficacy data and 12 months of safety data may be sufficient for submission of a Biologic License Application, or BLA. We further believe there is a potential accelerated approval pathway utilizing this single-arm trial design.

We also plan to expand our current Phase 1b/2 trial, with weekly 30 mg/kg dosing, to accrue a total of 91 patients, and we anticipate completing enrollment of this trial in the third quarter of 2020. We plan to use the 12 months of safety data from this trial as part of our BLA submission. In addition, in the first quarter of 2020, we plan to initiate a second trial of 5F9 plus azacitidine in untreated intermediate to very high risk MDS patients with dosing every two weeks. We plan to enroll approximately 91 patients in this trial, which is expected to allow us to explore a more convenient dosing regimen. We anticipate completing enrollment of this trial in the first quarter of 2021. At the completion of both trials, we intend to evaluate the data and determine which dosing regimen to submit as part of our BLA submission. We currently anticipate submitting our BLA in the fourth quarter of 2021.

5F9 for the Treatment of NHL

Clinical Trial Update

In June 2019, we also announced updated data from our ongoing Phase 1b/2 clinical trial evaluating 5F9 in combination with rituximab for the treatment of relapsed/refractory non-Hodgkin's lymphoma, or r/r NHL, including DLBCL and indolent lymphoma. These data showed clinical benefit across a range of patient populations — including patients who are heavily pre-treated, ineligible for CAR-T therapy or suffering from primary refractory disease — as well as durable responses in both DLBCL and FL.

The design of our Phase 1b/2 clinical trial allowed us to continue to explore the clinical benefit of 5F9 in combination with rituximab in patients with DLBCL and indolent lymphoma, while also expanding into a subset of older, sicker DLBCL patients who have been deemed ineligible for CAR-T therapy, a newly-defined population, which has never before been evaluated in clinical trials, and for whom there are few, if any, effective treatment options available.

Our Phase 1b/2 NHL trial is designed to evaluate 5F9 in combination with rituximab in patients with r/r B-cell NHL, who have failed standard-of-care therapies. All patients received a 1 mg/kg priming dose of 5F9 to mitigate on-target anemia. Patients in the Phase 1b portion of the trial were treated with 5F9 maintenance doses of 10 to 45 mg/kg, and patients in the Phase 2 portion of the trial were treated with 5F9 doses of either 30 or 45 mg/kg. All patients were also administered full doses of rituximab.

As of the data cutoff of May 2019, 115 patients had been treated in the Phase 1b/2 trial, including 70 patients with DLBCL, 41 patients with follicular lymphoma (FL) and four patients with marginal zone lymphoma, or MZL. The median number of prior therapies across all patients was three (range one to 10), and 85% of all patients were refractory to a prior rituximab-containing regimen, with 59% of DLBCL patients having primary refractory disease. Additionally, 42 of the 47 DLBCL patients enrolled in the Phase 2 portion of the trial were ineligible for CAR-T therapy (89%).

In this trial, 5F9 was well tolerated in combination with rituximab. The number and type of AEs were consistent with prior clinical experience. Most AEs were Grade 1 or Grade 2, and the most commonly-reported AEs were expected CD47-mechanism-based effects on red blood cells, which led to a temporary and reversible anemia, and infusion-site reactions. No autoimmune-related AEs were observed, nor were any significant late safety signals observed in patients treated with 5F9 for up to 24 months. No maximum tolerated dose was reached with up to 45 mg/kg of 5F9 dosing. Eight out of 115 patients discontinued treatment due to an AE (7%).

Ninety-seven patients were evaluable for response assessment, including 21 relapsed/refractory DLBCL patients who were treated in the Phase 1b portion of the study, thirty-eight DLBCL patients who were treated in the Phase 2 portion of the study and 38 indolent lymphoma patients (35 patients with FL and three patients with MZL).

DLBCL

Best Overall Response	Phase 1b N = 21 (%)	Phase 2 N = 38 (%)	≥ 3 Prior Lines of Therapy N = 39 (%)
Study Patient Population	Primary refractory disease or relapsed/refractory to ≥ 2 prior lines of therapy	Primary refractory disease or relapsed/refractory to ≥ 2 prior lines of therapy and ineligible for CAR-T therapy	Subgroup analysis of combined Phase 1b and Phase 2 Data
ORR	10 (48)%	11 (29)%	15 (38)%
CR	7 (33)%	2 (5)%	7 (18)%
PR	3 (14)%	9 (24)%	8 (20)%
SD	4 (19)%	3 (8)%	4 (10)%

Among patients treated in the Phase 1b portion of the trial, the median duration of response has not been reached, with a median follow-up of over 13.8 months. This includes one patient who has remained in a durable CR for more than 24 months.

Indolent Lymphoma

Best Overall Response	Phase 1b + 2 FL N = 35; MZL N = 3 (%)
Study Patient Population	Relapsed/refractory to ≥ 2 prior lines of therapy
ORR	23 (61)%
CR	9 (24)%
PR	14 (37)%
SD	9 (24)%

Among patients treated in the Phase 1b portion of the trial, the median duration of response has not been reached with a median follow-up of over 21 months. This includes the patient who has remained in a durable CR for more than 28 months.

Additionally, 5F9 tumor penetrance was evaluated at 30 and 45 mg/kg as a key pharmacodynamic endpoint. Data show that the 30 mg/kg maintenance dose of 5F9 saturated the tumor microenvironment similarly to 45 mg/ kg, with similar efficacy. As a result, a 30 mg/kg maintenance dose of 5F9 was selected as the recommended dose for use in future clinical studies.

We also intend to evaluate opportunities to advance 5F9 in combination with rituximab for patients with indolent lymphoma. In February 2019 we dosed our first patient in an expansion cohort of our 5F9003 NHL Phase 1 trial with a combination of 5F9 plus rituximab with gemcitabine and oxaliplatin. We anticipate enrolling up to 26 patients into this cohort. We anticipate sharing data from this cohort in the second half of 2020.

Registration Strategy Update

Based on feedback from a Type C meeting with the FDA in May 2019 we believe a single-arm trial design may be sufficient to support the approval of 5F9 plus rituximab in heavily pretreated relapsed or refractory DLBCL patients, including CAR-T ineligible patients.

We plan to initiate a registrational trial of 5F9 plus rituximab in DLBCL in the first quarter of 2020. We anticipate this trial will enroll approximately 100 patients with advanced forms of DLBCL using refined patient eligibility criteria based on our Phase 1 and 2 trials. We anticipate these will be patients that have had more than two or more lines of therapy and may include those ineligible for CAR-T therapy due to advanced age, significant co-morbidities or the diagnosis of rapidly progressive disease. The dosing regimen for the trial is anticipated to be 30 mg/kg every two weeks. The primary endpoints of the study are expected to be objective response rate, including both complete and partial responses, and durability of response. Because the CAR-T ineligible patient population has not been well characterized before, the FDA has requested informational data to better characterize and define CAR-T ineligibility. The anticipated efficacy follow up in this trial will be six months. We further believe there is a potential accelerated approval pathway utilizing this single-arm trial design.

Key Clinical and Regulatory Events Expected in 2019 and 2020

We expect to provide updates from our ongoing clinical trials at major medical meetings throughout the year. Notably, we expect to provide an interim efficacy readout from our DLBCL trial of 5F9 plus rituximab in the fourth quarter of 2020 and expanded efficacy and durability from our MDS trial of 5F9 plus azacitidine in the second half of 2019 and 2020. Our expected key clinical and regulatory events are shown in the table below.

Ono Pharmaceutical License and Collaboration Agreement

On July 10, 2019, we entered into an exclusive license and collaboration agreement with Ono Pharmaceutical Co., Ltd., or Ono. Under the agreement, we granted Ono an exclusive license to develop, manufacture and commercialize 5F9, our monoclonal antibody against CD47, as well as other anti-CD47 antibodies controlled by us in Japan, South Korea, Taiwan and the ASEAN countries, or the Ono Territory. We retain all rights to 5F9 and other licensed antibodies outside of the Ono Territory.

Under the agreement, the parties will collaborate on the development, manufacturing and commercialization of 5F9 and other licensed antibodies. Each party will be responsible for conducting development and commercialization of licensed antibodies in its respective territory at its own cost. Further, each party will have the right to participate, at its own cost, in global clinical studies of 5F9 and other licensed antibodies conducted by the other party. We will initially be responsible for supplying 5F9 and other licensed antibodies to Ono for development and commercialization within the Ono Territory at Ono's cost. Ono has the right to elect that such manufacturing activities be transferred to Ono. During the term of the agreement, neither party may manufacture or commercialize any competing products in the Ono Territory.

We will receive a one-time upfront payment from Ono of 1.7 billion Japanese Yen (approximately $15.7 million US Dollars based on the exchange rate at July 10, 2019) and will be eligible to receive up to an additional 11.2 billion Japanese Yen (approximately $103.3 million US Dollars based on the exchange rate at July 10, 2019) if specified future development and commercial milestones are achieved by Ono. We are also eligible to receive tiered percentage royalties spanning from the mid-teens to the low-twenties on future net sales of 5F9 and other licensed antibodies in the Ono Territory, subject to certain offsets. Ono's obligation to pay royalties expires, on a product-by-product and country-by-country basis, on the later of (1) the expiration of the first regulatory exclusivity for such product in such country, (2) the expiration of the last to expire patent controlled by us that covers the composition of matter of a licensed antibody in such product in such country, or (3) the tenth anniversary of the first commercial sale of such product in such country.

The agreement will remain in effect until the expiration of all of Ono's royalty obligations, after which Ono's license shall be fully paid-up. Ono may terminate the agreement on a country-by-country basis for convenience upon 90 days' prior written notice to us prior to the first commercial sale of the first licensed product in the Ono Territory, or 180 days' prior written notice after such first sale. Either party may also terminate the agreement for the other party's uncured material breach or insolvency, subject to specified notice and cure periods. In the event of any early termination, all rights in 5F9 and other licensed antibodies will revert to us, subject to certain royalties due to Ono in the case of Ono's termination for our breach or insolvency.

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, and other product candidates, which include:

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

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

The largest component of our operating expenses has historically been our investment in research and development activities related to the clinical development of our lead product candidate, 5F9. We recognize the funds from research and development grants as a reduction of research and development expense when the related eligible research costs are incurred. Research and development grants received during the year ended December 31, 2018 and the six months ended June 30, 2019 totaled $7.6 million and $2.7 million, respectively. In January 2018, we entered into a clinical trial collaboration and supply agreement with Ares Trading S.A, a subsidiary of Merck KGaA or Merck. Reimbursement under this collaboration agreement is recorded as a reduction to research and development expense. For the three and six months ended June 30, 2019 and 2018, we recognized $0.3 million and $0.9 million, and $0.4 million and $0.6 million, respectively, as a reduction to research and development expenses under this collaboration agreement.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, and as we begin to conduct larger clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative Expenses

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

Interest and Other Income, Net

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

Results of Operations

Three Months Ended June 30, 2019 and 2018

	Three Months Ended June 30,		
	2019	2018	Increase/ (Decrease)
	(In thousands)		
Operating expenses:			
Research and development	$ 18,829	$ 13,596	$ 5,233
General administrative	5,057	3,362	1,695
Total operating expenses	23,886	16,958	6,928
Loss from operations	(23,886)	(16,958)	(6,928)
Interest and other income, net	680	236	444
Net loss	$ (23,206)	$ (16,722)	$ (6,484)

Research and Development Expenses

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

	Three Months Ended June 30,		
	2019	2018	Increase (Decrease)
	(In thousands)		
Product-specific costs:			
5F9	$ 11,605	$ 9,411	$ 2,194
Grant funding and cost share reimbursement	(1,235)	(2,257)	1,022
Non product-specific costs:			
Stock-based compensation	431	162	269
Personnel-related	3,168	2,473	695
Other preclinical programs	4,860	3,807	1,053
Total research and development expenses	$ 18,829	$ 13,596	$ 5,233

Research and development expenses increased by $5.2 million, or 38%, to $18.8 million for the three months ended June 30, 2019 from $13.6 million for the three months ended June 30, 2018. The increase was primarily due to a $2.2 million increase in third-party costs related to advancing our current clinical programs focused on our lead product candidate, 5F9, and associated contract manufacturing costs and a $1.0 million increase in expense related to decreased grant and cost share funding recognized under the CIRM and LLS grants and the Merck collaboration agreement during the three months ended June 30, 2019. There was a $1.1 million increase in our other preclinical and discovery programs costs as we expanded our immuno-oncology efforts and a $0.9 million increase in personnel-related costs, including stock-based compensation.

General and Administrative Expenses

General and administrative expenses increased by $1.7 million, or 50%, to $5.1 million for the three months ended June 30, 2019 from $3.4 million for the three months ended June 30, 2018. The increase was primarily due to a $0.8 million increase in personnel-related costs driven by an increase in headcount, a $0.6 million increase in accounting and consulting expenses incurred in connection with operating as a public company and business expansion, and a $0.2 million increase in directors and officer’s insurance expense.

Interest and Other Income, Net

Interest and other income, net increased by $0.5 million to $0.7 million for the three months ended June 30, 2019 from $0.2 million for the three months ended June 30, 2018. The increase was primarily due to interest income earned from the investment of the net proceeds from our IPO in July 2018.

Six Months Ended June 30, 2019 and 2018

	Six Months Ended June 30,		
	2019	2018	Increase/ (Decrease)
	(In thousands)		
Operating expenses:			
Research and development	$ 37,955	$ 24,749	$ 13,206
General administrative	9,641	7,205	2,436
Total operating expenses	47,596	31,954	15,642
Loss from operations	(47,596)	(31,954)	(15,642)
Interest and other income, net	1,374	457	917
Net loss	$ (46,222)	$ (31,497)	$ (14,725)

Research and Development Expenses

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

	Six Months Ended June 30,		
	2019	2018	Increase (Decrease)
	(In thousands)		
Product-specific costs:			
5F9	$ 25,340	$ 19,439	$ 5,901
Grant funding and cost share reimbursement	(2,874)	(3,963)	1,089
Non product-specific costs:			
Stock-based compensation	886	297	589
Personnel-related	5,898	4,136	1,762
Other preclinical programs	8,705	4,840	3,865
Total research and development expenses	$ 37,955	$ 24,749	$ 13,206

Research and development expenses increased by $13.2 million, or 53%, to $38.0 million for the six months ended June 30, 2019 from $24.8 million for the six months ended June 30, 2018. The increase was primarily due to a $5.9 million increase in third-party costs related to advancing our current clinical programs focused on our lead product candidate, 5F9, and associated contract manufacturing costs and a $1.1 million increase in expenses related to a decrease in grant and cost share funding recognized under the CIRM and LLS grants and the Merck collaboration agreement during the six months ended June 30, 2019. There was a $3.9 million increase in our other preclinical and discovery programs costs as we expanded our immuno-oncology efforts and a $2.3 million increase in personnel-related costs, including stock-based compensation.

General and Administrative Expenses

General and administrative expenses increased by $2.4 million, or 34%, to $9.6 million for the six months ended June 30, 2019 from $7.2 million for the six months ended June 30, 2018. The increase was primarily due to a $1.8 million increase in personnel-related costs driven by an increase in headcount, a $0.4 million increase in directors and officer's insurance expense, and a $0.2 million increase in accounting and consulting expenses incurred in connection with operating as a public company.

Interest and Other Income, Net

Interest and other income, net increased by $0.9 million to $1.4 million for the six months ended June 30, 2019 from $0.5 million for the six months ended June 30, 2018. The increase was primarily due to interest income earned from the investment of the net proceeds from our IPO in July 2018.

Liquidity, Capital Resources and Plan of Operations

To date, we have incurred significant net losses and negative cash flows from operations. As of June 30, 2019, we had $99.0 million in cash, cash equivalents and short-term investments.

In July 2019, we completed an underwritten public offering of 10,781,250 shares of our common stock, including 1,406,250 shares sold pursuant to the underwriters' exercise of their option to purchase additional shares, at a public offering price of $8.00 per share. The gross proceeds from the offering to us, before underwriting discounts and commissions and offering expenses, were approximately $86.3 million.

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, other product candidates, 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 and assumptions, we believe that our existing cash, cash equivalents and short-term investments, including the proceeds from our recently completed public offering and upfront payment from Ono, will enable us to meet our financial needs through the first quarter of 2021. 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,	
	2019	**2018**
	(In thousands)	
Cash used in operating activities	$ (42,669)	$ (28,087)
Cash provided by investing activities	47,834	18,997
Net cash provided by (used in) financing activities	1,847	(2,213)
Net increase (decrease) in cash and cash equivalents	$ 7,012	$ (11,303)

Operating Activities

During the six months ended June 30, 2019, cash used in operating activities of $42.7 million was attributable to a net loss of $46.2 million, partially offset by a net change of $2.2 million in non-cash charges and a net change of $1.4 million in net operating assets and liabilities. The non-cash charges consisted primarily of stock-based compensation of $2.2 million, amortization of right-of-use assets of $0.5 million and depreciation and amortization of $0.2 million, partially offset by $0.7 million related to the accretion of discounts on marketable securities. The change in operating assets and liabilities was primarily due to a $4.3 million increase in accounts payable and accrued liabilities resulting from the timing of payments, a $1.6 million decrease in other noncurrent assets driven by timing of the research and development prepayments and offset by deferred offering costs incurred but not paid, a $1.0 million increase in deferred grant funding due to receipt of the research grant funding payments, partially offset by a $5.0 million increase in prepaid expense and other current assets driven by additional prepayments made for research and development activities and other receivables and a $0.5 million decrease in lease related liabilities due to lease payments.

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.

Investing Activities

During the six months ended June 30, 2019, cash provided by investing activities was $47.8 million related to the proceeds from maturities of short-term investments of $112.7 million and proceeds from the sale of short-term investments of $4.0 million, partially offset by the purchase of investments of $68.8 million.

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.

Financing Activities

During the six months ended June 30, 2019, cash provided by financing activities was $1.8 million related primarily to the proceeds received from the exercise of stock options of $1.4 million and from the issuance of common stock upon ESPP purchase of $0.6 million, partially offset by payments of deferred offering cost of $0.1 million.

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.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations as of June 30, 2019, as compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 28, 2019.

Off-Balance Sheet Arrangements

During 2018 and the six months ended June 30, 2019, 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 our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 28, 2019.

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 $99.0 million and $139.0 million as of June 30, 2019 and December 31, 2018, consist of bank deposits, money market funds and available-for-sale securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. Due to the short-term maturities of our cash equivalents and marketable securities, and the low risk profile of our marketable securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities.

Foreign Currency Risk

Our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with licensors and vendors for research and development services with payments denominated in foreign currencies, including the British Pound and Euro. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. Foreign currency transaction gains and losses were not significant to the financial statements for the three and six months ended June 30, 2019 and 2018. We have not had a hedging program with respect to foreign currency.

Our primary foreign currency exposure relates to our manufacturing commitments with Lonza for the manufacturing of 5F9-related products. Under the Lonza agreements, the Company is required to pay Lonza fixed fees based on manufacturing services performed. The fees payable under Lonza agreements are denominated in British Pounds. There was an immaterial foreign currency gain for the three months ended June 30, 2019 and we recognized $59,000 in net foreign currency losses for the six months ended June 30, 2019.

In July 2019, we entered into an exclusive license and collaboration agreement with Ono Pharmaceutical Co., Ltd., or Ono. Under the agreement, we will receive a one-time upfront payment from Ono of 1.7 billion Japanese Yen (approximately $15.7 million US Dollars based on the exchange rate at July 10, 2019). During the time that the receivable for the upfront payment is outstanding, we will be subject to exchange rate changes. Under the agreement we may also be eligible to receive up to an additional 11.2 billion Japanese Yen (approximately $103.3 million US Dollars based on the exchange rate at July 10, 2019) if specified future development and commercial milestones are achieved by Ono. Between the time that we recognize contract assets or receivables related to milestones payments and the time that those payments are collected, we will be subject to exchange rate changes. We are also eligible to receive tiered percentage royalties spanning from the mid-teens to the low-twenties on future net sales of 5F9 and other licensed antibodies in Japan, South Korea, Taiwan and the ASEAN countries, subject to certain offsets.

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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2019 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 $70.4 million and $44.9 million for 2018 and 2017, respectively and $46.2 million and $31.5 million for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, we had an accumulated deficit of $186.0 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, 2019, we had cash, cash equivalents and short-term investments of $99.0 million. In July 2019, we closed an underwritten public offering with gross proceeds of approximately $86.3 million. Based upon our current operating plan and assumptions, we believe that our existing cash, cash equivalents and short-term investments, including the proceeds from the recently completed public offering and the upfront payment from Ono, will enable us to meet our financial needs through the first quarter of 2021. 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 multiple 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, including FSI-189 and FSI-174, 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, FSI-189 and FSI-174 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 Innovent and others are developing drugs targeting the CD47 pathway that may have utility for the treatment of indications that we are targeting. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop.

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

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

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

If 5F9, FSI-189 and FSI-174 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 any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- 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, FSI-189, FSI-174 and our other product candidates, if any are approved, will depend on a number of factors, including, among others:

- the ability of 5F9 and our other product candidates to treat cancer, as compared with other available drugs, treatments or therapies;
- the prevalence and severity of any adverse side effects associated with 5F9 and our other product candidates;
- limitations or warnings contained in the labeling approved for 5F9 or our other product candidates by the FDA;
- availability of alternative treatments;
- the size of the target patient population, and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity for our product candidates and competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our product candidates through marketing efforts;
- our ability to obtain sufficient third-party coverage or reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage; and
- the likelihood that the FDA may impose additional requirements that limit the promotion, advertising, distribution or sales of our product candidates.

The market acceptance of our product candidates also will depend in part on the market acceptance of other immunotherapies for the treatment of cancer. While a number of other cancer immunotherapies have received regulatory approval and are being commercialized, our approach to targeting the CD47 pathway is novel. Adverse events in clinical trials for our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for 5F9 or any other product candidate that we may develop. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our products may not be accepted by the general public or the medical community. Future adverse events in immuno-oncology or the biopharmaceutical industry generally could also result in greater governmental regulation and stricter labeling requirements.

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

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

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

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

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

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

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

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

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

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future product candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

Risks Related to Our Dependence on Third Parties

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

We have limited experience in drug formulation and manufacturing and do not own or operate, and we do not expect to own or operate, facilities for drug manufacturing, storage, distribution, or testing. We have entered into a development and manufacturing agreement with Lonza, pursuant to which we agreed to purchase 5F9. Lonza is currently our sole supplier of 5F9. We have also entered into an agreement with BTPH as our sole supplier for our cKIT antibodies. If Lonza and BTPH are unable to supply us with sufficient clinical and commercial grade quantities of drug substances, 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 other product candidates 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 and combination clinical trials planned in AML and bladder cancer with Genentech. In addition, in July 2019, we entered into an exclusive license and collaboration agreement with Ono. 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. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. In addition, while Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and the Centers for Medicare & Medicaid Services ("CMS"), have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. 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 2027 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 legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers.

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, , including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties 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 Affordable Care Act, 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 multiple 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 SAS. As of June 30, 2019, 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-SIRPa 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-SIRPα 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. Subsequently, pursuant to a settlement and license agreement with Synthon Biopharmaceuticals B.V., or Synthon, the licensee of these patents, the inter partes review in the USPTO against U.S. Patent No. 9,352,037 was terminated, and the appeal in the opposition proceedings against European patent No. EP 2 282 772 was withdrawn, thereby terminating the opposition. The settlement agreement with Synthon is described briefly below.

In July 2018, we entered into a settlement and license agreement with Synthon. Under the agreement, we agreed to discontinue our ongoing oppositions and challenges at the EPO, and the USPTO, directed towards certain patents licensed by Synthon from Stichting Sanquin Bloedvoorziening, or SSB, including U.S. Patent No. 9,352,037 and European patent No. EP 2 282 772, that relate to the use of anti-CD47 products in combination with other antibodies to treat cancer. Pursuant to this agreement, we withdrew our challenges to these patents in the USPTO and EPO. In return Synthon granted us a non-exclusive, worldwide sublicense to certain patents they have licensed from SSB, including the SSB patents we are opposing at the USPTO and EPO to commercialize a single anti-CD47 product (such as 5F9 or an alternate anti-CD47 product) to treat cancer in combination with other antibodies. Pursuant to the agreement, we and Synthon, have each released the other party (and we have released SSB) from all claims and liabilities relating to the USPTO and EPO proceedings.

We may need to obtain additional licenses to use our anti-SIRPα antibodies for the treatment of cancer or risk litigation in connection with our commercialization of anti-SIRPα antibodies to treat cancer. Such licenses may not be available at all or may not be available on commercially reasonable terms such that we may be required to pay significant fees and royalties to secure licenses to the applicable patents. Moreover, such licenses, like our sublicense from Synthon, may only be non-exclusive, in which case our ability to stop others from using or commercializing technology and products similar or identical to ours may be limited. If we are unable to obtain and maintain such licenses, we may need to cease the commercialization of 5F9 and other anti-CD47 antibodies or anti-SIRPα 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, 2019, we had 62 employees. As our clinical development progresses, we expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of clinical operations, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA, the EMA, the MHRA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

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

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

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

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

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

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure or security breach to our knowledge to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future product candidates could be delayed.

Risks Related to Our Common Stock

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

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 management believes that these and other actions taken to remediate this material weakness have been fully implemented and that the previously reported material weakness had been remediated. However, we cannot assure you that the measures we have taken to date, and are continuing to implement, or any measures we may take in the future, will be sufficient to identify or prevent future material weaknesses. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

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

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

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

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

- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the United States or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales might occur, could cause the price of our common stock to decline significantly.

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, the market price of our common stock could decline significantly. All of our outstanding shares are eligible for sale in the public market, other than shares held by our directors and executive officers and our other affiliates which are subject to volume limitations under Rule 144 of the Securities Act. 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 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, 2019, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own a significant amount of our outstanding common stock. These stockholders, acting together, are able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

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

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

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

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As an "emerging growth company," we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an "emerging growth company." We could be an "emerging growth company" for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 (the end of our second quarter) before that time, in which case we would no longer be an "emerging growth company" as of the following December 31 (our year-end). We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

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

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees. Recently, the Delaware Chancery Court issued an opinion invalidating such provision. Until a final resolution is reached on this matter, we will not attempt to enforce this provision of our certificate of incorporation. As a result, we may incur additional costs associated with resolving disputes that would otherwise be restricted by that provision in other jurisdictions, which could harm our business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

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 our Registration Statements on Form S-1.

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	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Forty Seven, Inc.	8-K	001-38554	3.1	7/2/2018
3.2	Amended and Restated Bylaws of Forty Seven, Inc.	S-1	333-225390	3.4	6/1/2018
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1	333-225390	4.1	6/1/2018
10.1	Sublease and Consent to Sublease, dated April 24, 2019 by and among Forty Seven, Inc. Menlo Prepi I, LLC, TPI Investors 9, LLC and Teneobio, Inc.	8-K	001-38554	10.1	4/30/2019
10.2	First Amendment to Lease Agreement, dated April 28, 2019 by and among Forty Seven, Inc. and Menlo Prepi I, LLC.	8-K	001-38554	10.1	5/2/2019
31.1	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) of the Securities and Exchange Act of 1934, as amended.				
31.2	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) of the Securities and Exchange Act of 1934, as amended.				
32.1*	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.				
32.2*	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.				
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, 2019

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

Date: August 13, 2019

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

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark A. McCamish, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Forty Seven, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

Date: August 13, 2019

By: /s/ Mark A. McCamish

Mark A. McCamish, M.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ann D. Rhoads, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Forty Seven, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

Date: August 13, 2019

By: /s/ Ann D. Rhoads

Ann D. Rhoads
Chief Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report of Forty Seven Inc. ("the Company") on Form 10-Q for the period ending June 30, 2019 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 his 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, 2019

By: /s/ Mark A. McCamish

Mark A. McCamish, M.D.
President and Chief Executive Officer

Exhibit 32.2

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

In connection with the Quarterly Report of Forty Seven Inc. (the "Company") on Form 10-Q for the period ending June 30, 2019 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, 2019

By: /s/ Ann D. Rhoads

Ann D. Rhoads
Chief Financial Officer