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 September 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 November 5, 2019, the registrant had 42,276,130 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.

PART I: FINANCIAL INFORMATION

Item 1.Financial Statements.

Forty Seven Inc.
Condensed Balance Sheets
(In thousands)

	September 30, 2019	December 31, 2018
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 31,783	$ 10,837
Short-term investments	134,959	128,186
Prepaid expenses and other current assets	10,583	6,835
Total current assets	177,325	145,858
Property and equipment, net	1,315	1,360
Operating lease right-of-use assets	2,282	—
Other assets	2,661	2,219
Total assets	$ 183,583	$ 149,437
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,164	$ 4,621
Accrued liabilities	16,519	9,044
Lease liabilities, current	1,434	—
Deferred grant funding, current	2,585	1,744
Total current liabilities	23,702	15,409
Lease liabilities, noncurrent	1,228	—
Deferred rent, noncurrent	—	331
Other long-term liabilities	323	476
Total liabilities	25,253	16,216
Commitments and Contingencies		
Stockholders' equity:		
Common stock	4	3
Additional paid-in capital	359,390	273,069
Accumulated other comprehensive income (loss)	90	(82)
Accumulated deficit	(201,154)	(139,769)
Total stockholders' equity	158,330	133,221
Total liabilities and stockholders' equity	$ 183,583	$ 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 September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
License revenue	$ 15,678	$ —	$ 15,678	$ —
Operating expenses:				
Research and development	27,074	17,984	65,029	42,733
General and administrative	4,977	4,383	14,618	11,588
Total operating expenses	32,051	22,367	79,647	54,321
Loss from operations	(16,373)	(22,367)	(63,969)	(54,321)
Interest and other income, net	1,210	708	2,584	1,165
Net loss	(15,163)	(21,659)	(61,385)	(53,156)
Unrealized gains (losses) on available-for-sale securities	31	(4)	172	12
Comprehensive loss	$ (15,132)	$ (21,663)	$ (61,213)	$ (53,144)
Net loss per share, basic and diluted	$ (0.38)	$ (0.71)	$ (1.80)	$ (3.63)
Shares used in computing net loss per share, basic and diluted	39,772,452	30,430,898	34,129,449	14,643,348

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
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
Issuance of common stock in public offering, net of issuance costs	—	—	10,781,250	1	80,460	—	—	80,461
Issuance of common stock for exercise of stock options	—	—	7,568	—	24	—	—	24
Issuance of common stock pursuant to the ESPP	—	—	49,912	—	272	—	—	272
Vesting of early exercised stock options	—	—	—	—	13	—	—	13
Stock-based compensation	—	—	—	—	1,208	—	—	1,208
Net loss	—	—	—	—	—	—	(15,163)	(15,163)
Other comprehensive income	—	—	—	—	—	31	—	31
Balance at September 30, 2019	—	$ —	42,271,052	$ 4	$ 359,390	$ 90	$ (201,154)	$ 158,330

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
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
Issuance of common stock upon initial public offering, net of issuance costs	—	-	8,090,250	1	116,335	—	—	116,336
Preferred stock conversion to common stock	(16,215,896)	(149,397)	16,215,896	1	149,396	—	—	—
Issuance of common stock for exercise of options	—	—	4,106	—	11	—	—	11
Vesting of early exercised stock options	—	—	—	—	13	—	—	13
Stock-based compensation	—	—	—	—	1,271	—	—	1,271
Net loss	—	—	—	—	—	—	(21,659)	(21,659)
Other comprehensive loss	—	—	—	—	—	(4)	—	(4)
Balance at September 30, 2018	—	$ —	31,048,089	$ 3	$ 271,819	$ (32)	$ (122,555)	$ 149,235

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

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

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (61,385)	$ (53,156)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,437	2,318
Depreciation and amortization	386	289
Amortization of right-of-use assets	759	—
Accretion of discounts on marketable securities	(977)	(293)
Realized gain on sale of available-for-sale securities	(6)	—
Change in fair value of embedded derivative	(13)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,748)	(2,172)
Other assets	(445)	69
Accounts payable	(1,469)	185
Accrued liabilities	7,631	554
Deferred grant funding	841	1,375
Lease related liabilities	(866)	(86)
Other long-term liabilities	—	(1)
Net cash used in operating activities	(55,855)	(50,918)
Cash flows from investing activities:		
Purchases of property and equipment	(328)	(106)
Purchases of available-for-sale securities	(166,040)	(138,071)
Proceeds from sales of available-for-sale securities	3,996	—
Proceeds from maturities of available-for-sale securities	156,427	71,478
Net cash used in investing activities	(5,945)	(66,699)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon ESPP purchase	859	—
Proceeds from issuance of common stock upon exercise of stock options	1,426	166
Proceeds from public offering of common stock, net of issuance costs	80,461	116,460
Net cash provided by financing activities	82,746	116,626
Net increase (decrease) in cash and cash equivalents	20,946	(991)
Cash and cash equivalents — beginning of period	10,837	24,417
Cash and cash equivalents — end of period	$ 31,783	$ 23,426
Supplemental disclosures of cash flow information:		
Operating cash flows paid for operating leases	$ 1,015	$ —
Noncash investing and financing activities:		
Purchases of property and equipment included in accounts payable	$ 13	$ —
Lease liability obtained in exchange for right-of-use asset	$ 712	$ —
Conversion of convertible preferred stock to common stock at close of initial public offering	$ —	$ 149,397
Deferred offering costs included in accounts payable and accrued liabilities	$ —	$ 124

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, magrolimab (formerly known as 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 $166.7 million as of September 30, 2019. Since inception through September 30, 2019, the Company has incurred cumulative net losses of $201.2 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").

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"), related to the offering of up to $250.0 million of common stock, preferred stock, debt securities and warrants. The Company may seek to 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/or warrants. The Shelf Registration Statement also 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 September 30, 2019, the Company had not sold any securities pursuant to the Sales Agreement.

In July 2019, pursuant to the Shelf Registration Statement, the Company completed an underwritten public offering of 10,781,250 shares of the Company's 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 net proceeds from the offering to the Company were $80.5 million.

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 nine months ended September 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 revenue and expenses during the reporting period. Significant estimates and assumptions made in the accompanying financial statements include but are not limited to revenue recognition, 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.

Revenue Recognition

License and Collaboration Arrangements

The Company accounts for revenue recognition under Accounting Standards Codification ("ASC"), *Revenue from Contracts with Customers (Topic 606)* ("ASC 606"). Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services.

The Company enters into collaborative arrangements with partners that fall under the scope of ASC, *Collaborative Arrangements (Topic 808)* ("ASC 808"). The Company analyzes it collaboration arrangements to assess whether they are within the scope of ASC 808 to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. The accounting for some of the activities under collaboration arrangements may be analogized to ASC 606 for distinct units of account that are reflective of a vendor-customer relationship. For other elements of collaboration arrangements, such as research and development performed under cost-sharing arrangements, the Company follows the illustrative examples in ASC 808 and generally records research and development reimbursements received as a reduction of research and development expenses.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues attributed to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not generally considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of any development milestones, and if necessary, adjusts its estimate of the transaction price. Any such adjustments would be recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Foreign Currency Transactions

Gains or losses from foreign currency transactions are included in interest and other income, net, in the statements of operations and comprehensive loss. The Company recognized $0.3 million in foreign currency gains for the three months and nine months ended September 30, 2019. Foreign currency losses for the three months ended September 30, 2018 were immaterial. The Company recognized $0.2 million in foreign currency losses for the nine months ended September 30, 2018.

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 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 nine months ended September 30, 2019 are presented under ASC 842. The prior periods continue to be reported in accordance with previous lease guidance, ASC 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 ASC 842, the Company has elected to not separate lease and nonlease components. The Company has also elected to not apply the recognition requirement of ASC 842 to leases with a term of 12 months or less.

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

	December 31, 2018	Adjustments due to the adoption of ASC 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 ASC 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 ASC 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 and US government debt securities 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 September 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 nine months ended September 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 September 30, 2019 and December 31, 2018 are presented in the following tables:

	As of September 30, 2019				
	Fair Value Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Market Value
		(In thousands)			
Money market funds	Level 1	$ 30,546	$ —	$ —	$ 30,546
US government debt securities	Level 1	28,039	13	(10)	28,042
Commercial paper	Level 2	29,612	—	—	29,612
Corporate debt securities	Level 2	52,167	66	—	52,233
Asset-backed securities	Level 2	25,051	22	(1)	25,072
Total cash equivalents and available-for-sale securities		$ 165,415	$ 101	$ (11)	$ 165,505

	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
US government debt securities	Level 1	15,963	—	(1)	15,962
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
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 September 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:

	Nine Months Ended September 30, 2019
	(In thousands)
Beginning balance	$ 331
Change in fair value of embedded derivative	(13)
Ending balance	$ 318

4. Balance Sheet Components

Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2019	December 31, 2018
	(In thousands)	
Accrued research and development expenses	$ 12,605	$ 5,870
Accrued bonuses	2,119	1,602
Deferred rent, current	—	155
Other	1,795	1,417
Total accrued liabilities	$ 16,519	$ 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 months ended September 30, 2019, the Company did not receive any funding related to this grant. During the nine months ended September 30, 2019, the Company received $2.0 million related to this grant. As of September 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. In July 2019, the award was further amended to include the patient population expansion that the Company previously opted out of in 2018. In connection with the same, the award was reinstated to $5.0 million consistent with the original award amount. During the three and nine months ended September 30, 2019, the Company received $0.5 million and $1.2 million related to this grant, respectively. As of September 30, 2019, and December 31, 2018, the Company had received $3.6 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 any remaining unspent CIRM funds.

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 nine months ended September 30, 2019, the Company received $0.3 million related to this grant. As of September 30, 2019, and December 31, 2018, the Company had received $4.2 million and $3.9 million under the award, respectively. 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 September 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 to its agreement with LLS to further advance the treatment of myelodysplastic syndromes ("MDS"). Under the amendment, the Company is eligible for up to $3.0 million in additional grant funding based on milestone payments from LLS upon the achievement of certain clinical or regulatory milestones in addition to the $4.2 million award that the Company has received pursuant to the March 2017 agreement, as amended. Pursuant to the amendment, the Company could be required in the future to pay amounts to LLS upon reaching certain development and regulatory approval milestones on the additional funding, up to a maximum of $6.0 million in the aggregate. The Company concluded that the contingent milestone payments under the amendment were an embedded derivative. As of September 30, 2019, the Company had not received any funding related to this grant and therefore the Company did not record any liability related to this derivative as of September 30, 2019.

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 $0.6 million and $2.2 million as a reduction to research and development expenses for research grants for the three months ended September 30, 2019 and 2018, respectively. The Company recognized a total of $2.6 million and $5.6 million as a reduction to research and development expenses for research grants for the nine months ended September 30, 2019 and 2018, respectively.

Other Collaboration Agreements

Master Combination Study Agreement with Genentech, Inc.

In November 2017, the Company entered into a master clinical trial collaboration agreement with Genentech to evaluate the safety, tolerability and preliminary efficacy of magrolimab combined with Genentech's cancer immunotherapy, atezolizumab, a fully humanized monoclonal antibody targeting PD-L1, in two separate Phase 1b clinical trials (in patients with bladder cancer and AML, respectively). Pursuant to the agreement, the Company will supply magrolimab for the studies and will partially reimburse Genentech for its costs in connection with the bladder cancer study, and Genentech will supply atezolizumab for the studies and be solely responsible for all of its costs in connection with the AML study.

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 magrolimab 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.

bluebird bio, Inc. Research Collaboration Agreement

In September 2019, the Company entered into a research collaboration with bluebird bio, Inc. ("bluebird") to pursue clinical proof-of-concept for the Company's novel antibody-based conditioning regimen, FSI-174 (anti-cKIT antibody) plus magrolimab (anti-CD47 antibody), with bluebird's ex vivo lentiviral vector hematopoietic stem cell (LVV HSC) gene therapy platform. This collaboration will focus initially on diseases that have the potential to be corrected with transplantation of autologous gene-modified blood-forming stem cells.

As of September 30, 2019, the Company recorded a total receivable of $1.0 million from these collaborations for reimbursement of research and development costs incurred. Reimbursement under these collaboration agreements is recorded as a reduction to research and development expense. For the three months ended September 30, 2019 and 2018, the Company recognized $1.0 million and $0.4 million, respectively, as a reduction to research and development expenses under these collaboration agreements. For the nine months ended September 30, 2019 and 2018, the Company recognized $1.9 million and $1.0 million, respectively, as a reduction to research and development expenses under these collaboration agreements.

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 magrolimab, 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 magrolimab and other licensed antibodies outside of the Ono Territory.

Under the agreement, the parties will collaborate on the development, manufacturing and commercialization of magrolimab 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 magrolimab and other licensed antibodies conducted by the other party.

The Company received a one-time upfront nonrefundable payment from Ono of 1.7 billion Japanese Yen ($15.7 million US Dollars based on the exchange rate as of the date of the agreement) and is eligible to receive up to an additional 11.2 billion Japanese Yen 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 magrolimab and other licensed antibodies in the Ono Territory, subject to certain offsets.

The Company accounts for the Ono Agreement as a collaboration arrangement under ASC 808. The Company concluded that the license delivered to Ono is a distinct unit of account for which there is a vendor-customer relationship. For the license, the Company analogized to ASC 606 for the recognition, measurement and reporting of this unit of account. The up-front payment, future

milestones and royalties are attributed to the license component of the Ono Agreement. For the cost-sharing and reimbursement-based activities, the Company will follow the presentation and disclosure guidance of ASC 808. As of September 30, 2019, the cost-sharing and reimbursement-based activities had not commenced under the agreement.

The transaction price at inception included upfront fixed nonrefundable consideration of $15.7 million. All potential future milestones and other payments were considered constrained at the inception of the Ono Agreement. Revenue for the license of $15.7 million was recognized upon delivery of the license in July 2019.

6. Related-Party Relationship with Stanford University

In November 2015, the Company entered into a technology license agreement with Stanford University, under which Stanford granted the Company exclusive licenses under certain patents and other intellectual property rights relating to our current product candidates, including magrolimab, and non-exclusive licenses under certain other patents and other intellectual property rights to develop, manufacture and commercialize products for use in certain licensed fields, including oncology. Under the agreement, the Company is required to pay Stanford a minimum annual fee, milestone payments upon the achievement of certain specified events and a royalty of a tiered single digit percentage on net sales of licensed products, reimburse patent-related expenses and share any non-royalty sublicensing income received related to the licensed technology. As a result of the $15.7 million license payment received under the Ono License and Collaboration Agreement (see Note 5), the Company recorded an estimated sublicensing fee liability of $0.3 million due to Stanford under the agreement during the three and nine months ended September 30, 2019.

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

7. 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 the 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 September 30, 2019, the weighted average remaining lease term was 1.8 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:

	September 30, 2019 (In thousands)
Years	
Remaining 2019	$ 392
2020	1,584
2021	864
Total undiscounted lease payments	2,840
Present value adjustment for minimum lease commitments	(178)
Lease liabilities	$ 2,662

As of September 30, 2019, the current and noncurrent portion of the lease liabilities was $1.4 million and $1.2 million. Rent expense for the operating leases was $0.4 million and $0.2 million for the three months ended September 30, 2019 and 2018, respectively. Rent expense for the operating leases was $0.9 million and $0.8 million for the nine months ended September 30, 2019 and 2018, respectively. Variable lease payments for operating expenses were $0.2 million and $0.1 million for the three months ended September 30, 2019 and 2018, respectively. Variable lease payments for operating expenses were $0.4 million for the nine months ended September 30, 2019 and 2018.

8. Stockholders' Equity

2015 and 2018 Equity Incentive Plans

The following summarizes option activity for the nine months ended September 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	233,652	13.55		
Options exercised	(316,084)	4.51		
Options forfeited	(114,612)	7.86		
Balance outstanding September 30, 2019	3,207,803	$ 7.21	8.22	$ 3,158
Exercisable, September 30, 2019	2,161,959	$ 6.48	8.07	$ 2,505
Vested and expected to vest, September 30, 2019	3,207,803	$ 7.21	8.22	$ 3,158

Total stock-based compensation was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Research and development	$ 437	$ 477	$ 1,323	$ 774
General and administrative	771	794	2,114	1,544
Total	$ 1,208	$ 1,271	$ 3,437	$ 2,318

Restricted Stock

As of September 30, 2019, and December 31, 2018, there was $4,000 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	(45,289)
Unvested shares—September 30, 2019	3,763

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 nine months ended September 30, 2019 was $175,000 and $592,000, respectively. Total stock-based compensation related to the ESPP for the three and nine months ended September 30, 2018 was $231,000.

A total of 94,568 shares of common stock were purchased pursuant to the ESPP during the nine months ended September 30, 2019 for total proceeds of $860,000.

Convertible preferred stock

Through December 31, 2017, the Company's convertible preferred stock was classified in permanent equity as redemption of the convertible preferred stock was in the control of the Company. In February 2018, the Company appointed an additional director which increased the influence of the convertible preferred stockholders on the board of directors. This change to the Company's board composition resulted in the convertible preferred stock being reclassified outside of stockholders' deficit because, in the event of certain "liquidation events" that were not solely within the Company's control (including merger, acquisition, or sale of all or substantially all of the Company's assets), the shares could become redeemable at the option of the holders. Upon the closing of the initial public offering on July 2, 2018, all outstanding shares of convertible preferred stock were automatically converted into 16,215,896 shares of common stock.

9. Net Loss Per Share

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

	As of September 30,	
	2019	**2018**
Stock options to purchase common stock	3,207,803	3,345,155
Restricted stock subject to future vesting	3,763	60,342
Shares committed under ESPP	24,836	18,728
Total	3,236,402	3,424,225

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, magrolimab (formerly known as 5F9), can transform the treatment of cancer. magrolimab has demonstrated promising activity in multiple Phase 1b/2 clinical trials in which we have treated over 400 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 including myelodysplastic syndrome, or MDS, acute myelogenous leukemia, or AML, Non-Hodgkin's lymphoma, or NHL, colorectal cancer, or CRC, gastric cancer, lung cancer, and ovarian cancer with overexpression correlating with poor prognosis in many of these cancers. 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;
- Increasing "eat me" signal expression on cancer cells through cytotoxic and chemotherapeutic agents like azacitidine, which is synergistic with blocking CD47; and
- 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.

Our lead product candidate, magrolimab, 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 magrolimab, combined with our proprietary dosing regimen, overcomes the toxicity limitations of previously tested anti-CD47 therapies developed by others. Across all study populations, magrolimab 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 magrolimab, advancing our preclinical programs, conducting clinical trials and providing general and administrative support for these operations. To date, we have not generated any revenue from product sales. In July 2019, we recognized $15.7 million of license revenue under a license and collaboration arrangement. 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 and licensing revenue. We are eligible to receive up to $21.4 million in grants from the California Institute for Regenerative Medicine, or CIRM, and the Leukemia and Lymphoma Society, or LLS, of which $17.0 million has been received through September 30, 2019.

In June 2018, our Registration Statements on Form S-1 (File Nos. 333-225390 and 333-225933) relating to our initial public offering, or IPO, were declared effective by the Securities Exchange Commission, or SEC (the "Registration Statements"). Pursuant to the Registration Statements, we issued and sold an aggregate of 8,090,250 shares of common stock (inclusive of 1,055,250 shares pursuant to the underwriters' over-allotment option) at a price of $16.00 per share for aggregate cash proceeds of $116.3 million, net of underwriting discounts and commissions and estimated offering costs. The sale and issuance of 7,035,000 shares in the IPO closed on July 2, 2018 and the sale and issuance of an additional 1,055,250 shares pursuant to the underwriters' over-allotment option closed on July 27, 2018. Upon the closing of the IPO on July 2, 2018, all outstanding shares of convertible preferred stock automatically converted into 16,215,896 shares of common stock. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding.

In July 2019, we 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"), related to the offering of up to $250.0 million of common stock, preferred stock, debt securities and warrants. We 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/or warrants. The Shelf Registration Statement also included a prospectus covering the offering, issuance and sale of up to $60.0 million of shares of our common stock, from time to time, in "at-the-market offerings" pursuant to a Controlled Equity Offering^{SM} Sales Agreement (the "Sales Agreement") entered into with Cantor Fitzgerald & Co. (the "Sales Agent") on July 1, 2019. As of September 30, 2019, we had not sold any securities pursuant to the Sales Agreement.

In July 2019, pursuant to the Shelf Registration Statement, 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 net proceeds from the offering to us were approximately $80.5 million.

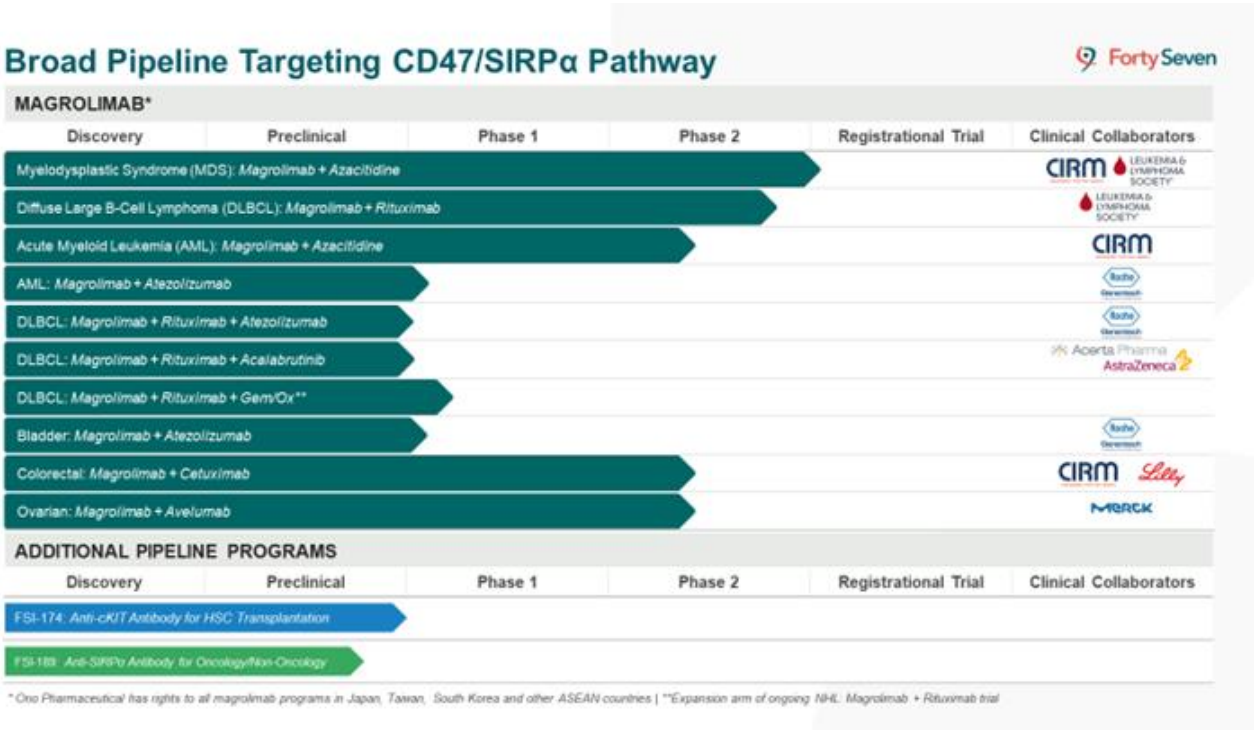
In July 2019, we entered into an amendment of our agreement with the Leukemia & Lymphoma Society, Inc. for up to an additional $3.0 million in grants upon the achievement of certain clinical or regulatory milestones.

We have incurred net losses in each year since inception. Our net losses were $15.2 million and $21.7 million for the three months ended September 30, 2019 and 2018, respectively, and $61.4 million and $53.2 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $201.2 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 magrolimab 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: magrolimab with chemotherapeutic agents, magrolimab with tumor targeting antibodies and magrolimab with T cell checkpoint inhibitors, in a wide variety of tumors, including both solid and hematological cancers. We have treated over 400 patients across programs with magrolimab both as a monotherapy and in combination with chemotherapy and cytotoxics like azacitidine, tumor targeting antibodies such as rituximab and cetuximab, and checkpoint inhibitors. 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.



Magrolimab Monotherapy

In our ongoing monotherapy trials, magrolimab 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 October 2019. 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 also investigated magrolimab as a monotherapy in ovarian cancer and other solid tumors. In a Phase 1 trial of magrolimab, 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 magrolimab, 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 magrolimab 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.

Magrolimab in Combination with Tumor Targeting Antibodies

We are also pursuing multiple trials of magrolimab 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 magrolimab on cancer by using tumor targeting antibodies that bind to cancer cells and present an "eat me" signal to macrophages. Hence, we are combining magrolimab 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 magrolimab could be highly effective. We are conducting a Phase 1b/2 combination trial using magrolimab 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 magrolimab 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 magrolimab 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 magrolimab and rituximab with CALQUENCE (acalabrutinib), an inhibitor of Bruton Tyrosine Kinase, in patients with DLBCL. We will supply magrolimab and Acerta will conduct the study. We are also conducting a Phase 1b/2 combination clinical trial using magrolimab and cetuximab in patients with CRC. Results from this trial are expected in the second half of 2019.

Magrolimab in Combination with Chemotherapeutic Agents

We are also exploring a combination of azacitidine, a chemotherapeutic agent, with magrolimab 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 magrolimab. These results were presented at the 2018 American Society of Hematology meeting. We are conducting a Phase 1b trial of magrolimab with azacitidine in untreated AML and MDS patients to evaluate the safety and efficacy of this combination therapy. Please see "—Recent Developments" below.

Magrolimab Combinations with Checkpoint Inhibitors

We believe there is a strong rationale to combine magrolimab and T cell checkpoint inhibitors and we plan to initiate combination clinical trials in both solid and hematological tumors. magrolimab 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 magrolimab 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 magrolimab 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 magrolimab with BAVENCIO (avelumab) in ovarian cancer patients; and with Genentech, Inc., a member of the Roche Group, on the combination of magrolimab 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 magrolimab in combination with rituximab and TECENTRIQ in patients with DLBCL. We will supply magrolimab, and Merck KGaA and Genentech will supply their respective drug products for these trials.

Recent Developments

Magrolimab for the Treatment of MDS

Clinical Trial Update

In November 2019, we announced ongoing results from our Phase 1b trial designed to evaluate magrolimab as a monotherapy in patients with relapsed or refractory, or r/r, MDS or AML, and magrolimab in combination with azacitidine in untreated higher-risk MDS patients and untreated, induction chemotherapy-ineligible AML patients. Previous results were disclosed at the American Society of Clinical Oncology meeting in June 2019. All patients received a 1 mg/kg priming dose of magrolimab, 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 magrolimab maintenance dose of 30 mg/kg once weekly.

As of the data cutoff of July 10, 2019, 53 patients had been treated in the Phase 1b portion of the trial, including 10 r/r MDS or AML patients who received monotherapy magrolimab, and 43 untreated higher-risk MDS patients or untreated AML patients ineligible for induction chemotherapy, who received magrolimab in combination with azacitidine.

Safety data are available for magrolimab in 10 patients treated with monotherapy and for 43 patients treated in combination with azacitidine. In both groups, magrolimab 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 magrolimab, and no significant cytopenias or autoimmune-related AEs were observed in patients treated with monotherapy magrolimab. 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. In the 43 treatment naïve patients, only one experienced neutropenic fever (2%) and only one patient out of 43 (2%) discontinued treatment due to a treatment-related AE.

Thirty-nine patients were evaluable for response assessment, including 29 patients with untreated higher-risk MDS or AML who were treated with magrolimab and azacitidine (13 patients with higher-risk MDS and 16 patients with untreated AML) and 10 patients with r/r MDS or AML who were treated with monotherapy magrolimab.

- In the 13 untreated higher-risk MDS patients, the overall response rate, or ORR, for the combination was 100%, with seven patients (54%) achieving a complete response, or CR, five patients (39%) achieving a marrow CR, with three of the five had hematologic improvement (HI) and one patient (7%) achieving HI alone.
- In 16 untreated AML patients, the ORR for the combination was 69%, with eight patients (50%) achieving a CR or a complete remission with incomplete hematologic recovery, or CRi, two patients (13%) achieving a PR, and one patient (6%) achieving a morphologic leukemia-free state, or MLFS. Additionally, five patients (31%) achieved stable disease, or SD.
- In r/r MDS or AML treated with monotherapy magrolimab, 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.
- For those untreated patients with abnormal cytogenetics at baseline, 40% and 44% of MDS and AML patients achieved a cytogenetic CR, respectively.
- No median duration of response was reached for either MDS or AML patients with a median follow-up of 4.9 months for MDS and 5.8 months for AML.
- 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 magrolimab in combination with azacitidine.

Registration Strategy Update

Based on the encouraging early clinical data and feedback from a Type B meeting with the FDA we believe a single-arm trial design may be sufficient to support the approval of magrolimab in combination with azacitidine for the treatment of naïve (1st line) intermediate to very high risk MDS patients. We are in ongoing discussions with the FDA through a Special Protocol Assessment, or SPA to determine the best approach and study design to follow for a registration strategy.

We 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. In addition, based on our ongoing interactions with the FDA as part of the SPA process, we plan to initiate a second trial of magrolimab plus azacitidine in untreated intermediate to very high risk MDS patients with dosing every two weeks in the first quarter of 2020. At the completion of both trials, we intend to evaluate the data and determine which dosing regimen to submit as part of our biologics license application ("BLA") submission. Based on chemistry manufacturing controls, CMC BLA enabling studies, the earliest we expect we can file our BLA will be in the fourth quarter of 2021.

Magrolimab 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 magrolimab 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 magrolimab 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 magrolimab 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 magrolimab to mitigate on-target anemia. Patients in the Phase 1b portion of the trial were treated with magrolimab maintenance doses of 10 to 45 mg/kg, and patients in the Phase 2 portion of the trial were treated with magrolimab 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, magrolimab 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 magrolimab for up to 24 months. No maximum tolerated dose was reached with up to 45 mg/kg of magrolimab 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, magrolimab 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 magrolimab saturated the tumor microenvironment similarly to 45 mg/ kg, with similar efficacy. As a result, a 30 mg/kg maintenance dose of magrolimab was selected as the recommended dose for use in future clinical studies.

We also intend to evaluate opportunities to advance magrolimab in combination with rituximab for patients with indolent lymphoma. In February 2019 we dosed our first patient in an expansion cohort of our magrolimab003 NHL Phase 1 trial with a combination of magrolimab 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 magrolimab plus rituximab in heavily pretreated relapsed or refractory DLBCL patients, defined as ≥ 2 prior lines of therapy.

We plan to initiate a registrational trial of magrolimab plus rituximab in DLBCL in the first quarter of 2020, and to report interim efficacy data by the fourth 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. 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. The anticipated efficacy follow up in this trial will be six months. In parallel with the foregoing, we continue to evaluate biomarkers for potential predictive value, which could enable advancement into earlier lines of treatment.

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 will be providing updates to our ongoing MDS and AML programs at The American Society of Hematology meeting in December 2019, as well as, nonhuman primate data on our anti-cKit or FSI-174 program to improve conditioning for stem cell transplants. We also expect to submit an investigational new drug ("IND") application for FSI-174 to the FDA during the fourth quarter of 2019 and we plan to initiate a Phase 1 clinical trial of FSI-174 in healthy volunteers in the first quarter of 2020. Similarly, we expect to submit an IND application for FSI-189 to the FDA during the first quarter of 2020 and we plan to initiate a Phase 1 clinical trial of FSI-189 in the second quarter of 2020.

Our other 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., ("Ono"). Under the agreement, we granted Ono an exclusive license to develop, manufacture and commercialize magrolimab, our monoclonal antibody against CD47, as well as other anti-CD47 antibodies controlled by us in Japan, South Korea, Taiwan and the ASEAN countries, ("the Ono Territory"). We retain all rights to magrolimab and other licensed antibodies outside of the Ono Territory.

Under the agreement, the parties will collaborate on the development, manufacturing and commercialization of magrolimab 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 magrolimab and other licensed antibodies conducted by the other party. We will initially be responsible for supplying magrolimab 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 received a one-time upfront payment from Ono of 1.7 billion Japanese Yen and will be eligible to receive up to an additional 11.2 billion Japanese Yen 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 magrolimab 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 magrolimab 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.

bluebird bio, Inc. Research Collaboration Agreement

In September 2019, we entered into a research collaboration with bluebird bio, Inc. ("bluebird") to pursue clinical proof-of-concept for our novel antibody-based conditioning regimen, FSI-174 (anti-cKIT antibody) plus magrolimab (anti-CD47 antibody), with bluebird's ex vivo lentiviral vector hematopoietic stem cell (LVV HSC) gene therapy platform. This collaboration will focus initially on diseases that have the potential to be corrected with transplantation of autologous gene-modified blood-forming stem cells.

Components of Results of Operations

License Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future. Under the Ono Agreement, we have recognized as revenue the upfront nonrefundable payment related to a license grant. Milestone and royalty payments related to the Ono Agreement will be recognized as the milestones are achieved and royalties are earned.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our lead product candidate, magrolimab, 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, magrolimab, as well as other product candidates in preclinical development including FSI-189, an anti-SIRPα antibody, and FSI-174, an anti-cKIT antibody. 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 nine months ended September 30, 2019 and the year ended December 31, 2018 totaled $3.5 million and $7.6 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 nine months ended September 30, 2019 and 2018, we recognized $0.5 million and $1.4 million, and $0.4 million and $1.0 million, respectively, as a reduction to research and development expenses under this collaboration agreement. In July 2019, we entered into the Ono Agreement. Reimbursement under this collaboration agreement is recorded as a reduction to research and development expense. There were no reimbursements under this collaboration agreement for the three and nine months ended September 30, 2019. In September 2019, we entered into a research collaboration agreement with bluebird. Reimbursement under this collaboration agreement is recorded as a reduction to research and development expense. We recognized $0.5 million of such expense reduction for the three and nine months ended September 30, 2019 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 September 30, 2019 and 2018

	Three Months Ended September 30,		
	2019	2018	Increase/ (Decrease)
	(In thousands)		
License revenue	$ 15,678	$ —	$ 15,678
Operating expenses:			
Research and development	27,074	17,984	9,090
General administrative	4,977	4,383	594
Total operating expenses	32,051	22,367	9,684
Loss from operations	(16,373)	(22,367)	5,994
Interest and other income, net	1,210	708	502
Net loss	$ (15,163)	$ (21,659)	$ 6,496

License Revenue

License revenue increased $15.7 million compared to the three months ended September 30, 2018. The increase in license revenue was due to the license granted under the Ono Agreement.

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 September 30,		
	2019	2018	Increase (Decrease)
	(In thousands)		
Product-specific costs:			
Magrolimab and other product candidates	$ 18,995	$ 9,791	$ 9,204
Grant funding and cost share reimbursement	(1,093)	(2,587)	1,494
Non product-specific costs:			
Stock-based compensation	437	477	(40)
Personnel-related	3,056	1,956	1,100
Other preclinical programs	5,253	2,023	3,230
License fees	426	6,324	(5,898)
Total research and development expenses	$ 27,074	$ 17,984	$ 9,090

Research and development expenses increased by $9.1 million, or 51%, to $27.1 million for the three months ended September 30, 2019 from $18.0 million for the three months ended September 30, 2018. The increase was primarily due to a $9.2 million increase in third-party costs related to advancing our current clinical programs focused on our lead product candidate, magrolimab, and associated contract manufacturing costs, a $1.5 million change in grant and cost share reimbursement primarily due to decreased funding recognized under the CIRM and LLS grants, a $3.2 million increase in our other preclinical and discovery programs costs as we expanded our immuno-oncology efforts, and a $1.1 million increase in personnel-related costs, including stock-based compensation, offset by a $5.9 million decrease in our license fees primarily due to the non-recurring upfront license fees related to the BliNK asset purchase and Synthon license agreements in 2018.

General and Administrative Expenses

General and administrative expenses increased by $0.6 million, or 14%, to $5.0 million for the three months ended September 30, 2019 from $4.4 million for the three months ended September 30, 2018. The increase was primarily due to a $0.4 million increase in personnel-related costs driven by an increase in headcount and a $0.3 million increase in directors and officer's insurance expense, partially offset by a $0.2 million decrease in professional services fees due to a decrease in legal services related to patents.

Interest and Other Income, Net

Interest and other income, net increased by $0.5 million to $1.2 million for the three months ended September 30, 2019 from $0.7 million for the three months ended September 30, 2018. The increase was primarily due to a $0.4 million increase in foreign currency gains primarily from gains arising from the Ono Agreement compared to foreign currency losses recognized in the comparable prior year period and a $0.1 million increase in interest income earned from the investment of net proceeds from our IPO in July 2018 and our public offering in July 2019.

Nine months ended September 30, 2019 and 2018

	Nine Months Ended September 30,		
	2019	2018	Increase/ (Decrease)
	(In thousands)		
License revenue	$ 15,678	$ —	15,678
Operating expenses:			
Research and development	65,029	42,733	22,296
General administrative	14,618	11,588	3,030
Total operating expenses	79,647	54,321	25,326
Loss from operations	(63,969)	(54,321)	(9,648)
Interest and other income, net	2,584	1,165	1,419
Net loss	$ (61,385)	$ (53,156)	$ (8,229)

License Revenue

License revenue increased $15.7 million compared to the nine months ended September 30, 2018. The increase in license revenue was due to the license granted under the Ono Agreement.

Research and Development Expenses

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

	Nine Months Ended September 30,		
	2019	2018	Increase (Decrease)
	(In thousands)		
Product-specific costs:			
Magrolimab and other product candidates	$ 44,334	$ 29,354	$ 14,980
Grant funding and cost share reimbursement	(3,967)	(6,549)	2,582
Non product-specific costs:			
Stock-based compensation	1,323	774	549
Personnel-related	8,955	6,092	2,863
Other preclinical programs	13,658	4,238	9,420
License fees	726	8,824	(8,098)
Total research and development expenses	$ 65,029	$ 42,733	$ 22,296

Research and development expenses increased by $22.3 million, or 52%, to $65.0 million for the nine months ended September 30, 2019 from $42.7 million for the nine months ended September 30, 2018. The increase was primarily due to a $15.0 million increase in third-party costs related to advancing our current clinical programs focused on our lead product candidate, magrolimab, and associated contract manufacturing costs, and a $2.6 million change in grant and cost share reimbursement primarily due to decreased funding recognized under the CIRM and LLS grants, a $9.4 million increase in our other preclinical and discovery programs costs as we expanded our immuno-oncology efforts, a $3.4 million increase in personnel-related costs, including stock-based compensation, offset by a $8.1 million decrease in our license fees primarily due to the non-recurring upfront license fees related to the BliNK asset purchase and Synthon license agreements in 2018.

General and Administrative Expenses

General and administrative expenses increased by $3.0 million, or 26%, to $14.6 million for the nine months ended September 30, 2019 from $11.6 million for the nine months ended September 30, 2018. The increase was primarily due to a $2.2 million increase in personnel-related costs driven by an increase in headcount and a $0.7 million increase in directors and officer's insurance expense.

Interest and Other Income, Net

Interest and other income, net increased by $1.4 million to $2.6 million for the nine months ended September 30, 2019 from $1.2 million for the nine months ended September 30, 2018. The increase was primarily due to a $1.0 million increase in interest income earned from the investment of the net proceeds from our IPO in July 2018 and our public offering in July 2019 and a $0.4 million increase in foreign currency gains primarily from gains arising from the Ono agreement compared to foreign currency losses recognized in the comparable prior year period.

Liquidity, Capital Resources and Plan of Operations

To date, we have incurred significant net losses and negative cash flows from operations. As of September 30, 2019, we had $166.7 million in cash, cash equivalents and short-term investments.

In connection with our initial public offering, which closed on July 2, 2018, we issued and sold an aggregate of 8,090,250 shares of common stock (inclusive of 1,055,250 shares of common stock from the exercise of the over-allotment option granted to the underwriters) at a price of $16.00 per share. We received proceeds from the offering of $116.3 million, net of underwriting discounts and commissions and estimated offering costs.

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. We received proceeds from the offering of $80.5 million, net of underwriting discounts and commissions and offering costs.

In July 2019, we entered into the Ono Agreement. Under the Ono Agreement, we received a one-time upfront nonrefundable payment from Ono of 1.7 billion Japanese Yen.

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to our lead product candidate, magrolimab, 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:

	Nine Months Ended September 30,	
	2019	2018
	(In thousands)	
Net cash used in operating activities	$ (55,855)	$ (50,918)
Net cash used in investing activities	(5,945)	(66,699)
Net cash provided by financing activities	82,746	116,626
Net increase (decrease) in cash and cash equivalents	$ 20,946	$ (991)

Operating Activities

During the nine months ended September 30, 2019, cash used in operating activities of $55.9 million was attributable to a net loss of $61.4 million, partially offset by $3.6 million in non-cash charges and a net change of $1.9 million in net operating assets and liabilities. The non-cash charges consisted primarily of stock-based compensation of $3.4 million, amortization of right-of-use assets of $0.8 million and depreciation and amortization of $0.4 million, partially offset by $1.0 million related to the accretion of discounts on marketable securities. The change in operating assets and liabilities was primarily due to a $6.1 million increase in accounts payable and accrued liabilities resulting from the timing of payments and a $0.8 million increase in deferred grant funding due to receipt of the research grant funding payments. These changes were partially offset by a $3.7 million increase in prepaid expense and other current assets driven by additional prepayments made for research and development activities and other receivables, a $0.9 million decrease in lease related liabilities due to lease payments and a $0.4 million increase in other noncurrent assets driven by timing of the research and development prepayments and payment of offering costs.

During the nine months ended September 30, 2018, cash used in operating activities of $50.9 million was attributable to a net loss of $53.2 million and a net change of $0.1 million in net operating assets and liabilities, partially offset by $2.3 million in non-cash charges. The non-cash charges consisted primarily of stock-based compensation of $2.3 million. The change in operating assets and liabilities was primarily due to a $2.2 million increase in in prepaid expense and other current assets driven by additional prepayments made for research and development activities and other receivables, offset by a $0.7 million increase in accounts payable and accrued liabilities resulting from an increase in accrued bonus and the timing of payments, and a $1.4 million increase in deferred grant funding due to research grant award payments received.

Investing Activities

During the nine months ended September 30, 2019, cash used in investing activities was $5.9 million related to the purchase of investments of $166.0 million and the purchase of property and equipment of $0.3 million, partially offset by the proceeds from maturities of investments of $156.4 million and the proceeds from the sale of investments of $4.0 million.

During the nine months ended September 30, 2018, cash used in investing activities was $66.7 million related to the purchase of short-term investments of $138.1 million, partially offset by the maturity of investments of $71.5 million.

Financing Activities

During the nine months ended September 30, 2019, cash provided by financing activities was $82.7 million related to the net proceeds received in the public offering of our common stock of $80.5 million, the proceeds received from the exercise of stock options of $1.4 million and the proceeds received from the issuance of common stock upon ESPP purchase of $0.9 million.

During the nine months ended September 30, 2018, cash provided by financing activities was $116.6 million related primarily to the net proceeds received from our initial public offering.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations as of September 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 nine months ended September 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, stock-based compensation and revenue recognition have the most significant impact on our condensed financial statements. Therefore, we consider these to be our critical accounting policies and estimates. For a discussion of our other significant accounting policies, please see our Annual Report on Form 10-K for the fiscal year ended December 31, 2018. Except for our revenue recognition policy, 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.

Revenue Recognition

We enter into license and collaboration agreements under which we may receive up-front license fees and potential development milestone payments. In accordance with ASC 606, we changed certain characteristics of our revenue recognition accounting policy as described below.

License and Collaboration Arrangements

We enter into collaborative arrangements with partners that fall under the scope of ASC 808. We analyze these collaboration arrangements to assess whether they are within the scope of ASC 808 to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. The accounting for some of the activities under collaboration arrangements may be analogized to ASC 606 for distinct units of account that are reflective of a vendor-customer relationship.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of its agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

If these arrangements contain a license to our intellectual property, we must use judgement to determine if the license is distinct from the other performance obligations identified in the arrangement. If the license is determined to be distinct, we recognize revenues attributed to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. Payment for the license typically includes non-refundable, upfront license fees, and potential development milestone payments. For the milestone payments, we must estimate whether the milestones are considered probable of being reached and estimate the amount, if any, to be included in the transaction price.

Recent Accounting Pronouncements

Please refer to Note 2 to our unaudited condensed consolidated financial statements appearing under Part I, 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 $166.7 million and $139.0 million as of September 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. 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 magrolimab-related products. Under the Lonza agreements, we are required to pay Lonza fixed fees based on manufacturing services performed. The fees payable under Lonza agreements are denominated in British Pounds. There were immaterial foreign currency gains and losses for the three and nine months ended September 30, 2019 and for the three months ended September 30, 2018 under the Lonza agreements. We recognized $0.2 million in foreign currency losses for the nine months ended September 30, 2018 under the Lonza agreements.

In July 2019, we entered into an exclusive license and collaboration agreement with Ono Pharmaceutical Co., Ltd., ("Ono"). Under the agreement, we received a one-time upfront nonrefundable payment from Ono of 1.7 billion Japanese Yen. During the time that the receivable for the upfront payment was outstanding, we were subject to exchange rate changes. We recognized $0.3 million in foreign currency transaction gains for the three and nine months ended September 30, 2019, due to the timing of license delivery and receipt of payment. Under the agreement, we may also be eligible to receive up to an additional 11.2 billion Japanese Yen 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 magrolimab 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

During the quarter ended September 30, 2019, we completed the implementation of an Enterprise Resource Planning System ("ERP"), including a core financial module. In connection with the implementation of the ERP system, we updated the processes that constitute our internal control over financial reporting to accommodate changes to our business processes and accounting procedures.

Except as otherwise described above, there have been no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934, as amended) during the quarter ended September 30, 2019, that 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 $61.4 million and $53.2 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $201.2 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 September 30, 2019, we had cash, cash equivalents and short-term investments of $166.7 million. In July 2019, we closed an underwritten public offering with net proceeds of approximately $80.5 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, magrolimab, 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, magrolimab, 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 magrolimab in one or more of these indications. We cannot be certain that magrolimab 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 magrolimab 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 magrolimab 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, magrolimab, 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 magrolimab 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 magrolimab for the treatment of relapsed and/or refractory DLBCL, relapsed and/or refractory FL, and myelodysplastic syndrome and acute myeloid leukemia, 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 magrolimab for the treatment of relapsed and/or refractory DLBCL and relapsed and/or refractory FL. In September 2019, the FDA granted Fast Track designations to magrolimab for the treatment of myelodysplastic syndrome and acute myeloid leukemia. 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 magrolimab, such Fast Track designations do not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe for any of these fast track-designated indications. 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 magrolimab, 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 magrolimab, 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 magrolimab 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 magrolimab and our other product candidates;
- limitations or warnings contained in the labeling approved for magrolimab 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 magrolimab 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 magrolimab 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 magrolimab. Lonza is currently our sole supplier of magrolimab. 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 magrolimab 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 magrolimab 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 magrolimab 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 magrolimab in treating AML is contingent upon a showing that magrolimab 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 magrolimab 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 magrolimab 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 September 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 magrolimab. 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 magrolimab 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 magrolimab 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 magrolimab 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 magrolimab 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 September 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 September 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 September 30 (the end of our third 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 (File Nos. 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^	Exclusive License and Collaboration Agreement, dated July 10, 2019 by and between Forty Seven, Inc. and Ono Pharmaceutical Co., Ltd.				
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.

^ Portions of this exhibit (indicated by asterisks) have been omitted as we have determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm to us if publicly disclosed.

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: November 12, 2019

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

Date: November 12, 2019

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

Exhibit 10.1

[***] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

EXECUTION VERSION
CONFIDENTIAL

EXCLUSIVE LICENSE AND COLLABORATION AGREEMENT

by and between

FORTY SEVEN, INC.

and

ONO PHARMACEUTICAL CO., LTD.

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EXCLUSIVE LICENSE AND COLLABORATION AGREEMENT

This **EXCLUSIVE LICENSE AND COLLABORATION AGREEMENT** (this "**Agreement**") effective as of July 10, 2019 (the "**Effective Date**"), is by and between **FORTY SEVEN, INC.**, a Delaware corporation with an address at 1490 O'Brien Drive, Suite A, Menlo Park, CA 94025, United States ("**Forty Seven**"), and **ONO PHARMACEUTICAL CO., LTD.**, a company organized and existing under the laws of Japan, with an address at 8-2, Kyutaromachi 1-chome, Chuo-ku, Osaka 541-8564, Japan ("**Ono**"). Forty Seven and Ono may be referred to herein each as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, Forty Seven is currently conducting research and development of its proprietary anti-CD47 antibodies, including Hu5F9-G4, for the treatment of cancer and other indications;

WHEREAS, Ono is a pharmaceutical company with experience in research, manufacturing, developing and commercializing pharmaceutical products in and outside Japan;

WHEREAS, Ono wishes to obtain exclusive license and rights to develop, seek regulatory approval for, manufacture, market and sell such anti-CD47 antibodies in the Ono Territory, as more fully described below, and Forty Seven wishes to grant such license and rights to Ono as set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the Parties hereby agree as follows:

ARTICLE I
DEFINITIONS

1.1 "**Adverse Event**" means any adverse medical occurrence in a patient or clinical investigation subject to whom a Licensed Antibody is administered and which could but does not necessarily have a causal relationship with such Licensed Antibody, including any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the administration of such Licensed Antibody, whether or not considered related to Licensed Antibody administration.

1.2 "**Affiliate**" means, with respect to a Person, an individual, trust, business trust, joint venture, partnership, corporation, association, or other legal entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a legal entity.

1.3 "**Antibody**" means any antibody or antigen binding fragment thereof (including any bispecific or multi-specific antibody, single chain antibody or domain antibody) and/or similar antigen binding protein, whether polyclonal, monoclonal, human, humanized, chimeric, murine, synthetic or from any other source.

1.4 "**Applicable Laws**" means any federal, state, local, national, and supra-national laws, statutes, rules, and/or regulations, including any rules, regulations, guidance, guidelines, or requirements of Regulatory Authorities, national securities exchanges, or securities listing organizations, that may be in effect from time to time during the Term and apply to a particular activity hereunder, including laws, regulations, and guidelines governing the import, export, Development, Manufacture, Commercialization of, or Medical Affairs Activities relating to, any Product in or for the applicable jurisdiction.

1.5 "**ASEAN Countries**" means Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

1.6 "**Attack Action**" has the meaning set forth in Section 10.11.1.

1.7 "**Bankruptcy Code**" has the meaning set forth in Section 2.11.

1.8 "**Bankruptcy Laws**" has the meaning set forth in Section 2.11.

1.9 "**Biosimilar Product**" means, with respect to a Product sold by Ono (or any of its Affiliates or Sublicensees) in a particular country, any product that (a) (i) is approved for sale in such country in reliance on or by reference to the prior Regulatory Approval of such Product as determined by the applicable Regulatory Authority or (ii) is approved for sale in such country as structurally similar to such Product as determined by the applicable Regulatory Authority; (b) is approved as an interchangeable substitute for such Product in such country; and (c) is sold by a Third Party that is not a Sublicensee of Ono (or any of its Affiliates) and did not acquire such product from a chain of distribution that included any of Ono or any of its Affiliates or Sublicensees. "Biosimilar Product" includes any biosimilar, follow-on biologic or generic biological product, as those terms are commonly understood under Title VII of the United States Patient Protection and Affordable Care Act (also known as the Biologics Price Competition and Innovation Act), the Hatch-Waxman Act, EU Directive 2004/27/EC, the PFSB/ELD Notification No. 0304007 dated March 4, 2009 and any successor legislation or regulations relating thereto, and all similar foreign legislation with regard to the foregoing.

1.10 "[***]" has the meaning set forth in Exhibit D.

1.11 "**Business Day**" means a day that is not a Saturday, Sunday, a day on which banking institutions in Tokyo, Japan, or San Francisco, California, are required by law to remain closed, or a day within Forty Seven's corporate holidays (for Forty Seven's obligations) or Ono's corporate holidays (for Ono's obligations).

1.12 "**Calendar Quarter**" means each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30, or December 31; provided, however that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the first to occur of March 31, June 30, September 30, or December 31 of the calendar quarter in which the Effective Date falls; and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.

1.13 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31; provided however, that (a) the first Calendar Year of the Term shall extend from the Effective Date to the first December 31 of the calendar year in which the Effective Date falls; and (b) the last Calendar Year of the Term shall end upon the expiration or termination of this Agreement.

1.14 "**CD47**" means the human transmembrane protein known as Cluster of Differentiation 47, also known as integrin associated protein (IAP).

1.15 "[***]" means [***].

1.16 "**Chairperson**" has the meaning set forth in Section 3.2.2.

1.17 "[***]" means those Patents set forth in Exhibit A.

1.18 "**Claims**" has the meaning set forth in Section 13.1.

1.19 "**Clinical Study**" means a clinical trial of a Licensed Antibody or Product in humans, including a Phase 1 study, Phase 2 study, Phase 3 study, an Ono post-registration study, a Forty Seven post-registration study or a Global Study.

1.20 "**Commercialization**" means any and all activities undertaken before and after obtaining Regulatory Approval relating specifically to the pre-launch, launch, promotion, marketing, sale, and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling, and delivering a Product to customers) of such Product, including: (a) seeking Pricing Approval for such Product, (b) strategic marketing, sales force detailing, advertising, medical education, and market and product support within the Field, and (c) all customer support, invoicing and sales activities within the Field; but excluding in all cases Medical Affairs Activities. "**Commercialize**" means to engage in Commercialization activities.

1.21 "**Commercialization Plan**" has the meaning set forth in Section 6.2.3.

1.22 "**Commercially Reasonable Efforts**" means, with respect to a Party in the performance of its obligations hereunder, (a) where such obligations relate to the Development or Commercialization of a Product, the application by or on behalf of such Party of a level of efforts that a similarly-situated pharmaceutical company which is engaged in the development and commercialization of pharmaceutical or biological products, as the case may be, would apply to such activities in relation to a similar pharmaceutical or biological product owned by it or to which it has exclusive rights, which product is at a similar stage in its development or product life and is of similar market potential and strategic value (in each case as compared to such Product) taking into account efficacy, safety, expected labeling, price, the competitiveness of alternative products in the marketplace sold by Third Parties, the patent and other proprietary position of the product, the likelihood of regulatory approval given the regulatory structure involved, the expected and actual profitability of the product and other relevant factors, based on conditions then prevailing; and (b) with respect to any other obligations, the same level of efforts as such Party would apply if it were performing a similar obligation solely on its own behalf.

1.23 "**Competing Product**" means [***].

1.24 "**Competing Program**" has the meaning set forth in Section 2.10.1.

1.25 "**Composition of Matter**" means, with respect to a Licensed Antibody, its composition of matter or its molecular structure. It is confirmed that, as of the Effective Date, [***].

1.26 "**Confidential Information**" means all information of a confidential or proprietary nature disclosed by a Party to the other Party under this Agreement, including any such information related to any scientific, clinical, engineering, manufacturing, marketing, financial, or personnel matters relating to a Party, or related to a Party's present or future products, sales, suppliers, customers, employees, investors, business plans, Know-How, regulatory filings, data, compounds, research projects, work in progress, future developments or business, in all such cases whether disclosed in oral, written, graphic or electronic form, and whether or not specifically marked as confidential or proprietary, where under the circumstances in which such disclosure was made or given the nature of information disclosed, a reasonable person would consider such information confidential; provided, however, that in any event, Confidential Information excludes any information that the receiving Party can show through competent evidence: (a) is known by receiving Party at the time of disclosure, and not through a prior disclosure by or on behalf of the disclosing Party; (b) is or becomes properly in the public domain through no fault of the receiving Party; (c) is subsequently rightfully disclosed to the receiving Party by a Third Party who is not directly or indirectly under an obligation of confidentiality to the disclosing Party; or (d) is developed by the receiving Party independently of, and without reference to or use of, the information received from the disclosing Party. Confidential Information shall include: (i) the terms and conditions of this Agreement (which shall be both Parties' Confidential Information); and (ii) Confidential Information disclosed by either Party pursuant to the Confidentiality Agreement.

1.27 "**Confidentiality Agreement**" means the One-Way Non-Disclosure Agreement between the Parties dated February 8, 2017, as amended January 17, 2019.

1.28 "**Control**" means with respect to any Know-How, Patent, or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license, or otherwise, to grant a license, sublicense, or other right to or under, such Know-How, Patent, or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party at the time when such license, sublicense, or other right is first granted hereunder, subject to Section 2.9.2.

1.29 "**Cover**" means, with respect to a Patent and a product, such Patent would (absent a license thereunder or ownership thereof) be infringed by the manufacture, use or sale of such product, provided, however, that in determining whether a claim of a pending Patent application would be infringed, it shall be treated as if issued in the form then currently being prosecuted. "**Covered**" and "**Covering**" shall have correlative meanings.

1.30 "**CREATE Act**" has the meaning set forth in Section 10.6.7.

1.31 "**Data**" means any and all scientific, technical, test, marketing, or sales data pertaining to any Product that is Controlled by Forty Seven or its Affiliates, or Ono, its Affiliates, and Sublicensees, including research data, clinical pharmacology data, pre-clinical data, non-clinical data, CMC data, clinical data (including clinical data and other related information generated in compliance with standards regulated by the Clinical Data Interchange Standards Consortium / CDISC), Safety Data, clinical study reports, or submissions made in association with an IND or an MAA with respect to any Product.

1.32 "**Development**" means all development activities for the Product that are directed to obtaining Regulatory Approval(s) of the Product, including all non-clinical, preclinical, and clinical testing and studies of the Product; toxicology, pharmacokinetic, and pharmacological studies; statistical analyses; assay development; protocol design and development; all development activities for and related to chemical, manufacture and control portion of any MAA; the preparation, filing, and prosecution of any IND or MAA for the Product; development activities directed to label expansion and/or obtaining Regulatory Approval for one or more additional indications following initial Regulatory Approval; development activities conducted after receipt of Regulatory Approval; and all regulatory affairs related to any of the foregoing. "**Develop**" and "**Developing**" have correlative meanings.

1.33 "**Development Costs**" means, with respect to any Development activities, all costs incurred by or on behalf of either Party, as applicable, that are reasonably and directly allocable to the conduct of such activities and shall consist of the fully burdened internal and external costs actually incurred by each Party, including costs of Product or any comparator drug used in such activities.

1.34 "**Development Plan**" means the Global Development Strategy, the Ono Development Plan, the Forty Seven Development Plan or the Global Study Development Plan, as applicable.

1.35 "**Divest**" means, for purposes of Section 2.10.2, the sale or transfer of rights to the Competing Program to a Third Party such that neither Party nor any of its Affiliates, Sublicensees or Forty Seven Partners have the right to engage, and neither a Party nor any of its Affiliates, Sublicensees or Forty Seven Partners in fact engage, in any management, governance or decision-making activities in connection with such Competing Program. "**Divestiture**" shall have the correlative meaning.

1.36 "[***]" means [***].

1.37 "**Enrollment Threshold**" has the meaning set forth in Section 4.3.1.

1.38 "**Exchange Rate**" means the exchange rate as follows: (a) for Ono's payment pursuant to Sections 9.1, 9.2.1 and 9.2.2, the exchange rate published by OANDA.com "The Currency Site" under the heading "FxHistory: historical currency exchange rates" at www.OANDA.com/convert/fxhistory as of the applicable payment date, and (b) for Ono's payment pursuant to Section 9.3, the average of said exchange rate during the relevant calendar month in the relevant Calendar Quarter.

1.39 "**Executive Officers**" means [***] or his or her designee in case of Forty Seven, and [***] or his or her designee in case of Ono.

1.40 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.41 "**Field**" means [***].

1.42 "**First Commercial Sale**" means, with respect to a country in the Ono Territory, the first commercial sale under this Agreement by Ono, its Affiliates, or its Sublicensees of any Product to a Third Party, which is not an Affiliate or a Sublicensee of Ono, after obtaining all Regulatory Approval legally required for such sale of the Product from the Regulatory Authority. For the avoidance of doubt, (i) sales of Products to an Affiliate or Sublicensee of Ono shall not constitute a First Commercial Sale unless such Affiliate or Sublicensee is an end user or prescriber of the Product and (ii) complimentary delivery and delivery at nominal value of the Products for end use or consumption as "named patient sales", as "compassionate use" or through other "patient access programs" shall not constitute a First Commercial Sale.

1.43 "**Fiscal Year**" means Ono's fiscal year, which runs from April 1 to March 31.

1.44 "[***]" means [***].

1.45 "**Forty Seven Corporate Marks**" has the meaning set forth in Section 6.6.2.1.

1.46 "**Forty Seven Development Plan**" has the meaning set forth in Section 4.1.2.

1.47 "**Forty Seven Group**" has the meaning set forth in Section 13.1.

1.48 "**Forty Seven Indemnitees**" has the meaning set forth in Section 13.2.

1.49 "**Forty Seven Know-How**" means all Know-How owned or Controlled by Forty Seven or its Affiliates as of the Effective Date or during the Term which are necessary or reasonably useful for the research, Development, Manufacture, Commercialization, sale, distribution, importation, exportation, or use of a Licensed Antibody or a Product, excluding (a) any such Know-How to the extent relating to the Composition of Matter or method of manufacturing of any Antibody (or other active ingredient) that is not a Licensed Antibody, and (b) Forty Seven's interest in any Joint Know-How. For clarity, such Forty Seven Know-How includes Know-How related to [***].

1.50 "**Forty Seven Partner**" and "**Forty Seven Partner Agreement**" have the respective meanings set forth in Section 4.4.3.

1.51 "**Forty Seven Patents**" means all Patents, including those set forth in Exhibit B, Controlled by Forty Seven or its Affiliates as of the Effective Date or during the Term which Cover the research, Development, Manufacture, use, sale, distribution, importation, exportation, or Commercialization of the Licensed Antibody or Products in the Field, excluding (a) any such Patent to the extent relating to the Composition of Matter or method of manufacturing of any Antibody (or other active ingredient) that is not a Licensed Antibody and (b) Forty Seven's interest in any Joint Patents.

1.52 "**Forty Seven Manufactured Product**" means any Product, other than a Hu5F9-G4 Product, for which Forty Seven has developed a GMP Manufacturing process. For clarity, a Forty Seven Manufactured Product is limited to such Product as Manufactured using such GMP Manufacturing process.

1.53 "**Forty Seven Technology**" means the Forty Seven Patents, Forty Seven Know-How and Forty Seven's interest in Joint Technology.

1.54 "**Forty Seven Territory**" means the world other than the Ono Territory.

1.55 "**GAAP**" means generally accepted accounting principles of the United States.

1.56 "**GCP**" means the current standards for clinical studies for pharmaceuticals, as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("**ICH**") guidelines and applicable regulations promulgated thereunder, as amended from time to time.

1.57 "**Global Commercialization Strategy**" has the meaning set forth in Section 6.1.1.

1.58 "**Global Common Activities**" has the meaning set forth in Section 4.3.4.

1.59 "**Global Common Costs**" has the meaning set forth in Section 4.3.4.

1.60 "**Global Development Strategy**" has the meaning set forth in Section 4.1.2.

1.61 "**Global Development Working Group**" has the meaning set forth in Section 3.5.

1.62 "**Global Medical Affairs Strategy**" has the meaning set forth in Section 8.2.

1.63 "**Global Registration Strategy**" has the meaning set forth in Section 5.1.1.

1.64 "**Global Study**" has the meaning set forth in Section 4.3.1.

1.65 "**Global Study Development Plan**" has the meaning set forth in Section 4.3.4.

1.66 "**Global Study Proposal**" has the meaning set forth in Section 4.3.2.

1.67 "**GLP**" means the current standards for laboratory activities for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development, as amended from time to time, and such standards of good laboratory practice as are required by the MHLW and other organizations and Governmental Authorities in countries in which a Product is intended to be sold, to the extent such standards are not less stringent than United States Good Laboratory Practice.

1.68 "**GMP**" means all Applicable Laws and guidelines applicable to Manufacture of the Licensed Antibody or Product, including (a) the FD&C Act (21 U.S.C. 321 et seq.); (b) relevant United States regulations in Title 21 of the United States Code of Federal Regulations (including Parts 11, 210, and 211); (c) European Community Directives 2001/83/EC and 2003/94/EC; (d) the EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, as set out in Volume 4 of the European Commission's Rules governing medicinal products in the EU; (e) those standards required by the MHLW; (f) ICH, Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; (g) similar standards and Applicable Laws to those in (a) through (f), as are in effect at the time of Manufacture of the Licensed Antibody and/or Product; and (h) all additional Regulatory Authority documents or regulations that replace, amend, modify, supplant or complement any of the foregoing.

1.69 "**Governmental Authority**" means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.

1.70 "[***]" means [***].

1.71 "**HHMI**" means the Howard Hughes Medical Institute.

1.72 "**Hu5F9-G4**" means the antibody having the protein sequence set forth in Exhibit C.

1.73 "**Hu5F9-G4 Product**" means any Product containing Hu5F9-G4.

1.74 **"IFRS"** means International Financial Reporting Standards.

1.75 "**Improvement**" shall mean (a) any modifications to the structure (including by mutation, conjugation, ligation, post-translational modification or otherwise), or (b) any enhancement or change in the formulation, ingredients, preparation, presentation, means of delivery, dosage, packaging, or manufacture, in each case of (a) and (b) of any Licensed Antibody or Product.

1.76 "**IND**" means an investigational new drug application filed with the FDA pursuant to 21 CFR 312.20, a clinical trial notification filed with the PMDA, or a corresponding filing required for the clinical testing in humans of a pharmaceutical product, and all amendments and supplements thereto.

1.77 "**Indemnified Party**" has the meaning set forth in Section 13.3.

1.78 "**Indemnifying Party**" has the meaning set forth in Section 13.3.

1.79 "**Investigator Sponsored Clinical Study**" means a Clinical Study of a Licensed Antibody or Product in the Field that is sponsored and conducted by a physician, physician group or other Third Party not acting on behalf of a Party, its Affiliates, Sublicensees or Forty Seven Partners and who does not have a license from a Party, its Affiliates, Sublicensees or Forty Seven Partners to Commercialize such Licensed Antibody or Product, pursuant to an IND owned by such Third Party, and with respect to which a Party, its Affiliates, Sublicensees or Forty Seven Partners provides clinical supplies of the Licensed Antibody and Product, funding or other support for such Clinical Study.

1.80 "**Joint Know-How**" means any Know-How (other than Forty Seven Know-How or Ono Know-How) that is discovered, made or developed jointly by one or more employees of Forty Seven or its Affiliates (or a Third Party acting on any of their behalf) and one or more employees of Ono or its Affiliates (or a Third Party acting on any of their behalf).

1.81 "**Joint Patent**" means any Patent that is jointly owned by Forty Seven and Ono during the Term which Cover the research, Development, Manufacture, use, sale, distribution, importation, exportation, or Commercialization of the Licensed Antibody or Products in the Field.

1.82 "**Joint Patent Costs**" has the meaning set forth in Section 10.6.3.3.

1.83 "**Joint Patent Prosecuting Party**" has the meaning set forth in Section 10.6.3.1.

1.84 "**Joint Technology**" means the Joint Know-How and the Joint Patents.

1.85 "**JSC**" has the meaning set forth in Section 3.1.

1.86 "**Know-How**" means any non-public knowledge, experience, know-how, technology, information, and data, trade secrets, formulas and formulations, processes, techniques, unpatented inventions, methods, discoveries, specifications, formulations, compositions, materials, ideas, and developments, protocols, test procedures, and results, together with all documents and files embodying the foregoing, but excluding any issued Patents to the extent claiming any of the foregoing.

1.87 "**Knowledge**" means, with respect to a Party, the actual knowledge of any of such Party's executive officers and employees.

1.88 "**Liaison**" has the meaning set forth in Section 3.6.1.

1.89 "**Licensed Antibody**" means any Antibody Controlled by Forty Seven during Term that specifically binds to CD47, [***] Hu5F9-G4 [***].

1.90 "**Licensing Party**" has the meaning set forth in Section 2.9.2.2.

1.91 "[***]" means [***], as applicable.

1.92 "[***]" means the [***] and the [***].

1.93 "[***]" has the meaning set forth in Exhibit D.

1.94 "[***]" has the meaning set forth in Exhibit D.

1.95 "[***]" has the meaning set forth in Section 7.3.1.]

1.96 "**MAA**" means a marketing authorization application or equivalent application (including a new drug application or biological license application), and all amendments and supplements thereto, filed with the applicable Regulatory Authority.

1.97 "**Manufacture**" and "**Manufacturing**" mean activities directed to manufacturing, processing, filling, finishing, packaging, labeling, quality control, quality assurance testing and release, post-marketing validation testing, inventory control and management, storing and transporting any Product, including oversight and management of vendors therefor. For avoidance of doubt, Manufacture excludes all development activities for and related to the chemical, manufacture and control portion of an MAA.

1.98 "**Manufacturing Coordinator**" has the meaning set forth in Section 7.1.

1.99 "**Manufacturing Costs**" means, with respect to a particular Licensed Antibody or Product (whether as active pharmaceutical ingredient or finished form) supplied by Forty Seven pursuant to Section 7.2 or 7.3.3: (a) (i) if Forty Seven or its Affiliate Manufactures the applicable Product, the fully-burdened costs for such Manufacture; or (ii) if a Third Party Manufactures such Licensed Antibody or Product, the actual acquisition cost paid by Forty Seven or its Affiliate to such Third Party for the Manufacture of such Licensed Antibody or Product (inclusive of all amounts paid by Forty Seven to such Third Party in connection with such Manufacturing, or for amounts not specific to such Manufacturing run, a reasonable allocation thereof) without mark-up; (b) in each case, the external costs of insurance and transportation for such Licensed Antibody or Product (including any customs charges and fees and taxes assessed for the Ono Territory); and (c) [***]. For clarity, Manufacturing Costs shall [***]. Notwithstanding the foregoing, Manufacturing Costs shall not include costs and expenses incurred for Development activities for and related to chemical, manufacture and control part of an MAA, which shall [***], unless such activities are required solely for the Ono Territory and not the Forty Seven Territory, in which case such costs and expenses shall be included in Manufacturing Costs. In the case of Manufacturing Costs made in one or more currencies other than US Dollars, the amount of Manufacturing Costs in such other currencies shall be converted into US Dollars in accordance with Forty Seven's accounting procedure, to the extent reasonable and consistently applied by Forty Seven across all of its products and in accordance with US-GAAP.

1.100 "**Medical Affairs Activities**" means: (a) the coordination of medical information requests and field based medical liaisons with respect to Products commercially launched in any Territory; and (b) those clinical studies conducted in any Territory after Regulatory Approval of a Product has been obtained which are neither intended nor designed to support a Regulatory Filing including medical affairs studies, post marketing studies, and Investigator Sponsored Clinical Studies.

1.101 "**Medical Affairs Plan**" has the meaning set forth in Section 8.2.

1.102 "[***] **Agreement**" has the meaning set forth in Exhibit D.

1.103 "**MHLW**" means the Japanese Ministry of Health, Labour and Welfare and any successor Governmental Authority having substantially the same function.

1.104 "**Net Sales**" means, with respect to any Product, all gross revenue received by Ono, its Affiliates, or Sublicensees, from the sale, transfer or other disposition of such Product to an end user in the Ono Territory. Net Sales excludes the following items (but only as they pertain to the making, using, importing or selling of Product, are included in gross revenue, and are separately accounted for):

[***]

Components of Net Sales shall be determined in the ordinary course of business in accordance with IFRS, consistently applied throughout Ono. For purposes of determining when a sale of any Product occurs for purposes of calculating Net Sales, the sale will be deemed to occur on the date of Ono's shipment of the Product to the customer or wholesaler. No deductions will be permitted for commissions paid to individuals or agents, nor for the cost of collections. For purposes of determining Net Sales, a "sale" shall not include transfers or dispositions, at no cost or below cost, of Products for charitable, pre-clinical, clinical, or regulatory purposes, including for purposes of analytical testing, or for promotional samples or free goods. Amounts invoiced by Ono or its Affiliates or its Sublicensees for the sale of Products to or among such Affiliates or Sublicensees for resale shall not be included in the computation of Net Sales hereunder.

In the event that Ono sells a Product (a) to a Third Party in a bona fide arm's length transaction, for material consideration, in whole or in part, other than cash (but excluding, for the avoidance of doubt, consideration in the form of non-financial legal terms and conditions incident to sale), (b) to a Third Party in other than a bona fide arm's length transaction, or (c) with discounts of Products that are disproportional to the discounts of other products sold by Ono in conjunction with such Products, the Net Sales price for such Product shall be deemed to be the standard invoice price then being invoiced by Ono in an arm's length transaction with similar customers in the Ono Territory.

If a Product either is sold in the form of a combination product containing both a Licensed Antibody and one or more active ingredient(s) as separate molecular entity(ies) that are not Licensed Antibodies (a "**Combination Product**"), the Net Sales of such Product for the purpose of calculating royalties and sales-based milestones owed under this Agreement for sales of such Product, shall be determined as follows with respect to the country of sale: [***]

1.105 "[***]" has the meaning set forth in Section 2.13.2.

1.106 "[***]" has the meaning set forth in Section 2.13.3.

1.107 "**New Intellectual Property**" has the meaning set forth in Section 2.9.2.1.

1.108 "[***]" means [***].

1.109 "[***]" has the meaning set forth in Section 2.13.2.

1.110 "**Ono Development Plan**" has the meaning set forth in Section 4.1.2.

1.111 "**Ono Group**" has the meaning set forth in Section 13.2.

1.112 "**Ono Indemnitees**" has the meaning set forth in Section 13.1.

1.113 "**Ono Know-How**" means all Know-How owned or Controlled by Ono during the Term (a) which is necessary or reasonably useful for the research, Development, Manufacture, Commercialization, sale, distribution, importation, exportation or use of a Licensed Antibody or a Product, and (b) which is actually used by Ono or its Affiliates at any time during the Term for research, Development, Manufacture, use, sale, distribution, importation, exportation or Commercialization of a Licensed Antibody or Product for the Ono Territory, excluding (i) any such Know-How to the extent relating to the Composition of Matter or method of manufacturing of any Antibody (or other active ingredient) that is not a Licensed Antibody and (ii) Ono's interest in any Joint Know-How.

1.114 "**Ono Patents**" means all Patents Controlled by Ono during the Term which Cover the research, Development, Manufacture, use, sale, distribution, importation, exportation, or Commercialization of the Licensed Antibody or the Products in the Field, excluding (a) any such Patent to the extent relating to the Composition of Matter or method of manufacturing of any Antibody (or other active ingredient) that is not a Licensed Antibody and (b) Ono's interest in any Joint Patents.

1.115 "**Ono Technology**" means the Ono Patents, Ono Know-How and Ono's interest in Joint Technology.

1.116 "**Ono Territory**" means Japan, South Korea, Taiwan and the ASEAN Countries.

1.117 "**Opt-In Request**" has the meaning set forth in Section 4.3.3.

1.118 "**Opt-In Period**" has the meaning set forth in Section 4.3.3.

1.119 "**Patents**" means (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings, and patent applications (including provisional patent applications); (b) any renewals, divisions, or continuations (in whole or in part) of any of such patents, certificates of invention and patent applications, and any all patents or certificates of invention issuing thereon; and (c) any and all reissues, reexaminations, extensions, supplementary protection certificates, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

1.120 "**Person**" means any individual, corporation, association, partnership (general or limited), joint venture, trust, estate, limited liability company, limited liability partnership, unincorporated organization, government (or any agency or political subdivision thereof) or other legal entity or organization.

1.121 "**Pivotal Trial**" means a Clinical Study that is intended to be a basis of Regulatory Approval by the applicable Regulatory Authority and to provide an adequate basis for physician labeling, as described in 21 C.F.R. 312.21(c), as amended from time to time, or the corresponding regulations in jurisdictions other than the United States. Any clinical trial or portion thereof that is designated in the protocol or deemed by a Party or its Affiliates or Sublicensees as Phase 2b or Phase 3 and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product, or a similar Clinical Study prescribed by the relevant Regulatory Authorities shall be deemed to be a Pivotal Trial.

1.122 "**PMDA**" means the Japanese Pharmaceuticals and Medical Devices Agency, or any successor agency thereto.

1.123 "**Pricing Approval**" means the approval, agreement, determination or governmental decision establishing the list price for the Product to be paid by the applicable insurance provider and the individual end-consumer or patient.

1.124 "[***]" has the meaning set forth in Section 4.3.4.

1.125 "**Product**" means any pharmaceutical product consisting of or containing a Licensed Antibody, whether dosage form is same or different, whether formulation is same or different, whether mode of administration is same or different, and whether alone or in combination with one or more other therapeutically active ingredients.

1.126 "**Product Trademark**" has the meaning set forth in Section 6.6.1.1.

1.127 "**Prosecuting Party**" has the meaning set forth in Section 10.6.5.

1.128 "**Recall**" has the meaning set forth in Section 5.8.

1.129 "**Registration Plan**" has the meaning set forth in Section 5.1.1.

1.130 "**Regulatory Approval**" means any approval, product and establishment license, registration, or authorization of any Regulatory Authority required for the manufacture, use, storage, import, transport, or Commercialization of a Licensed Antibody or Product in accordance with Applicable Laws, excluding Pricing Approval.

1.131 "**Regulatory Authority**" means any applicable government regulatory authority involved in granting approvals for the Manufacture, Commercialization, reimbursement, and/or pricing of a Licensed Antibody or Product.

1.132 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights (other than Patent(s)) conferred by any Regulatory Authority with respect to a pharmaceutical product, including orphan drug exclusivity, new chemical entity exclusivity, data exclusivity, or pediatric exclusivity.

1.133 "**Regulatory Filings**" means all documentation, correspondence, submissions, and notifications submitted to or received from a Regulatory Authority that are necessary or reasonably useful in order to Manufacture, Develop or Commercialize the Product in the Field. For the avoidance of doubt, Regulatory Filings include, with respect to each Product, all INDs, MAAs, Regulatory Approvals, and amendments and supplements of any of the foregoing, as well as the contents of any minutes from meetings (whether in person or by audio conference or videoconference) with a Regulatory Authority.

1.134 "**Responding Party**" has the meaning set forth in Section 11.3.1.

1.135 "[***]" has the meaning set forth in Section 2.13.1.

1.136 "[***]" means [***].

1.137 "**Royalty Term**" has the meaning set forth in Section 9.3.2.

1.138 "**Safety Data**" means Data related solely to any adverse drug experiences and serious adverse drug experience as such information is reportable to Regulatory Authorities. Safety Data also includes "adverse events", "adverse drug reactions", and "unexpected adverse drug reactions" as defined in the ICH Harmonised Tripartite Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

1.139 "**SEC**" has the meaning set forth in Section 11.4.3.

1.140 "[***]" has the meaning set forth in Section 2.13.1.

1.141 "[***]" means [***].

1.142 "[***]" means [***].

1.143 "[***]" has the meaning set forth in Exhibit D.

1.144 "[***]" means [***].

1.145 "**Subcontractor**" has the meaning set forth in Section 2.2.2.

1.146 "**Sublicensee**" means either a Third Party or an Affiliate of Ono, in each case which is granted a sublicense by Ono (whether directly or through multiple tiers) to any of the Forty Seven Technology to Develop, use, Manufacture, have Manufactured, sell, offer for sale, distribute, import and export or otherwise Commercialize the Licensed Antibody and the Product in the Field in the Ono Territory pursuant to Section 2.2.1. For clarity, "Sublicensee" excludes any Subcontractor.

1.147 "**Submitting Party**" has the meaning set forth in Section 11.3.1.

1.148 "**Sunshine Reporting Laws**" has the meaning set forth in Section 5.9.

1.149 "[***]" has the meaning set forth in Exhibit D.

1.150 "**Tax**" or "**Taxes**" means (a) any taxes, assessments, fees, including income, profits, gross receipts, net proceeds, sales, alternative or add on minimum, ad valorem, turnover, property, personal property (tangible and intangible), environmental, stamp, leasing, lease, user, duty, franchise, capital stock, transfer, registration, license, withholding, social security (or similar), unemployment, disability, payroll, employment, social contributions, fuel, excess profits, occupational, premium, windfall profit, severance, estimated, or other charge of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not and (b) any liability for the payment of any amounts of the type described in clause (a) as a result of the operation of law or any express obligation to indemnify any other person.

1.151 "**Tax Residence Certificate**" has the meaning set forth in Section 9.8.3.

1.152 "**Technology Transfer Completion**" has the meaning set forth in Section 7.3.1.

1.153 "**Term**" has the meaning set forth in Section 14.1.

1.154 "**Territory**" means Ono Territory or Forty Seven Territory, as applicable.

1.155 "**Third Party**" means a Person other than Ono, Forty Seven, or their respective Affiliates.

1.156 "**Upstream Agreements**" means the agreements listed in Exhibit D, as such agreements may be amended from time to time.

1.157 "**Upstream Licensor**" means a counterparty to an Upstream Agreement or such counterparty's licensor (directly or indirectly) of any of the Forty Seven Patent or Forty Seven Know-How.

1.158 "**Valid Claim**" means: (a) a claim of an issued and unexpired Patent included within the Forty Seven Patents, which has not been permanently revoked or declared unenforceable or invalid by an unappealable or unappealed decision of a court or other appropriate body of competent jurisdiction, and that has not been abandoned, disclaimed, denied, or admitted to be invalid or unenforceable through reissue, re-examination, or disclaimer or otherwise; or (b) a claim of a pending patent application included within the Forty Seven Patents, which claim has not been cancelled, withdrawn or abandoned, nor been pending for more than [***] from the earliest filing date to which such patent application or claim is entitled.

1.159 "**Withholding Tax Action**" has the meaning set forth in Section 9.8.5.

1.160 "**Working Group**" has the meaning set forth in Section 3.5.

ARTICLE II
LICENSES

2.1 **License Grant to Ono**.

2.1.1 Subject to the terms and conditions of this Agreement, Forty Seven hereby grants to Ono an exclusive license (or sublicense, as applicable), with the right to sublicense through multiple tiers (subject to Section 2.2), under the Forty Seven Technology to research, Develop, use, Manufacture, have Manufactured, sell, offer for sale, distribute, import and export or otherwise Commercialize the Licensed Antibodies and the Products in the Field in the Ono Territory.

2.1.2 Upon Ono's reasonable request in writing and solely with Forty Seven's prior written consent on a case-by-case basis, not to be unreasonably withheld, delayed or conditioned, Forty Seven shall grant to Ono, subject to the terms and conditions of this Agreement, a non-exclusive, royalty-free license (or sublicense, as applicable), under the Forty Seven Technology to Manufacture or have Manufactured the Licensed Antibodies and the Products in the Forty Seven Territory solely for Development and Commercialization in the Field in the Ono Territory.

2.1.3 Upon Ono's reasonable request in writing, Forty Seven shall grant to Ono, subject to the terms and conditions of this Agreement, a non-exclusive, royalty-free license (or sublicense, as applicable), under the Forty Seven Technology to conduct non-clinical testing of the Licensed Antibodies and/or the Products, including process research, in countries in the Forty Seven Territory solely for Development and Commercialization in the Field in the Ono Territory.

2.2 **Sublicensing by Ono**.

2.2.1 Subject to the terms and conditions of this Agreement, Ono shall have the right to sublicense the rights granted to it under Section 2.1 to:

2.2.1.1 any of its Affiliates without Forty Seven's consent, provided that (a) Ono provides Forty Seven with prior notice of the name of the Affiliate and the rights to be sublicensed, and (b) any such sublicense granted by Ono to an Affiliate shall terminate if (i) such entity is no longer an Affiliate of Ono and (ii) Ono or such entity does not obtain Forty Seven's prior written consent to continue such sublicense, which consent shall not be unreasonably withheld, delayed or conditioned; and

2.2.1.2 Third Parties solely with the prior written consent of Forty Seven, except as set forth in Section 2.2.2;

provided that, for any sublicense granted by Ono under this Section 2.2.1, (a) such Affiliate or Third Party shall agree in writing to comply with the terms and conditions of this Agreement that are applicable to activities by such Affiliate and Third Party under such sublicense; (b) Ono shall remain fully liable for the performance of such Affiliate and Third Party in connection with this Agreement; and (c) Ono shall provide Forty Seven with a copy of each agreement with any Third Party pursuant to which a sublicense is granted pursuant to this Section 2.2.1, from which Ono may redact any terms unrelated to this Agreement.

2.2.2 Subject to the terms and conditions of this Agreement, Ono shall have the right to sublicense the rights granted to it under Section 2.1 to Third Parties that (a) are solely performing services on behalf of, or for the benefit of, Ono or its Affiliates or Sublicensees in connection with Ono's or its Affiliates' or Sublicensees' efforts to Develop, use, Manufacture, have Manufactured, sell, offer for sale, distribute, import and export or otherwise Commercialize the Licensed Antibodies and the Products in the Ono Territory (or in the Forty Seven Territory, to the extent permitted pursuant to Sections 2.1.2 and 2.1.3) in accordance with the terms of this Agreement, including for example, academic institutions, clinical trial sites, investigators, contract research organizations, Third Party Manufacturers, co-promotion partner or any similar independent contractors, and (b) in each case, are not granted any rights to use such sublicensed rights for any other purposes and will obtain no rights to any Licensed Antibody or Product in connection with the exercise of such sublicensed rights (each such Third Party, a "**Subcontractor**"), provided that any such sublicense shall be made pursuant to a written agreement that is consistent with this Agreement, including the intellectual property and confidentiality provisions hereof. Ono shall identify its Subcontractors to Forty Seven upon request by Forty Seven.

2.3 **Forty Seven Retained Rights**. Forty Seven hereby expressly retains, for itself and its Affiliates and Forty Seven Partners:

2.3.1 the rights under the Forty Seven Technology to exercise its rights and perform its obligations under this Agreement and the Upstream Agreements, whether directly or through one or more Affiliates or licensees (other than Ono) or subcontractors, including Forty Seven's obligations to Manufacture and supply Hu5F9-G4 Product and Forty Seven Manufactured Product;

2.3.2 the rights to Manufacture and have Manufactured the Licensed Antibodies and Products (and to perform and have performed Development activities related to such Manufacturing) in the Ono Territory, solely for Development and Commercialization in the Forty Seven Territory and fulfillment of its obligations to Manufacture and supply Hu5F9-G4 Product and Forty Seven Manufactured Product; and

2.3.3 all rights to practice, and to grant licenses, under the Forty Seven Technology outside of the scope of the licenses granted in Section 2.1, and the exclusive right to practice the Forty Seven Patents and Forty Seven Know-How worldwide with respect to compounds and products other than the Licensed Antibodies and Products.

2.4 **Licenses to Forty Seven**.

2.4.1 Ono hereby grants to Forty Seven, subject to the terms and conditions of this Agreement, an exclusive, royalty-free license, with the right to sublicense through multiple tiers, under the Ono Technology to use, research, Develop, Commercialize, Manufacture, have Manufactured, import, export and otherwise exploit the Licensed Antibodies and Products in the Forty Seven Territory.

2.4.2 Ono hereby grants to Forty Seven, subject to the terms and conditions of this Agreement, a non-exclusive, royalty-free license, with the right to sublicense through multiple tiers, under the Ono Technology to Manufacture, have Manufactured and import the Licensed Antibodies and Products (and to perform and have performed Development activities related to such Manufacturing) in the Ono Territory, solely in connection with the performance of its obligations and exercise of its rights hereunder, including fulfillment of its obligations to Manufacture and supply Hu5F9-G4 Product and Forty Seven Manufactured Products.

2.5 **No Implied License**. Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, other than the license rights that are expressly granted under this Agreement.

2.6 **Ono Covenants.**

2.6.1 Ono covenants that, during the Term, it shall not practice any Forty Seven Technology outside the scope of the licenses expressly granted by Section 2.1. All Know-How and materials disclosed or provided under this Agreement by or on behalf of Forty Seven shall be used by Ono solely for the purposes of performing its obligations or exercising the licenses and rights expressly granted herein.

2.6.2 Ono covenants that, during the Term, it shall not and shall cause its Affiliates and Sublicensees not to (a) Develop or Manufacture any Product in the Forty Seven Territory, except to the extent permitted under Sections 2.1.2 and 2.1.3, (b) Commercialize or conduct Medical Affairs Activities for any Product in the Forty Seven Territory, or (c) knowingly assist any Third Party in undertaking any activity described in subclause (a) or (b) above. For clarity, the foregoing shall not prevent Ono or its Affiliates or Sublicensees from filing for and prosecuting Regulatory Approval in the Forty Seven Territory for one or more products (which shall not be Product(s) or Competing Product(s)) to be used in combination with a Licensed Antibody (including by cross-referencing an IND or MAA with respect to such Licensed Antibody in accordance with Section 5.4) and Commercializing and conducting Medical Affairs Activities for such product in the Forty Seven Territory for use in combination with such Licensed Antibody, provided that Ono and its Affiliates and Sublicensees shall not conduct any other Development activity with respect to such Licensed Antibody (including conducting any Clinical Study with such Licensed Antibody in the Forty Seven Territory) other than the non-clinical testing of the Licensed Antibodies and/or the Products as permitted under Ono's license rights set forth in Section 2.1.3, without Forty Seven's prior written consent, not to be unreasonably withheld, delayed or conditioned.

2.6.3 [***].

2.7 **Forty Seven Covenants**.

2.7.1 Forty Seven hereby covenants that, during the Term, it shall not practice any Ono Technology that is outside the scope of the license expressly granted by Section 2.4. All Know-How or materials disclosed or provided under this Agreement by or on behalf of Ono shall be used by Forty Seven solely for the purposes of performing its obligations or exercising the licenses and rights expressly granted herein.

2.7.2 Forty Seven hereby covenants that, during the Term, it shall not and will cause its Affiliates and Forty Seven Partners not to (a) Develop any Product in the Ono Territory, except to the extent permitted under Forty Seven's retained rights set forth in Section 2.3; (b) Commercialize or conduct Medical Affairs Activities for any Product in the Ono Territory; or (c) knowingly assist any Third Party in undertaking any activity described in subclause (a) or (b) above. For clarity, the foregoing shall [***], provided that Forty Seven and its Affiliates and Forty Seven Partners shall [***].

2.7.3 [***].

2.7.4 Forty Seven hereby covenants that it shall not (i) terminate any Upstream Agreement to the extent relating to any Licensed Antibody or Product in the Ono Territory, (ii) assign any Upstream Agreement or any obligation of Forty Seven thereunder, except in connection with an assignment of this Agreement in its entirety pursuant to Section 16.4, or (iii) change any term and condition of any Upstream Agreement that is expected to adversely impact Ono's exercise of its license rights granted in Section 2.1.1 (it being confirmed that [***]), in each of case (i), (ii) or (iii), without the prior written consent of Ono, not to be unreasonably withheld, delayed or conditioned.

2.7.5 Forty Seven hereby covenants that it shall use Commercially Reasonable Efforts to [***].

2.8 **Upstream Agreements**.

2.8.1 To the extent that any rights granted to Ono under this Agreement are Controlled by Forty Seven pursuant to an Upstream Agreement, (a) such rights are subject to the terms and conditions of such Upstream Agreement, and (b) Ono agrees to comply with such terms and conditions.

2.8.2 Without limiting the generality of Section 2.8.1:

2.8.3 Ono acknowledges that any sublicense granted to Ono under the [***], unless otherwise agreed in writing by [***]. Ono further acknowledges that any further sublicense of such rights to a Third Party, including contract manufacturers, is limited to certain Third Parties approved by [***], and shall not purport to grant any such sublicense to any Third Party that has not been approved by [***].

2.8.4 Solely to the extent that Ono (or its Affiliate or Sublicensee) elects to [***], Ono hereby grants (and will cause such Affiliate or Sublicensee to grant) to Forty Seven such rights [***].

2.8.5 [***].

2.9 **Third Party Agreements**

2.9.1 **Existing Intellectual Property**. Each Party shall be solely responsible for any and all amounts due to any Third Party under any agreement entered into by and between such Party or its Affiliates and such Third Party prior to the Effective Date relating to such Party's and its Affiliates' intellectual property due to the other Party's use of such intellectual property in accordance with this Agreement.

2.9.2 New Intellectual Property.

2.9.2.1 If a Party identifies during the Term any intellectual property of a Third Party (a) directed to one or more Licensed Antibodies or Products in the Territory that (i) is necessary or useful for Manufacture, use or Commercialization of a Licensed Antibody or Product and (ii) is not Controlled by either Party, or (b) relates to any anti-CD47 Antibody (the intellectual property described in subclauses (a) and (b), "**New Intellectual Property**"), then such Party promptly shall notify the other Party through appropriate working group established by the JSC hereof in writing prior to acquiring or obtaining license under such New Intellectual Property. In such event, Forty Seven shall have the first right to acquire or obtain a world-wide license to such intellectual property and to negotiate the terms and conditions for acquisition of or obtaining license under such New Intellectual Property, but shall keep Ono reasonably informed of such negotiations in a timely manner and duly consider Ono's comments with respect thereto. In the event that Forty Seven elects not to acquire or obtain license under such New Intellectual Property or fails to acquire or obtain license under such New Intellectual Property within [***] following the initial notice mentioned in this Section, then Ono may proceed to acquire or obtain license under such New Intellectual Property.

2.9.2.2 If a Party (the "**Licensing Party**") acquires or obtains rights (whether by license or acquisition) under any New Intellectual Property from a Third Party pursuant to Section 2.9.2.1 that is subject to royalty, milestone or other payment obligations to such Third Party with respect to the exercise of such rights in the other Party's Territory, then the Licensing Party shall so notify such other Party and shall disclose to such other Party a true, complete and correct written description of such payment obligations. If such other Party agrees in writing to reimburse the Licensing Party for a reasonable portion (as mutually agreed by the Parties in writing) of any upfront fee, milestone payments, royalties or other amounts (A) due to such Third Party by reason of the acquisition by, grant to, or exercise by or under the authority of, the non-Licensing Party of such rights with respect to such New Intellectual Property and (B) that are paid or owing by the Licensing Party in connection therewith, the rights to such New Intellectual Property shall be deemed included in the Forty Seven Technology (where Forty Seven is the Licensing Party) or Ono Technology (where Ono is the Licensing Party); provided, however, that the non-Licensing Party's obligation to reimburse such amounts shall be limited to those payment obligations as disclosed by the Licensing Party pursuant to the first sentence of this Section 2.9.2.2. For clarity, if the non-Licensing Party does not agree in writing to reimburse the Licensing Party for such amounts as set forth above, then the applicable New Intellectual Property shall not be included in the Forty Seven Technology or Ono Technology, as applicable, hereunder.

2.9.2.3 The Licensing Party shall notify the other Party in writing within [***] of acquiring or licensing any New Intellectual Property, which notice shall specify the applicable terms and conditions, including any payments therefor .

[***]

2.10 [***].

2.11 **Rights in Bankruptcy**. All licenses and similar use rights granted under or pursuant to any Section of this Agreement are and will otherwise be deemed to be for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, U.S. Code), as amended (the "**Bankruptcy Code**"), and of any comparable or similar laws and regulations in any other country or jurisdiction (collectively, such laws and regulations with the Bankruptcy Code, the "**Bankruptcy Laws**"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that the applicable Party, as licensees or sublicensees of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the applicable Bankruptcy Laws. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the applicable Bankruptcy Laws, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) such intellectual property and all embodiments of such intellectual property (including supporting materials such as files relating to prosecution or enforcement), which, if not already in such other Party's possession, will be promptly delivered to it upon its written request thereof. Any agreements supplemental to this Agreement will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code and all similar provisions of the other Bankruptcy Laws.

2.12 **Subcontractors**. Either Party may engage Third Party subcontractors in the performance of its obligations or exercise of its rights hereunder, subject to Section 2.2.2, provided that the activities of any such Third Party subcontractors will be considered activities of such Party under this Agreement. The subcontracting Party will be responsible for ensuring compliance by each such Third Party subcontractor with the terms of this Agreement, as if such Third Party were such Party hereunder, and shall remain directly liable to the other Party for any non-compliance with this Agreement by such Third Party subcontractors.

2.13 [***]

ARTICLE III
GOVERNANCE

3.1 **JSC; Formation and Purpose**. Within [***] of the Effective Date, the Parties will establish a joint steering committee (the "**JSC**") to provide strategic oversight and facilitate communication with respect to the Development, Manufacturing, and Commercialization under this Agreement with respect to the Licensed Antibodies and Products in the Field. The Parties anticipate that the JSC will not be involved in day-to-day implementation of such activities under this Agreement. Except as otherwise provided herein, the role of the JSC will be to:

3.1.1 coordinate the management and implementation of the Parties' Manufacturing, Development (including regulatory matters), Commercialization and Medical Affairs Activities under this Agreement;

3.1.2 ensuring harmonization of the Development and Commercialization strategy for the Licensed Antibodies and Products in the Ono Territory and the Development and Commercialization strategy for the Licensed Antibodies and Products in the Forty Seven Territory;

3.1.3 review and provide comments with respect to the Development and Commercialization strategy of (a) Forty Seven, its Affiliates and/or licensees in the Forty Seven Territory and (b) Ono, its Affiliates and/or Sublicensees in the Ono Territory, and any material updates or amendments thereto, including those recommended by the Global Development Working Group;

3.1.4 review, coordinate, and discuss the overall strategy for seeking Regulatory Approval of the Products in the Field in the Parties' respective Territories;

3.1.5 review either Party's Global Study Proposal pursuant to Section 4.3.2;

3.1.6 review, discuss, and oversee the conduct of the Development Plans and Commercialization Plans, including any amendments or revisions thereto;

3.1.7 review relevant Data (including clinical data) and market metrics (e.g., sales, market share and prescriber perceptions) to track the progress toward goals set forth in the Development Plans, Medical Affairs Plans and Commercialization Plans;

3.1.8 review and coordinate forecasting of Ono's expected requirements for Hu5F9-G4 Product and Forty Seven Manufactured Products and discuss any supply chain issues;

3.1.9 review progress reports provided by Forty Seven with respect to Development activities by Forty Seven, its Affiliates and/or licensees, and by Ono with respect to its Development activities by or on behalf of Ono;

3.1.10 oversee the Manufacturing and supply relationship between the Parties with respect to Manufacture of Hu5F9-G4 Product and Forty Seven Manufactured Product in connection to Forty Seven's supply obligations set forth in Sections 7.2 and 7.3;

3.1.11 providing a forum for the Parties to discuss Commercialization of Products in the Field worldwide, including coordination regarding Products positioning and messaging, key opinion leader relationship management, Medical Affairs Activities, and marketing and promotional materials for each Territory;

3.1.12 oversee the Global Development Working Group and create and oversee any subcommittees or other working groups as the JSC may deem appropriate;

3.1.13 address any issues expressly delegated to the JSC under this Agreement; and

3.1.14 performing such other activities as the Parties determine to be the responsibility of the JSC.

3.2 **Membership and Procedures**.

3.2.1 **Membership**. Promptly after the Effective Date, each Party will designate three (3) representatives with appropriate expertise to serve as members of the JSC. Each Party may replace its representatives on the JSC at any time upon written notice to the other Party.

3.2.2 **Chairperson**. The JSC shall be co-chaired, with one (1) member of the JSC designated by Forty Seven and one (1) member of the JSC designated by Ono (the "**Chairperson**"), who will be responsible for organizing meetings, including, if feasible, ensuring that objectives for each meeting are set and achieved. Either Party shall have the right to change its Chairperson by written notice to the other Party. Responsibility for running each meeting of the JSC will alternate between the Chairpersons from meeting to meeting, with Forty Seven's Chairperson running the first meeting.

3.2.3 **Meetings**. Until the [***] of the First Commercial Sale of the first Product in the Ono Territory, the JSC will hold meetings no less frequently than twice per Calendar Year during the Term. Thereafter, the JSC will hold meetings no less frequently than once per Calendar Year. Meetings of the JSC shall be effective only if at least one (1) representative of each Party is present or participating. The JSC may meet either (a) in person at either Party's facilities or at such locations as the Parties may otherwise agree; or (b) by audio or video teleconference, provided that at least one (1) meeting per Calendar Year shall be held in person with the location to alternate between Forty Seven's and Ono's offices, with the first such meeting to be held at Forty Seven's offices. With the prior consent of the other Party's representatives (such consent not to be unreasonably withheld or delayed), each Party may invite non-members to participate in the discussions and meetings of the JSC, provided that such participants shall have no vote and shall be subject to the confidentiality provisions set forth in Article XI. Additional meetings of the JSC may also be held with mutual agreement of the Parties, or as required under this Agreement, and neither Party will unreasonably withhold, delay or condition its consent to hold such an additional meeting.

3.2.4 **Limitation of Authority**.

3.2.4.1 The JSC and its subcommittees will have only such powers as are specifically delegated to it hereunder and will not be a substitute for the rights of the Parties. Without limiting the generality of the foregoing, neither the JSC nor any of its subcommittees will have any power to amend this Agreement, waive compliance with any obligation hereunder or determine whether any breach hereunder has occurred.

3.2.4.2 For clarity, the JSC does not have the authority to commit Forty Seven to conduct or complete any activity of Forty Seven or its Affiliates or Forty Seven Partners set forth in any Development Plan, which activities are included for informational purposes only.

3.3 **Decision-Making**.

3.3.1 The JSC will make good faith efforts to make all decisions on matters before it by consensus. Subject to the terms of this Section 3.3, actions to be taken by the JSC shall be taken only following a unanimous vote, with each Party's representatives collectively having one (1) vote on behalf of such Party. For each meeting of the JSC, the attendance of at least one (1) representative of each Party shall constitute a quorum. Action on any matter may be taken at a meeting, by teleconference, videoconference or by written consent. If the JSC fails to reach unanimous consent on a particular matter within [***] of a Party having requested a formal vote on such matter (or, if such matter is urgent, within [***] of such request), then either Party may submit such matter for resolution to the Executive Officers pursuant to Section 15.2, subject to Section 3.3.2.

3.3.2 If the JSC is unable to reach a decision by unanimous vote pursuant to Section 3.3.1 and the Executive Officers cannot unanimously agree on such matter within [***] of such matter being submitted to them pursuant to Section 3.3.1 (or, if such matter is urgent, within [***] of such request), then, such dispute shall be subject to this Section 3.3.2:

[***].

3.3.3 Notwithstanding the foregoing, neither Party shall have the right to use its deciding vote in Section 3.3.2 to decide on any of the following matters, which shall be mutually agreed to by the Parties:

(a) the feasibility of a Clinical Study as a Global Study pursuant to Section 4.3.2;

(b) any matter that would conflict with a Global Study Development Plan (provided that, to the extent that a Global Study Development Plan would require a Party to take or refrain from any action in a manner that would constitute a violation of Applicable Laws, the foregoing shall not require such Party to take or refrain from such action);

(c) any matter that would materially adversely impact the safety, commercial value or reputation of the Product in the other Party's Territory;

(d) the imposition of any requirements on the other Party to undertake obligations beyond those for which it is responsible, or to forgo any of its rights, under this Agreement;

(e) the imposition of any requirements that the other Party take or decline to take any action that would result in a violation of any Applicable Laws or any agreement with any Third Party or the infringement of intellectual property rights of any Third Party;

(f) any matter that would excuse such Party from any of its obligations under this Agreement; or

(g) modifying the terms and conditions of this Agreement, including taking any action to expand or narrow the responsibilities of the JSC.

3.3.4 Notwithstanding anything to the contrary set forth herein,

(a) the decision-making Party shall make its decision in good faith, subject to the terms and conditions of this Agreement;

(b) in no event may the decision-making Party unilaterally determine that it has fulfilled any obligations hereunder or that the non-deciding Party has breached any obligations hereunder; and

(c) each Party may not make a decision that would cause the other Party to be in breach of a provision of any Upstream Agreement.

3.4 **Expenses**. Each Party will be responsible for all of its own travel and other costs and expenses for its respective members, designees, and non-member invitees to attend meetings of, and otherwise participate on, the JSC and any subcommittees or working groups.

3.5 **Working Groups**. Upon mutual agreement, the Parties may establish other committees or working groups (each, a "**Working Group**") as they deem appropriate. These Working Groups shall report to the JSC depending on the subject matter of such Working Group's oversight. Each Working Group shall have equal number of representatives from each Party. Working Group may be established on an ad hoc basis for purposes of a specific project. In no event shall the authority of a Working Group exceed that of the JSC. The Parties agree to the establishment of a global development working group (the "**Global Development Working Group**") after the Effective Date. The Global Development Working Group shall share and exchange enough information on such matters reasonably in advance of planned JSC meetings so that the JSC members may make enough preparation and have discussion in efficient and effective manner.

3.6 **Liaison**.

3.6.1 Promptly after the Effective Date, each Party shall appoint an individual who shall be an employee of such Party having appropriate qualification and experience to act as the liaison for such Party (the "**Liaison**"). Each Liaison shall be responsible for coordinating and managing processes and interfacing between the Parties on a day-to-day basis throughout the Term. The Liaison will ensure communication to the JSC of all relevant matters raised at any joint subcommittees or working groups. Each Liaison shall be permitted to attend meetings of the JSC as a non-voting participant. The Liaison shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Liaison with an alternative employee at any time in its sole discretion with prior written notice to the other Party. Each Liaison shall be charged with creating and maintaining a collaborative work environment within the JSC and its subcommittees. Each Party will be responsible for all of its own costs with respect to its Liaison.

3.6.2 The Liaisons shall be responsible for (i) scheduling meetings of the JSC, (ii) preparing and circulating an agenda in advance of each JSC meeting and (iii) acting as secretary at each JSC meeting and preparing the draft minutes of such JSC meeting, which shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the JSC. Within [***] after each JSC meeting, the drafting Liaison shall provide the draft minutes to the other Liaison for review and comment. The minutes shall be finalized by approval of all the members of JSC. Beginning with Forty Seven's Liaison, such responsibilities shall alternate between the Liaisons on a meeting-by-meeting basis after each JSC meeting of the applicable committee.

3.7 **Discontinuation of the JSC**. The activities to be performed by the JSC shall solely relate to governance under this Agreement, and are not intended to be or involve the delivery of services. The JSC shall continue to exist until the first to occur of: (a) the date when the Parties mutually agree to disband the JSC, and (b) the date when either Party provides written notice to the other Party of its intention to disband and no longer participate in the JSC. Once the Parties mutually agree or either Party has provided the other Party with such written notice to disband the JSC, the JSC shall have no further obligations under this Agreement; provided, however, that the Parties may re-establish the new JSC after the disbandment of the former one upon the request of either Party. After the disbandment of the JSC, each Party shall designate a contact person for the exchange of information under this Agreement or such exchange of information shall be made through the Liaison, and decisions of the JSC shall be decisions as between the Parties, subject to the other terms and conditions of this Agreement. In the event the JSC is disbanded as provided above, any decisions that are designated under this Agreement as being subject to the review, discussion or decision-making of the JSC shall be subject to the review, discussion or decision-making of the Parties directly.

ARTICLE IV
DEVELOPMENT

4.1 **Overview**.

4.1.1 **Diligence**.

4.1.1.1 As between the Parties, Ono shall be solely responsible and shall have sole discretion and control (at Ono's sole cost and expense) for all preclinical, clinical, and other Development activities (including regulatory activities) with respect to Products in the Ono Territory. Ono shall use Commercially Reasonable Efforts to Develop the Licensed Antibodies and Products and obtain Regulatory Approval for the Products in the Field in each country in the Ono Territory. Without limiting the generality of the foregoing, Ono shall use Commercially Reasonable Efforts to conduct its Development activities under and in accordance with the Ono Development Plan.

4.1.1.2 As between the Parties, Forty Seven shall be solely responsible and shall have sole discretion and control (at Forty Seven's sole cost and expense) for all preclinical, clinical, and other Development activities (including regulatory activities) with respect to Products in the Forty Seven Territory.

4.1.2 **Development Plans**. Forty Seven shall prepare and present at the first JSC meeting for discussion a global development strategy that sets forth the high-level objectives and strategy (e.g., priority of target indications/tumor types) for the Development of Licensed Antibodies and Products worldwide (such strategy, and any amendments thereto, the "**Global Development Strategy**"). Within [***] following the Effective Date, each Party will be responsible for preparing a plan containing the strategy, activities and timeline for the Development of the Licensed Antibodies and Products in its respective Territory (as updated pursuant to this Section 4.1.2, the "**Ono Development Plan**" and "**Forty Seven Development Plan**"). Each Party's Development Plan shall include a planning horizon of [***] for all Clinical Studies and other Development activities with respect to the Licensed Antibodies and Products that are planned or are being conducted by such Party in its respective Territory, and to the extent reasonably practicable and subject to Section 3.3.2, be aligned with the Global Development Strategy. Each Party will deliver to the JSC an update of the relevant sections of its Development Plan no less frequently than [***] per Calendar Year during the Term. Subject to Section 4.1.1, Ono will be solely responsible for all decisions regarding the day-to-day conduct of Development within the Ono Territory. Subject to Sections 3.2.4.2 and 4.3.5, Forty Seven will be solely responsible for all decisions regarding the day-to-day conduct of Development within the Forty Seven Territory.

4.1.3 **Review of Clinical Study Protocols; Updates**. Each Party shall provide to the other Party directly, or through the JSC, with a reasonable opportunity to review and comment upon a draft protocol synopsis for each of the Clinical Studies occurring within its respective Territory and conducted by or on behalf of it and the summary of any material modification of such draft protocol synopsis. Each Party shall provide regular updates to the JSC regarding the Development of Licensed Antibodies and Products in its respective Territory.

4.2 **Development in the Respective Territories**.

4.2.1 Forty Seven shall be solely responsible and shall have sole discretion and control (at Forty Seven's sole cost and expense) for all non-clinical, preclinical, clinical, and other Development activities (including regulatory activities) with respect to Products in the Forty Seven Territory. For clarity, to the extent the results of such activities are Controlled by Forty Seven or its Affiliates, such results shall be deemed to be Forty Seven Know-How.

4.2.2 Ono shall be solely responsible and shall have sole discretion and control (at Ono's sole cost and expense) for all non-clinical, preclinical, clinical, and other Development activities (including regulatory activities) with respect to Products in the Ono Territory. For clarity, to the extent the results of such activities are Controlled by Ono, its Affiliates or Sublicensees, such results shall be deemed to be Ono Know-How.

4.2.3 If the Parties jointly conduct a non-clinical, preclinical, clinical, and other Development activities (including regulatory activities) with respect to Products in the Territory, then the results of such activities shall be deemed to be Joint Know-How.

4.3 **Global Studies**.

4.3.1 The Parties acknowledge that the Development of Licensed Antibodies and Products on a global basis is desirable for maximizing the value of the Products. As such, in addition to each Party's Development rights in their respective Territories as set forth in Sections 4.1 and 4.2, each Party may participate, at its sole cost and subject to the remainder of this Section 4.3, in one or more Clinical Study(ies) planned by the other Party or its Affiliates or Sublicensees to be conducted in such other Party's Territory by participating in such Clinical Study(ies) in its own Territory, provided that such Clinical Study includes a sufficient number of study subjects in each Party's Territory to achieve Regulatory Approval in such Territory for the relevant indication (with respect to each Territory and Clinical Study, the "**Enrollment Threshold**"). Each such Clinical Study in which both Parties will participate in accordance with this Section 4.3 shall be deemed a "**Global Study**".

4.3.2 During the Term, if a Party intends to conduct in its Territory (i) a Clinical Study (which is not an Pivotal Trial) that is eligible to be a Global Study based on the applicable Enrollment Threshold or (ii) a Pivotal Trial, then such Party shall inform the other Party in writing of such intention, specifying (a) the Product and indication for such study that would support the filing of an NDA for the Product with Regulatory Authorities in both the Forty Seven Territory and the Ono Territory, as applicable, (b) study design, (c) planned sample size, (d) study population, (e) study treatment, (f) primary endpoints, (g) secondary endpoints, (h) study timeline, (i) planned study location and (j) target timelines for study initiation (a "**Global Study Proposal**"). In such event, with respect to a Clinical Study (including a Pivotal Trial), the Parties shall discuss in good faith through the JSC the feasibility of such Clinical Study as a potential Global Study.

4.3.3 Within [***] (or within a period otherwise agreed by the Parties in writing) following the date of submission by one Party to the JSC of a Global Study Proposal (the "**Opt-In Period**"), the other Party may notify the proposing Party of its desire to participate in the applicable Clinical Study as part of a Global Study by delivering to the proposing Party a written notice of such request (an "**Opt-In Request**"). Upon receipt of the Opt-In Request, the proposing Party shall determine whether to accept the other Party's Opt-In Request based on its good faith consideration of the JSC's discussion pursuant to Section 4.3.2 and other relevant factors, and shall notify the other Party of its determination within [***] of the proposing Party's receipt of the Opt-In Request; [***]. If the proposing Party does not receive an Opt-In Request for a Global Study Proposal prior to the expiration of the applicable Opt-In Period, or if the proposing Party notifies the other Party that it does not accept the Opt-In Request for such Clinical Study within such [***] period, then each Party shall have the right to proceed independently with respect to such Clinical Study for such Product and indication in its own Territory, subject to the terms and conditions of this Agreement, and such Clinical Study shall not be deemed to be a Global Study.

4.3.4 With respect to any Global Study Proposal for which an Opt-In Request is accepted by the proposing Party pursuant to Section 4.3.3, the Parties shall promptly prepare a draft development plan for such Global Study, and consider in good faith and reflect each Party's comments to the extent that such comments are reasonably based on scientific, business, and/or other relevant considerations, containing the regulatory and manufacturing strategy, activities to be conducted by each Party, and timeline for the conduct of such Global Study based on such Global Study Proposal, which plan shall, to the extent reasonably practicable and subject to Section 3.3.2, be consistent with the Global Development Strategy (such plan, and any amendments thereto, a "**Global Study Development Plan**"). For clarity, a Global Study Development Plan may be amended only by the Parties' agreement. The Parties shall negotiate in good faith the number of patients intended to be enrolled in such Global Study in its respective Territory. Each Party shall have the sole right to decide the number of study subjects enrolled in such Global Study at sites within its Territory, provided that such number meets or exceeds the applicable Enrollment Threshold for such Global Study and Territory. Each Global Study Development Plan shall include the determination of a dosing regimen of the applicable Product(s) with respect to the applicable target indication (including, as applicable, [***]) for such Global Study intended to obtain Regulatory Approval of such Product(s) in each Party's Territory. Each Global Study Development Plan, as may be updated by the Parties hereunder, shall form a part of this Agreement and shall be deemed to be incorporated herein. Under each such Global Study Development Plan, each Party shall conduct such Global Study and related Development activities in its respective Territory and shall bear its own costs in connection therewith. Notwithstanding the foregoing, each Party shall be responsible for [***] as set forth in the Global Study Development Plan (with respect to each Party, its "[***]"). [***].

4.3.5 Each Party shall use Commercially Reasonable Efforts to conduct its activities under each Global Study Development Plan, and shall report regularly on the status and results of such activities through the JSC (or a subcommittee or working group established by the JSC). Subject to Section 4.2, all Data arising from such Global Study Development Plan shall be shared between the Parties in accordance with a data-sharing plan to be developed by the JSC. [***].

4.4 **Data**

4.4.1 **Data Ownership**. As between the Parties, the Party generating any Data shall own such Data, subject to the licenses and other rights granted by such Party to the other Party under this Agreement with respect to the use of or access to such Data.

4.4.2 **Data Exchange**. During the Term, and subject to Applicable Laws and good scientific practice, each Party shall provide to the other Party promptly upon reasonable request by such other Party to the extent not already provided and at no additional cost to such other Party, electronic access to all Data generated by or on behalf of the Party, its Affiliates or Sublicensees (and with respect to Forty Seven Partners, Data generated by or on behalf of a Forty Seven Partner from any Global Study or which a Forty Seven Partner has agreed to provide to Ono in accordance with Section 4.4.3) with respect to and in the course of conducting studies with respect to the Products (including all study reports analyzing such Data), which are necessary or reasonably useful for such other Party to obtain or maintain Regulatory Approval of such Products in its respective Territory. For clarity, neither Party shall have any obligation to provide any Data

beyond such Data in such Party's Control at the time of such request (which Data shall be provided in the format maintained by the providing Party, subject to the following sentence), nor to conduct any analyses with respect to any such Data; provided that, if certain Data that is requested by one Party is not Controlled by the other Party at the time of such request, but subsequently becomes Controlled by the requested Party, the requested Party shall provide such Data in a timely manner. Any Data provided by one Party to the other Party under this Section 4.4.2 shall be provided in the original language in which such Data was generated, provided that, if such original language is not English, then the Party supplying such Data shall also provide English translations thereof at the receiving Party's request [***]. The Parties will cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of such Data. Subject to Sections 2.9.2.3 and 4.4.3, such other Party and its Affiliates and (sub)licensees shall have the right to use and reference any such Data to obtain and maintain Regulatory Approval for the Products and otherwise Commercialize the Products in its respective Territory in accordance with the terms of this Agreement.

4.4.3 **Data from Forty Seven Partners**. Ono acknowledges that Forty Seven may, in its sole discretion, enter into one or more agreements with Third Parties and grant such Third Parties a license to Develop and/or Commercialize the Products in the Forty Seven Territory (each such Third Party, a "**Forty Seven Partner**" and each such agreement, a "**Forty Seven Partner Agreement**"). If Forty Seven enters into a Forty Seven Partner Agreement, then Forty Seven's obligation to share (a) the Safety Data related to the Products generated by such Forty Seven Partner and (b) [***], in each case of (a) and (b) for Ono's use in the Ono Territory in accordance with this Agreement shall be stipulated in such Forty Seven Partner Agreement. [***].

4.5 **Compliance**. Each Party shall perform its Development activities relating to the Licensed Antibodies and Products in accordance with all Applicable Laws, including good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted.

4.6 **Records, Reports and Information**. Each Party shall maintain complete, current and accurate records of all work conducted by it under each Development Plan, and all Data resulting from such work. Such records shall fully and properly reflect all work done and results achieved in the performance of such Development Plan in good scientific manner appropriate for regulatory purposes. Each Party shall document all preclinical studies, non-clinical studies and Clinical Studies in formal written study reports according to applicable national and international guidelines (*e.g.*, ICH, GCP, GLP and GMP). Each Party shall have the right to review such records maintained by the other Party at reasonable times, upon written request, which shall not exceed once a year unless such request for review is required by (a) Applicable Laws or (b) its voluntary CAPA initiative. Each Party shall present reports in English at the JSC meetings on its Development and regulatory activities with respect to the Products, including any significant formal or informal meetings between such Party and the Regulatory Authorities in its respective Territory, at a level of detail to be agreed by the JSC; provided, however, that any such presentation shall include at least a summary of the resulting Data for all preclinical studies, non-clinical studies and all Clinical Studies conducted by such Party with the Product, subject to Forty Seven's obligations to its licensees and the Upstream Agreements.

ARTICLE V
REGULATORY MATTERS

5.1 **Overview; Diligence**.

5.1.1 The Parties shall discuss the regulatory strategy for the Products in their respective Territories through the JSC in order to identify any material risk, value and impact on regulatory assessment and labeling, in markets throughout the world. Forty Seven shall prepare and present at a JSC meeting for discussion a global registration strategy for such Product for consistency of content and labeling, and optimal filing timelines (parallel and staggered) for markets throughout the world (such strategy, and any amendments thereto, the "**Global Registration Strategy**"). Each Party's registration plan for its respective Territory (such plan, and any amendments thereto, the "**Registration Plan**") shall, to the extent reasonably practicable and subject to Section 3.3.2, be aligned with the Global Registration Strategy. Each Party will deliver to the JSC an update of the relevant sections of its Registration Plan no less frequently than twice per Calendar Year during the Term. Ono will be solely responsible for all decisions regarding the day-to-day conduct of registration activities within the Ono Territory. Forty Seven will be solely responsible for all decisions regarding the day-to-day conduct of registration activities within the Forty Seven Territory.

5.1.2 Ono shall be responsible for, and shall use Commercially Reasonable Efforts to conduct, all regulatory activities relating to the Licensed Antibodies and Products within the Ono Territory at its own cost, as further described in Section 5.2, supported by Forty Seven as reasonably requested by Ono. Ono shall promptly provide to Forty Seven any and all material correspondence and key filings with PMDA and other Regulatory Authorities in the Ono Territory, which shall be translated into English.

5.1.3 Forty Seven shall be responsible for, and, solely to the extent set forth in a Global Study Development Plan, shall use Commercially Reasonable Efforts to conduct, all regulatory activities relating to the Licensed Antibodies and Products within the Forty Seven Territory at its own cost, supported by Ono as reasonably requested by Forty Seven. Forty Seven shall promptly provide to Ono any and all material correspondence and key filings with FDA and other Regulatory Authorities in the Forty Seven Territory.

5.2 **Regulatory Activities**. Ono, at its sole cost and expense and in accordance with this Agreement and the requirements of all Applicable Laws, will use Commercially Reasonable Efforts to take all actions necessary to prepare and file all Regulatory Filings with respect to the Products required to obtain and maintain Regulatory Approval for the Products in the Ono Territory. Without limiting the applicability of the foregoing and the remainder of this ARTICLE V, Ono and Forty Seven, through the JSC, will keep the other Party reasonably informed of all material events and developments occurring in the course of obtaining Regulatory Approval in its own Territory. Neither Party shall file any Regulatory Filings for Products in the other Party's Territory, except as reasonably necessary for Forty Seven to fulfill its Manufacturing and supply obligations hereunder or as expressly permitted under Section 2.6.2 or 2.7.2.

5.3 **Regulatory Data and Regulatory Approvals**.

5.3.1 **Regulatory Filings**. Each Party shall be solely responsible for preparing, maintaining, formatting, and filing Regulatory Filings for Product(s) in its respective Territory; provided that (a) to the extent reasonably practicable and subject to Section 3.3.2, any such Regulatory Filing shall be aligned with the Global Registration Strategy, and (b) Ono shall use Commercially Reasonable Efforts to submit any MAA in the Ono Territory after receiving and considering in good faith Forty Seven's comments on the content of such MAA filing. Each Party shall from time to time provide the other Party with an update on the status of such Regulatory Filings and any material correspondences relating thereto.

5.3.2 **Regulatory Meetings**. Each Party will provide the other Party with advance notice of any formal, scheduled meetings with any Regulatory Authority in its respective Territory (including any meetings related to the final positioning of labeling and safety claims within the original and subsequent regulatory submissions), and provide a brief description of the topics to be presented or discussed at each such meeting, in English. Each Party shall be solely responsible for responding to any material communications with Regulatory Authorities with respect to any Product(s) in its respective Territory; provided that, to the extent reasonably practicable, any such response shall be aligned with the Global Registration Strategy. Each Party may request the other Party to be present in any meeting with a Regulatory Authority in its respective Territory and, upon such request, such other Party shall use Commercially Reasonable Efforts to cause its appropriate representative(s) to assist the requesting Party in such meeting, whether in person or by teleconference. Promptly following any meeting with a Regulatory Authority with respect to a Product, the Party receiving notice for such meeting shall provide to the other Party the minutes of such meeting, in English.

5.3.3 **Holder of Regulatory Filings**. Each Party will hold title to all Regulatory Filings (including MAAs) and Regulatory Approvals with respect to the Products in and for its respective Territory, except as may be required in connection with the other Party's exercise of its rights and performance of its obligations hereunder with respect to the Manufacturing of Licensed Antibodies and Products; provided, however, that, Ono shall file for and obtain Regulatory Filings and Regulatory Approvals in such manner as may be required under Applicable Laws in the Ono Territory to allow for the expeditious transfer thereof to Forty Seven or Forty Seven's designee pursuant to Section 14.5.4 upon certain terminations of this Agreement.

5.4 **Rights of Reference**. Subject to Sections 2.9.2.3 and 4.4.3, each Party hereby grants, at no cost, to the other Party and the other Party's Affiliates, Sublicensees and Forty Seven Partners the right to use, cross-reference, file or incorporate by reference all Regulatory Filings pertaining to a Product submitted by or on behalf of such granting Party (including its Affiliates, Sublicensees and, to the extent Forty Seven has the right under the applicable Forty Seven Partner Agreement to provide such rights to Ono and its Affiliates and Sublicensees, Forty Seven Partners). The receiving Party and its Affiliates, Sublicensees and Forty Seven Partners may use such rights of reference for the purpose of seeking, obtaining and maintaining Regulatory Approval and Commercializing Products in its respective Territory and otherwise performing its and their rights and obligations under this Agreement.

5.5 **Safety; Adverse Event Reporting**.

5.5.1 **Pharmacovigilance and Safety Data**. Forty Seven shall establish and maintain, at Forty Seven's sole cost and expense, a global drug safety database for the Products. Ono shall have the right to access from such global drug safety database all Safety Data necessary for Ono to comply with all Applicable Laws in the Ono Territory. Ono may establish and maintain, at Ono's sole cost and expense, a local drug safety database for the Products in the Ono Territory. Each Party will be responsible, at its sole cost and expense, for: (a) collecting all pharmacovigilance and other Safety Data for the Products in its respective Territory as required by Applicable Laws; and (b) reporting any such pharmacovigilance and other Safety Data, including Adverse Events in its respective Territory, to the applicable Regulatory Authorities in its respective Territory, as appropriate to be in compliance with all Applicable Laws, including reporting Safety Data to the other Party in XML files (or CIOMS format) (in English) for entry into the global safety database. Each Party expressly acknowledges that the other Party may provide information it receives pursuant to this Section 5.5 to appropriate Regulatory Authorities within its respective Territory by itself or through any of its Affiliates, Sublicensees and Forty Seven Partners engaged in Development and Commercialization activities of the Products in its respective Territory.

5.5.2 **Pharmacovigilance Agreement**. Within [***] following the Effective Date or such other period as the Parties may agree (but in any case before the first IND filing of the first Product in the Ono Territory), the Parties shall enter into a mutually acceptable pharmacovigilance agreement setting forth the Parties' respective obligations in detail regarding pharmacovigilance and the exchange of Safety Data during the period before the First Commercial Sale of the first Product in the Ono Territory. Further, at least [***] before the estimated date of the first Regulatory Approval of the first Product in the Ono Territory, the Parties shall amend such pharmacovigilance agreement to set forth the Parties' respective obligations in the detail regarding pharmacovigilance and the exchange of Safety Data during the period after the First Commercial Sale of the first Product in the Ono Territory.

5.6 **No Harmful Actions**. If a Party reasonably believes that the other Party is taking or intends to take any action with respect to a Product that could reasonably be expected to have a material adverse impact upon the regulatory status of any Product in such Party's Territory, then such Party may bring the matter to the attention of the JSC and the Parties shall seek in good faith to promptly resolve such concern.

5.7 **Notification of Threatened Action**. Each Party shall notify the other Party within [***] of any information it receives regarding any threatened or pending action, inspection, or communication by any Regulatory Authority which may affect the safety or efficacy claims of any Product or the continued Development or Commercialization of any Product. Upon receipt of such information, the Parties shall promptly consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

5.8 **Recalls**. If a recall, withdrawal, or correction (including the dissemination of relevant information) of any Product in a Party's Territory is required by a Regulatory Authority of competent jurisdiction, or if a recall, withdraw, or correction of a Product in its respective Territory is deemed advisable by such Party in its sole discretion, then such Party shall so notify the other Party no later than [***] in advance of the earlier of (a) initiation of a recall, withdrawal, or correction, or (b) the submission of plans for such an action to a Regulatory Authority. Any such recall, withdrawal, or correction shall be referred to herein as a "**Recall**". Promptly after being notified of a Recall, each Party shall provide the other Party with such assistance in connection with such Recall as may be reasonably requested by such other Party. All costs and expenses in connection with a Recall in a Party's Territory, including the costs and expenses related to the dissemination of relevant information, shall be borne by such Party unless such Party proves that such Recall is required due to (i) the other Party's breach of the representations, warranties, covenants or obligations under this Agreement and/or violation of Applicable Laws or (ii) the intentional misconduct or negligent acts by the other Party; provided that, with respect to a Recall of Licensed Antibody or Product that is supplied by or on behalf of Forty Seven pursuant to a supply agreement entered into between the Parties pursuant to Section 7.2 or 7.3.3, the provisions of such supply agreement shall solely apply. Each Party shall handle exclusively the organization and implementation of all Recalls of Products in its respective Territory.

5.9 **Sunshine Reporting Laws**. Each Party acknowledges that the other Party may be subject to national, state, local, and international laws, regulations, and rules related to the tracking and reporting of payments and transfers of value provided to health care professionals, health care organizations, and other relevant individuals and entities (collectively, "**Sunshine Reporting Laws**"), and agrees to provide the other Party with all information regarding such payments or transfers of value by such Party as necessary for such other Party to comply in a timely manner with its reporting obligations under the Sunshine Reporting Laws.

ARTICLE VI
COMMERCIALIZATION

6.1 **Global Commercialization Strategy**.

6.1.1 No less than [***] prior to the reasonably anticipated date for a First Commercial Sale of a Product in the Territory, Forty Seven shall prepare and present at the next-occurring JSC meeting for discussion a global sales and marketing strategy (e.g., reimbursement, positioning, segmentation, sales force, messaging and branding) for the Products worldwide (such strategy, and any amendments thereto, the "**Global Commercialization Strategy**"). Subject to Section 3.3.2, each Party's Commercialization Plan of the Products in each Territory shall be, to the extent reasonably practicable, aligned with the Global Commercialization Strategy.

6.1.2 To the extent that market conditions or Applicable Laws in each Territory reasonably require variance from the Global Commercial Strategy, the Parties shall discuss in good faith on such variances through the JSC or appropriate subcommittee or working group.

6.2 **Commercialization in the Respective Territories**.

6.2.1 **Overview**. Subject to, and in accordance with, the terms and conditions of this Agreement and all Applicable Laws, each Party, at its sole cost and expense, will be solely responsible for Commercializing the Products in its respective Territory, including market planning and implementation, distribution, sales booking, pricing and reimbursement activities with respect thereto.

6.2.2 **Diligence.** Ono shall use Commercially Reasonable Efforts to Commercialize each Product in each indication that receives Regulatory Approval in the Ono Territory in the country in which such Regulatory Approval was granted. Without limiting the generality of the foregoing, Ono shall use Commercially Reasonable Efforts to conduct its Commercialization activities under and in accordance with its Commercialization Plan.

6.2.3 **Commercialization Plan**. Without limiting the generality of the other provisions in this ARTICLE VI, each Party will prepare and submit to the JSC a plan containing the strategy, activities and timeline for marketing and selling the Products in its respective Territory (as updated pursuant to this Section 6.2.3, the "**Commercialization Plan**"). The Commercialization Plan shall include, among other things, all market planning and implementation, distribution, sales booking, pricing and reimbursement activities with respect to the Products that are conducted in its respective Territory, and shall be, to the extent reasonably practicable and subject to Section 3.3.2, aligned with the Global Commercialization Strategy, subject to Section 6.1. Ono will submit a proposed draft of the Commercialization Plan for the Ono Territory to the JSC no later than [***] prior to the anticipated date of the First Commercial Sale of any Product in the Ono Territory. Forty Seven will submit a proposed draft of the Commercialization Plan for Forty Seven Territory to the JSC no later than [***] prior to the anticipated date of the first commercial sale of any Product in the Forty Seven Territory. Following the submission of the Commercialization Plan, each Party will deliver to the JSC an update of the relevant sections of the Commercialization Plan at least once every [***] during the Term. Updates to the Commercialization Plan will reflect, among other things, each new indication in the Field for which the Product has received Regulatory Approval. Each Party will be solely responsible for all decisions regarding the day-to-day conduct of Commercialization within its respective Territory.

6.2.4 **Pricing**.

6.2.4.1 Each Party shall be responsible, at its own expense, for seeking Pricing Approval in its respective Territory.

6.2.4.2 Subject to Section 6.2.4.3, each Party shall have the sole right to make all decisions regarding the pricing of the Products in its respective Territory. Notwithstanding anything in this Agreement express or implied to the contrary, neither Party shall have any right to direct, control, or approve the other Party's decision regarding the pricing of Products for the other Party's Territory. Each Party shall inform the other Party of the results of Pricing Approval and update thereof, through the JSC, provided that the provision to the other Party of those information shall be for informational purposes only.

6.2.4.3 If Ono sells a Product in a "bundle" with one or more other products or services at a discount to the purchaser, then Ono shall not disproportionately or unreasonably discount such Product relative to the other products or services composing such bundle.

6.2.5 **Reports**. Commencing upon the First Commercial Sale of a Product in the Ono Territory, Ono shall in advance of each Fiscal Year provide Forty Seven with a good faith forecast of estimated Net Sales of such Product in the Ono Territory during the subsequent [***]. Ono shall update the JSC at the JSC's regularly-scheduled meetings regarding Ono's significant Commercialization activities (such as its progress in obtaining Pricing Approval, its strategy for and progress in promotion campaigns and planned Phase 4 studies and material interactions with Regulatory Authorities) for the Products in the Ono Territory. In addition, Ono shall present written reports to the JSC annually, summarizing Ono's significant Commercialization activities with respect to Products in the Ono Territory pursuant to this Agreement and including a forecast for the following year's sales of the Product in the Ono Territory. Such reports shall cover subject matter at a level of detail reasonably sufficient to enable Forty Seven to determine Ono's compliance with its diligence obligations pursuant to this ARTICLE VI. Forty Seven shall provide a top-level update to the JSC at the JSC's regularly-scheduled meetings with respect to Forty Seven's Commercialization and future initiatives for the Products, as well as any competition updates for the Products, in the Forty Seven Territory.

6.3 **Communications**. To the extent permitted by Applicable Laws, and subject to Section 6.2.4, the Parties shall seek to coordinate their communications relating to the Commercialization of the Products in their respective Territories in a manner consistent with the Global Commercialization Strategy, subject to Section 6.1.2. Without limiting the generality of the foregoing, upon the other Party's reasonable request, each Party shall provide such other Party any materials, information and Data relating to the Licensed Antibody and Product that is reasonably useful for the Commercialization of the Licensed Antibody and Product in such other Party's Territory.

6.4 **Marketing and Promotional Literature**. Each Party shall prepare all marketing and promotional literature related to Products for use in its respective Territory in accordance with Applicable Laws and consistent with the Global Commercialization Strategy, subject to Section 6.1.2. Each Party shall promptly provide the other Party with copies of such marketing and promotional literature utilized by such Party, its Affiliates, Sublicensees and Forty Seven Partners. In certain marketing and promotional literature, Forty Seven may be presented and described as the Party who developed the Product in a manner to be determined by the JSC on, by way of example, all labels, packaging, packaging inserts, and promotional literature related to the Product, in each case to the extent permitted by Applicable Laws.

6.5 **Diversion**. Each Party hereby covenants and agrees that it and its Affiliates shall not, and it shall contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligations for) Sublicensees or Forty Seven Partners, as the case may be, not to, directly or indirectly, promote, market, distribute, import, sell, or have sold any Product, including via the Internet or mail order, to any Third Party, or to any address or Internet Protocol address or the like, in the other Party's Territory. Neither Party shall engage, nor permit its Affiliates, Sublicensee and Forty Seven Partner to engage, in any advertising or promotional activities

relating to any Product that are directed primarily to customers or other buyers or users of such Product located in any country or jurisdiction in the other Party's Territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's Territory. If a Party, its Affiliates, Sublicensee or Forty Seven Partner receives any order for a Product for use from a prospective purchaser located in a country or jurisdiction in the other Party's Territory, in timely manner, such Party shall refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates, Sublicensees or Forty Seven Partners to, deliver or tender any Product for use in the other Party's Territory.

6.6 **Trademarks**.

6.6.1 Product Trademarks.

6.6.1.1 Both Parties acknowledge and agree that Commercialization of each Product under a common brand name or product trademark throughout the world may be beneficial for both Parties in order to maximize the value of the Product. In furtherance of the foregoing, each Party shall have the right (but not the obligation) to propose to the other Party a limited number of product trademarks under consideration for use in Commercializing the Product and shall consider in good faith any comments the other Party has on such product trademarks. If Forty Seven selects a product trademark for Commercializing the Product in the Forty Seven Territory (the "**Product Trademark**"), then it shall notify Ono of its selection, and Ono may elect to use the Product Trademark for Commercializing the Product in the Ono Territory. If Ono so elects, subject to successful registration and approval of such Product Trademark by the applicable Governmental Authorities in the Ono Territory, each Party shall use such Product Trademark for Commercialization of the Product in its respective Territory. Forty Seven shall search for and determine the possibility of the registration of such Product Trademark worldwide, and to the extent possible, Forty Seven shall file the application for registration of the trademark rights for the Product Trademark using counsel of its own choice, at Forty Seven's cost for the Forty Seven Territory and Ono's cost for the Ono Territory. After such registration, Forty Seven shall assign the rights to the Product Trademark in the Ono Territory to Ono without requiring Ono any compensation for such assignment. The costs of procedure related to such assignment shall be borne by Ono. Forty Seven shall be responsible for the prosecution, registration and maintenance of such trademark rights in the Forty Seven Territory at Forty Seven's sole costs. Forty Seven shall be responsible for the prosecution and registration of such trademark rights in the Ono Territory at Ono's sole costs, and Ono shall be responsible for the maintenance of such trademark rights in the Ono Territory at Ono's sole costs.

6.6.1.2 If Ono does not elect to use a Product Trademark for the applicable Product, each Party may use, for Commercializing the Product in countries in each Party's respective Territory, its own product trademark it considers appropriate and which is reasonably suitable for the Product in such countries. Each Party shall own respectively all rights, title and interests in and to its own product trademark throughout the world and shall have the sole right to register, prosecute and maintain its product trademark using counsel of its own choice and at its own expense.

6.6.1.3 Each Party shall promptly notify the other Party in writing upon becoming aware of any infringement of a Product Trademark in the Ono Territory, in which event the Parties shall promptly confer in good faith and determine how to proceed with any enforcement activity. Until completion of the assignment of the Product Trademark in the Ono Territory to Ono, Forty Seven shall have the sole right, but not the obligation, to enforce the Product Trademark in the Ono Territory at Ono's expense. After completion of the assignment of the Product Trademark in the Ono Territory to Ono, Ono shall have the first right, but not the obligation, to enforce the Product Trademark in the Ono Territory at its own expense.

6.6.2 **Forty Seven Corporate Marks**.

6.6.2.1 Except to the extent prohibited by Applicable Law in the Ono Territory, or otherwise directed by Forty Seven in writing, all packaging, labeling, advertising and promotional material used by Ono, its Affiliates and Sublicensees in connection with the Products may feature Forty Seven's corporate trade name and logo ("**Forty Seven Corporate Marks**").

6.6.2.2 Subject to the terms and conditions of this Agreement, Forty Seven hereby grants to Ono during the Term a non-exclusive, royalty-free license, with the right to sublicense solely in conjunction with the grant of a permitted sublicense under Section 2.2, to use the Forty Seven Corporate Marks solely in connection with the Commercialization of Products in the Field in the Ono Territory in accordance with this Agreement, including the use of the Forty Seven Corporate Marks on Product packaging, labeling, advertising and promotional material.

6.6.2.3 As between the Parties, Forty Seven shall have the sole right, but not the obligation, to prosecute, maintain and enforce the Forty Seven Corporate Marks in the Ono Territory at its own expense. Ono shall as soon as practicable notify Forty Seven of any apparent infringement by a Third Party of any of the Forty Seven Corporate Marks.

6.6.3 **Use of Forty Seven Corporate Marks**.

6.6.3.1 Ono shall use the Forty Seven Corporate Marks in a manner consistent with Forty Seven's usage guidelines for such Forty Seven Corporate Marks. Forty Seven shall exclusively own and retain all right, title and interest in and to the Forty Seven Corporate Marks, and all goodwill associated with or attached to the Forty Seven Corporate Marks arising out of the use thereof by Ono, its Affiliates and sublicensees shall vest in and inure to the benefit of Forty Seven. Ono acknowledges Forty Seven's exclusive ownership of the Forty Seven Corporate Marks and agrees not to take any action inconsistent with such ownership. Ono shall not, and shall cause its Affiliates and sublicensees not to, (a) use, seek to register, or otherwise claim rights in the Ono Territory in any trademark that is confusingly similar to, misleading or deceptive with respect to, or that materially dilutes, any of the Forty Seven Corporate Marks, or (b) knowingly do, cause to be done, or knowingly omit to do any act, the doing, causing or omitting of which endangers, undermines, impairs, destroys or similarly affects, in any material respect, the validity or strength of any of the Forty Seven Corporate Marks (including any registration or pending registration application relating thereto) or the value of the goodwill pertaining to any of the Forty Seven Corporate Marks.

6.6.3.2 Ono agrees to cooperate with Forty Seven to enable Forty Seven to control the nature and quality of the use of the Forty Seven Corporate Marks by Ono, its Affiliates or its Sublicensees in the Ono Territory such that Forty Seven may verify that the use of the Forty Seven Corporate Marks by Ono, its Affiliates or its Sublicensees in the Ono Territory is consistent with Forty Seven's quality standards.

ARTICLE VII
MANUFACTURING AND SUPPLY

7.1 **Manufacturing Coordinators**. Each Party shall designate one (1) qualified and experienced supply chain professional to serve as that Party's primary contact and coordinator regarding the supply of Products within this Agreement (a "**Manufacturing Coordinator**"). Each Party may replace its Manufacturing Coordinator with an alternative representative at any time with prior written notice to the other Party. The Manufacturing Coordinators shall be responsible for facilitating information exchange and discussion between the Parties regarding the supply of Products under this Agreement. Each Manufacturing Coordinator shall be subject to the authority of the JSC. Each Party will be responsible for all of its own costs with respect to its Manufacturing Coordinator.

7.2 **Clinical Supply**.

7.2.1 Ono shall have the right to purchase from Forty Seven, and Forty Seven shall use Commercially Reasonable Efforts to supply to, Ono Hu5F9-G4 or Hu5F9-G4 Product, in each case, in the same dose and formulation as Forty Seven Manufactures or has Manufactured [***] for Ono to conduct non-clinical, preclinical and clinical studies for obtaining any Regulatory Approval in the Ono Territory. Ono shall be [***] relating to the supply of Hu5F9-G4 Product and Forty Seven Manufactured Products for the Ono Territory [***]. Promptly following the earlier of (a) Ono's delivery to the JSC of the Ono Development Plan for a Hu5F9-G4 Product and Forty Seven Manufactured Products pursuant to Section 4.1.2 and (b) Forty Seven's acceptance of Ono's Opt-In Request for a Global Study for a Hu5F9-G4 Product and Forty Seven Manufactured Products pursuant to Section 4.3.3, within [***] following the Effective Date, the Parties shall negotiate in good faith a clinical supply agreement and a quality agreement therefor on reasonable and customary terms, including provisions for forecasting and ordering, quality matters and recalls. For clarity, Ono may Manufacture the Product (subject to the Technology Transfer Completion with respect to Hu5F9-G4 Product and Forty Seven Manufactured Products) in any Territory for non-clinical, preclinical and clinical studies in the Ono Territory, subject to the terms of the applicable Upstream Agreement.

7.2.2 Subject to the terms of this ARTICLE VII, Forty Seven shall supply to Ono [***]. Details (including delivery timing) of the other clinical supplies for the Development in the Ono Territory shall be separately communicated and agreed by the Parties in writing.

7.3 **Commercial Supply**.

7.3.1 **Technology Transfer**. Upon Ono's reasonable request, Forty Seven shall use Commercially Reasonable Efforts to transfer to Ono the Manufacturing technology for the Hu5F9-G4 Product and, to the extent that Forty Seven Controls the rights to such technology, Forty Seven Manufactured Products for the Ono Territory in accordance with a schedule to be agreed in writing in good faith by the Parties (the completion of such transfer, the "**Technology Transfer Completion**"). Such transfer shall, to the extent made available by the applicable Third Party manufacturer, include [***].

7.3.2 If Forty Seven desires to purchase any Product Manufactured by Ono or its Affiliates (or by a Third Party on Ono or its Affiliate's behalf) for the Forty Seven Territory, then Forty Seven shall so notify Ono in writing and the Parties shall negotiate in good faith a supply agreement and a quality agreement therefor on reasonable and customary terms (including, provisions for forecasting and ordering, quality matters, recalls, and allocation of all transfer cost incurred by Ono for such transfer).

Forty Seven Commercial Supply to Ono. Subject to the Parties' entering into a commercial supply agreement pursuant to this Section 7.3.3, Ono shall have the right to purchase from Forty Seven, and Forty Seven shall use Commercially Reasonable Efforts to supply to Ono, Ono's requirements of Hu5F9-G4 Product and Forty Seven Manufactured Products, in each case, in the same dose and formulation as Forty Seven Manufactures or has Manufactured [***] for Commercialization of such Product in the Ono Territory. Ono shall be [***] relating to the commercial supply of Hu5F9-G4 Product and Forty Seven Manufactured Products for the Ono Territory [***]. If Ono wishes to exercise such right, it shall provide written notice to Forty Seven thereof no less than [***] prior to the anticipated date of First Commercial Sale of an Hu5F9-G4 Product and Forty Seven Manufactured Products in the Ono Territory, and promptly thereafter the Parties shall negotiate in good faith a commercial supply agreement and a quality agreement therefor on reasonable and customary terms.

7.4 **Related Substances**. Subject to the terms of the applicable supply agreement, Ono shall have the right to purchase from Forty Seven, and Forty Seven shall supply to Ono, related substances for the Hu5F9-G4 Product and Forty Seven Manufactured Products (e.g., reference standard, internal standard, impurities and radio-labelled equivalent) necessary for Ono to conduct acceptance tests, non-clinical studies, preclinical studies or Clinical Studies, including for analytical test method development and/or validation, for regulatory submissions or Commercialization in the Ono Territory, [***] for the applicable related substance.

7.5 **Delivery**. The terms of delivery for clinical supplies, commercial supplies and related substances shall be [***], as set forth in the applicable agreement between Forty Seven and its contract manufacturer.

ARTICLE VIII
MEDICAL AFFAIRS

8.1 **Generally**. Ono shall have the sole right to conduct Medical Affairs Activities in the Ono Territory for the Products in the Field, at its own expense. Forty Seven shall have the sole right to conduct Medical Affairs Activities in the Forty Seven Territory for the Products in the Field, at its own expense. Each Party shall conduct its Medical Affairs Activities in accordance with all Applicable Laws.

8.2 **Medical Affairs Plan.** No less than [***] prior to the reasonably anticipated date for a First Commercial Sale of a Product in the Territory, Forty Seven shall prepare and present at a JSC meeting for discussion a strategy containing the worldwide strategy, activities and timeline with respect to the Medical Affairs Activities in support of the Products in the Field (such strategy, and any amendments thereto, the "**Global Medical Affairs Strategy**"). No less than [***] prior to the reasonably anticipated date for a First Commercial Sale of a Product in its respective Territory, each Party shall prepare and present at a JSC meeting a plan containing the strategy, activities and timeline with respect to the Medical Affairs Activities in support of the Products in the Field in its respective Territory (each, "**Medical Affairs Plan**") that shall, to the extent reasonably practicable, be aligned with the Global Medical Affairs Strategy. The JSC will review and discuss such Medical Affairs Plan and its amendments under which the Parties shall review, discuss, and coordinate the Parties' scientific presentation and publication strategy relating to the Products in the Field in each Party's Territory. Each Party may propose to the other Party the conduct of any Phase 4 Clinical Study (i.e. Clinical Study, epidemiological study and post-marketing surveillance, which is commenced after receipt of the Regulatory Approval, but excluding any Phase 3b trial) in its respective Territory, following which the Parties shall discuss to determine whether to jointly conduct such Phase 4 Clinical Study as a Global Study pursuant to the terms and conditions set forth in Section 4.3.

8.3 **Investigator Sponsored Clinical Study.** Each Party shall have the right to authorize the protocol for each Investigator Sponsored Clinical Study in its respective Territory and support such Investigator Sponsored Clinical Study at its own discretion; provided that (a) such Party agrees to inform the other Party of any such Investigator Sponsored Clinical Study in a timely manner, (b) each proposal shall be subject to review and comment by a Working Group designated by the JSC, and (c) if the other Party reasonably believes that such Investigator Sponsored Clinical Study could reasonably be expected to have a material adverse impact upon the Development or Commercialization of any Product in such other Party's Territory, then such other Party may refer the matter to the JSC and the Parties shall seek in good faith to promptly resolve such concern. Neither Party shall authorize or support an Investigator Sponsored Clinical Study in the other Party's Territory without such other Party's prior written consent, which consent may be granted or withheld in the sole discretion of the other Party.

ARTICLE IX
FINANCIAL TERMS

9.1 **Upfront Payment**. Within [***] after the date of Ono's receipt of Forty Seven's invoice therefor, which shall be issued after the Effective Date, as a material inducement to Forty Seven entering into this Agreement, Ono shall pay to Forty Seven a non-refundable, non-creditable, upfront payment of One Billion and Seven Hundred Million Japanese Yen (JPY 1,700,000,000).

9.2 **Milestone Payments**.

9.2.1 **Development and Regulatory Milestones**. Ono shall notify Forty Seven in writing within [***] after the first achievement by a Product of the applicable milestone event below (whether by Ono or its Affiliate or Sublicensee). Ono shall pay to Forty Seven the one-time, non-refundable, non-creditable payment for such milestone event set forth in the table below within [***] of receipt by Ono of Forty Seven's invoice for such milestone payment. For the avoidance of doubt, each of the following milestone payments shall be payable only once regardless of the number of times achieved by one or more Products.

Milestone Event	Milestone Payment
1.[***]	[***]

[***]

9.2.2 **Sales Milestones**. Ono shall notify Forty Seven in writing within [***] after the end of the Fiscal Year in which the applicable sales milestone event below is first achieved by Ono, its Affiliates, and Sublicensees. Ono shall pay to Forty Seven the additional one-time, non-refundable, non-creditable payment for such milestone event set forth in the table below within [***] of receipt by Ono of Forty Seven's invoice for such milestone payment. If more than one (1) sales milestone events are achieved in the same Fiscal Year, then Ono shall pay to Forty Seven all of such milestone payments. For the avoidance of doubt, each of the following milestone payments shall be payable only once regardless of the number of times such milestone is achieved.

Sales Milestone Event	Sales Milestone Payment
[***]	**[***]**

9.3 **Royalties on Net Sales**.

9.3.1 **Royalty Rates**. Subject to the terms and conditions of this Section 9.3, Ono shall pay to Forty Seven non-creditable, non-refundable royalties on Net Sales in the Ono Territory during such Calendar Quarter, as calculated by multiplying the applicable royalty rate by the corresponding amount of incremental Net Sales in the Ono Territory, as follows:

Annual Net Sales of all Product in the Ono Territory	Royalty Rate
[***]	[***]

9.3.2 **Royalty Term**. The term of the royalties payable under Section 9.3.1, on a Product-by-Product and country-by-country basis, shall commence on the First Commercial Sale of the Product in the relevant country in the Ono Territory and shall end upon later of: (a) the expiration of the first Regulatory Exclusivity of the Product in such country; (b) the expiration of the last to expire Valid Claim of any Forty Seven Patent or Joint Patent that Covers the Composition of Matter of a Licensed Antibody in the Product in such country; or (c) the tenth (10th) anniversary of such First Commercial Sale (with respect to the Product and country, the "**Royalty Term**").

9.3.3 **Royalty Reductions**.

9.3.3.1 [***]

9.3.3.2 [***]

9.3.3.3 [***]

9.3.3.4 **Royalty Floor**. Notwithstanding the foregoing, during any Calendar Quarter in the Royalty Term for a Product in a country in the Ono Territory, the operation of Sections 9.3.3.1, 9.3.3.2 and 9.3.3.3 above, individually or in combination, shall not reduce by more than [***] of the royalties that would otherwise have been due to Forty Seven under Section 9.3.1 with respect to Net Sales of such Product in such country during such Calendar Quarter.

9.4 **Royalty Payments and Reports**. Ono shall report to Forty Seven in writing all amounts payable to Forty Seven pursuant to Section 9.3 within [***] following the end of each Calendar Quarter. Such report shall include the converted US Dollar amounts, which conversion shall be made at the Exchange Rate for each calendar month in the Calendar Quarter. Such written report shall include, on a consolidated basis in reasonably specific detail and on a country-by-country basis, (a) the Net Sales of Products sold by Ono, its Affiliates and its Sublicensees in the Ono Territory during the corresponding Calendar Quarter, including a description of the credits and offsets deducted on a Product-by-Product and country-by-country basis to calculate Net Sales; (b) the royalties payable in US Dollars, if any, which shall have accrued hereunder based upon such Net Sales of Products; (c) the withholding taxes, if any, required by law to be deducted in respect of such royalties; (d) the dates of the First Commercial Sale of each Product in each country in the Ono Territory, if it has occurred during the corresponding Calendar Quarter; and (e) an itemized calculation of the exchange rate used by Ono in determining the royalty amount expressed in Japanese Yen, in accordance with Ono's consolidated accounting procedure, as consistently

applied and in accordance with IFRS. In the case of Net Sales made in one or more currencies other than Japanese Yen during a Calendar Quarter, the amount of Net Sales made during any Calendar Quarter in Japanese Yen shall be determined by converting the portion of such Net Sales made in each third-country currency into Japanese Yen in accordance with Ono's consolidated accounting procedure, to the extent reasonable and consistently applied by Ono across all of its products and in accordance with IFRS. To the extent any additional information is required in accordance with the applicable Upstream Agreement, Ono shall promptly provide such additional information upon Forty Seven's request. Ono shall pay Forty Seven the royalties set forth in each such report within [***] of receipt by Ono of Forty Seven's invoice for such royalty payment.

9.5 [***]**, Manufacturing Cost and Other Reimbursements**.

9.5.1 [***]

9.5.2 **Manufacturing Costs**. Unless otherwise set forth in the applicable supply agreement between the Parties, in consideration for Licensed Antibodies, Products and related substances supplied from Forty Seven pursuant to Sections 7.2, 7.3 and 7.4, Forty Seven shall invoice Ono [***] for Manufacturing Costs and other costs incurred pursuant to Sections 7.2, 7.3 and 7.4 in US Dollars, provided that any currency conversion into US Dollars will be made pursuant to the currency conversion scheme set forth in Section 1.99 (definition of "Manufacturing Costs").

9.5.3 **Other Reimbursements**. To the extent that either Party incurs costs that are subject to reimbursement by the other Party hereunder, other than as set forth in Section 9.5.1 or 9.5.2, the Party incurring such costs shall provide such other Party an invoice therefor in US Dollars, based on the applicable exchange rate. The invoicing Party shall provide the other Party with such supporting documentation for such invoice as such other Party may reasonable request.

9.5.4 **Payment of Invoices; Disputes.** Each Party shall pay any such undisputed invoice provided by the other Party under this Section 9.5 within [***] following its receipt thereof. All payments shall be made in US Dollars, calculated at the applicable exchange rate. If the Party receiving such invoice disputes any portion thereof in good faith, then it shall give the invoicing Party written notice of such dispute and pay the undisputed portions of such invoice and the Parties shall promptly seek to reasonably resolve the disputed portions. Any disputes with respect to the amounts set forth in a report or invoice delivered under this Section that are not resolved by the Parties within [***] after such dispute is first raised shall be referred to the JSC for attempted resolution. If the JSC does not resolve such dispute within [***], the Parties shall mutually select and engage an independent Third Party accounting firm that has no auditing or other financial relationship with either Party or any of its Affiliates to resolve such matter. Such accounting firm shall, as soon as reasonably practicable after such firm is engaged, deliver a report to each Party with its analysis and determination of such matter. Such determination shall be final and binding on the Parties. The costs of such firm's services shall be shared equally by the Parties.

9.5.5 **Audits.** The audit rights set forth in Section 9.9 shall apply to any payment made pursuant to this Section.

9.5.6 **No Double Charges**. Neither Party will double charge the other Party for any costs or expenses subject to reimbursement under this Section 9.5.

9.6 **Remittance**. All amounts paid under this Agreement will be made in US Dollars through wire transfer to such bank account as the invoicing Party may designate in writing from time to time. The first designated bank account of Forty Seven shall be as follows:

Account name:	[***]
Account number:	[***]
Bank name:	[***]
Beneficiary Address:	[***]
Swift code:	[***]
Routing/Transit for Wires:	[***]

9.7 **Late Payments**. If either Party does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to such Party until the date of payment at the per annum rate of [***] over the then-current prime rate quoted by Citibank in New York City, NY, USA or the maximum rate allowable by Applicable Laws, whichever is lower.

9.8 **Taxes**.

9.8.1 **Cooperation and Coordination**. The Parties acknowledge and agree to cooperate in order to appropriately calculate consistently with Applicable Laws, taxes payable with respect to their collaborative efforts under this Agreement and any appropriate reductions, credits, or deductions that may lawfully reduce otherwise applicable taxes. If one Party is required to make a payment to the other Party subject to a deduction or withholding of tax, and if such deduction or withholding of tax obligation arises as a result of such other Party's failure of collaborative efforts (e.g., failure of submission of necessary taxation documents to the paying Party in timely manner), the paying Party may deduct or withhold the applicable tax without increase of the amount set forth in Section 9.8.5, provided, however, that the paying Party shall give the other Party cooperation set forth in Section 9.8.2.

9.8.2 **Payment of Tax**. A Party receiving a payment pursuant to this Agreement shall pay any and all taxes levied on such payment except as provided in this Section 9.8. If Applicable Laws requires that taxes be deducted and withheld from a payment made pursuant to this Agreement, the remitting Party shall (a) deduct those taxes from the payment; (b) pay the taxes to the proper taxing authority; and (c) send evidence of the obligation together with proof of payment to the other Party within [***] following that payment.

9.8.3 **Tax Residence Certificate**. A Party (including any entity to which this Agreement may be assigned, as permitted under Section 16.4) receiving a payment pursuant to this ARTICLE IX shall provide the remitting Party appropriate certification from relevant revenue authorities that such Party is a tax resident of that jurisdiction (a "**Tax Residence Certificate**"), if such receiving Party wishes to claim the benefits of an income tax treaty to which that jurisdiction is a party. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate. For clarity, Forty Seven shall provide to Ono any taxation documents (Japan Form 3 and Form 17, which Ono shall provide to Forty Seven), the Tax Residence Certificate (Form 6166) of Forty Seven issued by the US Internal Revenue Service (which Tax Residence Certificate is effective for three (3) years after its issuance to a public company) and other documents that may be reasonably necessary in order for Ono not to withhold tax or to withhold tax at a reduced rate under an appropriate income tax treaty.

9.8.4 **Assessment**. Either Party may, at its own expense, protest any assessment, proposed assessment, or other claim by any Governmental Authority for any additional amount of taxes, interest or penalties or seek a refund of such amounts paid if permitted to do so by Applicable Laws. The Parties shall cooperate with each other in any protest by providing records and such additional information as may reasonably be necessary for a Party to pursue such protest.

9.8.5 **Withholding Taxes Resulting from a Party's Action**. If one Party (or a Party's assignees or successors) is required to make a payment to the other Party subject to a deduction or withholding of tax, and if such deduction or withholding of tax obligation arises as a result of any action taken by such required Party or its Affiliates or successors, including an assignment of this Agreement as permitted under Section 16.4, as a result of which (a) the payment arises in a territory other than such required Party's Territory, (b) there is a change in the tax residency of such required Party, or (c) the payments arise or are deemed to arise through a branch of such required Party in a territory other than such required Party's Territory and such action has the effect of increasing the amount of tax deducted or withheld (each, an "**Withholding Tax Action**"), then notwithstanding Section 9.8.2, the payment by such required Party (in respect of which such deduction or withholding of tax is required to be made) shall be increased by the amount necessary to ensure that the other Party receives an amount equal to the same amount that it would have received had no Withholding Tax Action occur.

9.9 **Records; Audits**. Ono and its Affiliates and Sublicensees on one hand, and Forty Seven and its Affiliates on the other hand, will maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of royalty and other payments under this Agreement. Upon reasonable prior notice, such records shall be available during regular business hours for a period of [***] from the creation of individual records for examination at the auditing Party's expense, and not more often than once each Calendar Year, by an independent certified public accountant selected by one Party and reasonably acceptable to the other Party, for the sole purpose of verifying the accuracy of the financial reports furnished by the audited Party pursuant to this Agreement. Any such auditor shall not disclose Confidential Information of the audited Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the audited Party or the amount of payments due under this Agreement. For clarity, the auditor shall disclose the Confidential Information of the

audited Party to the auditing Party only to the extent necessary to confirm calculation of royalty payments and supply price under this Agreement, as applicable. The auditing Party shall provide the audited Party with a copy of audit report within [***] from its receipt of the accountant's report. Any amounts shown to be owed but unpaid shall be paid within [***] from the accountant's report, plus interest (as set forth in Section 9.7) from the original due date. Any amounts shown to have been overpaid shall be creditable and refunded within [***] from the accountant's report. The auditing Party shall bear the full cost of such audit unless such audit discloses an underpayment of the amount actually owed during the applicable Calendar Year of more than [***], in which case the audited Party shall bear the full cost of such audit.

ARTICLE X
INTELLECTUAL PROPERTY

10.1 **Inventorship.** For purposes of Section 10.2, inventorship for inventions and discoveries first made during the course of the performance of activities pursuant to this Agreement shall be determined in accordance with U.S. Patent Law.

10.2 **Ownership**. Forty Seven shall own the entire right, title and interest in and to all inventions first made, conceived or reduced to practice solely by or on behalf of Forty Seven or its Affiliates. Ono shall own the entire right, title and interest in and to all inventions first made, conceived or reduced to practice solely by or on behalf of Ono or its Affiliates. The Parties shall jointly own the entire right, title and interest in and to all inventions first made, conceived or reduced to practice jointly by employees of Forty Seven or its Affiliates and employees of Ono or its Affiliates.

10.3 **Disclosure.** Each Party shall promptly disclose to the other Party any invention, whether patentable or not, made by or on behalf of such Party or its Affiliates (or otherwise Controlled by such Party) in the performance of its obligations or the exercise of its rights under this Agreement.

10.4 **Invention Assignment**. Each Party shall ensure that all of its and its Affiliates' employees and contractors acting under its or its Affiliates' authority in the performance of this Agreement assign to such Party (or to an entity that is obligated to assign to such Party) under a binding written agreement all rights, titles and interests in and to all Know-How discovered, made, conceived or reduced to practice by such employee or contractor and any intellectual property rights thereunder. For clarity, each Party shall be solely liable for any compensation required by such written agreement, laws or otherwise to its and its Affiliates' employee or contractor who is the inventor or creator of such Know-How.

10.5 **Right to Practice Joint Technology**. Except to the extent either Party is restricted by the express terms of this Agreement, each Party shall have the right to practice and exploit Joint Technology, with full rights to license its interest therein in its respective Territory, and without the duty of accounting to or any duty to seek consent from the other Party, and upon the reasonable request of either Party, the other Party shall execute documents that evidence or confirm the requesting Party's right to engage in such activities.

10.6 **Prosecution of Patents**.

10.6.1 **Definition of Prosecution**. As used herein, "prosecution" of Patents shall include all communication and other interaction with any patent office or patent authority having jurisdiction over a Patent application throughout the world in connection with pre-grant proceedings. Post-grant proceedings shall be governed by Sections 10.7 and 10.11.

10.6.2 **Forty Seven Patents**.

10.6.2.1 Forty Seven shall prepare, file, prosecute and maintain the Forty Seven Patents Covering the Composition of Matter of a Licensed Antibody in the Ono Territory [***]. Except as otherwise provided in Section 10.6.2.2, and subject to the terms of the applicable Upstream Agreement and the rights of the applicable Upstream Licensor, Forty Seven shall have the first right, but not the obligation, to prepare, file, prosecute and maintain the Forty Seven Patents with respect to any matter other than the Composition of Matter of a Licensed Antibody in the Ono Territory, through counsel reasonably acceptable to Ono, at Forty Seven's sole expense.

10.6.2.2 Forty Seven may elect to cease prosecution and maintenance, or not to file an application for, any Forty Seven Patents in any country in the Ono Territory by written notice to Ono given at least [***] prior to any upcoming deadline in any patent office with respect to such Forty Seven Patents (or with respect to a new application, the deadline by which such application must be filed). In such event, and subject to the terms of the applicable Upstream Agreement and the rights of the applicable Upstream Licensor, Ono shall have the right, but not the obligation, to assume the responsibility for the prosecution and maintenance of such Forty Seven Patents in such country in the Ono Territory in the name of Ono [***], in which event Forty Seven shall cause the files for such Forty Seven Patents to be transferred to such counsel as Ono may designate and shall take such actions as Ono may reasonably request to preserve Ono's ability to effectively prosecute and maintain such Forty Seven Patents. [***].

10.6.2.3 As between the Parties, Forty Seven shall be have the sole right, but not the obligation, to prepare, file, prosecute, and maintain the Forty Seven Patents in the Forty Seven Territory at its sole expense.

10.6.3 **Joint Patents**.

10.6.3.1 Upon receiving notice of the creation of Joint Patents, the Parties shall determine which Party will be responsible for obtaining and maintaining Joint Patents. Such Party (the "**Joint Patent Prosecuting Party**") shall prepare, file, prosecute, and maintain all Joint Patents throughout the world, in the names of both Forty Seven and Ono. The Joint Patent Prosecuting Party shall provide the other Party an opportunity to review and comment on material documents related to such filing, prosecution and maintenance in accordance with this Section 10.6.3, which comments the Joint Patent Prosecuting Party shall consider in good faith. Each Party shall at its own cost, sign, or use Commercially Reasonable Efforts to have signed, all legal documents necessary to file and prosecute patent applications or to obtain or maintain patents in respect of such Joint Patents.

10.6.3.2 In the event that the Joint Patent Prosecuting Party elects not to file or continue to prosecute or maintain patent protection on any Joint Patents in any country in the world by written notice to the other Party given at least [***] prior to any upcoming deadline in any patent office with respect to such Joint Patents (or with respect to a new application, the deadline by which such application must be filed), the other Party shall have the right (but not the obligation) to file, prosecute and maintain such Joint Patents in such country in its name at its sole expense, in which event such Joint Patent Prosecuting Party shall cause the files for such Joint Patent Prosecuting Party's interest in Joint Patents to be transferred to the other Party to preserve the other Party's ability to effectively prosecute and maintain such Joint Patents in such country. [***].

10.6.3.3 The Parties shall share equally the reasonable out-of-pocket costs incurred for the common activities for patent filing, prosecution and maintenance of Joint Patents and each Party shall be responsible for other costs for patent filing, prosecution and maintenance of Joint Patents in its respective Territory (collectively, "**Joint Patent Costs**"). The Joint Patent Prosecuting Party shall invoice the other Party for such other Party's responsible part of such Joint Patent Costs under this Section 10.6.3.3 within [***] after the Calendar Quarter in which such Joint Patent Costs were incurred and the other Party shall pay such Joint Patent Costs within [***] after receipt of such invoice.

10.6.4 **Ono Patents**.

10.6.4.1 Ono shall have the sole right, but not the obligation, to prepare, file, prosecute, and maintain the Ono Patents in the Ono Territory at its sole expense.

10.6.4.2 Except as otherwise provided in Section 10.6.4.3, as between the Parties, Ono shall be have the first right, but not the obligation, to prepare, file, prosecute, and maintain the Ono Patents in the Forty Seven Territory, through counsel reasonably acceptable to Forty Seven, [***].

10.6.4.3 Ono may elect to cease prosecution and maintenance, or not to file an application for, any Ono Patents in any country in the Forty Seven Territory by written notice to Forty Seven given at least [***] prior to any upcoming deadline in any patent office with respect to such Ono Patents (or with respect to a new application, the deadline by which such application must be filed). In such event, Forty Seven shall have the right, but not the obligation, to assume the responsibility for the prosecution and maintenance of such Ono Patents in such country in the Forty Seven Territory in the name of Forty Seven [at its sole expense], in which event Ono shall cause the files for such Ono Patents to be transferred to such counsel as Forty Seven may designate and shall take such actions as Forty Seven may reasonably request to preserve Forty Seven's ability to effectively prosecute and maintain such Ono Patents. [For clarity, such Ono Patents in such country shall be deemed and treated as Forty Seven Patents and cease to be Ono Patents under this Agreement upon completion of such transfer of the patent files to Forty Seven's patent counsel].

10.6.5 **Cooperation**. Each Party shall provide the other Party who has the right to prosecute and maintain the Forty Seven Patents, Ono Patents, and Joint Patents under this Section 10.6 (the "**Prosecuting Party**") with all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this Section 10.6, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution, as well as further actions set forth herein. The Prosecuting Party shall periodically inform the other Party of all material steps with regard to the preparation, filing, prosecution and maintenance of the (i) Forty Seven Patents Covering inventions made in the performance of this Agreement, (ii) Ono Patents Covering inventions made in the performance of this Agreement, and (iii) Joint Patents Covering inventions made in the performance of this Agreement, including by providing the non-Prosecuting Party with (a) a copy of material communications to or from any patent authority regarding such Patents; and (b) drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for the review and comment thereupon. The Prosecuting Party shall consider in good faith, and if requested discuss with the non-Prosecuting Party, the requests and suggestions of the non-Prosecuting Party with respect to such drafts.

10.6.6 **Confidentiality.** All communications between the Parties relating to the preparation, filing, prosecution, or maintenance of the Forty Seven Patents, Ono Patents, and Joint Patents, including copies of any draft or final documents or any communications received from or sent to patent offices or patenting authorities with respect to such Patents, shall be considered Confidential Information of the Prosecuting Party subject to the confidentiality provisions of ARTICLE XI.

10.6.7 **CREATE Act**. The Parties acknowledge that any inventions may be generated with different assigning entities which, during the course of U.S. patent prosecution, may benefit from use of the CREATE Act of 2004 (70 Fed. Reg. 177(54259-54267) as amended by the Leahy-Smith America Invents Act of 2011 (35 U.S.C. §§102(b)(2)(c) and 102(c)) (the "**CREATE Act**"). For the purposes of the benefit of the CREATE Act, the Parties deem this Agreement and/or the written memorandum of transactions contemplated hereunder, such as pertaining to the Development of the Licensed Antibodies and Products, to constitute a qualifying written Joint Research Agreement.

10.7 **Patent Term Extensions in the Ono Territory**. The Parties will discuss which, if any, of the Patents within the Forty Seven Patents, Ono Patents, and Joint Patents in the Ono Territory the Parties should seek patent term extensions in the Ono Territory. Ono shall have the final decision-making authority with respect to applying for any such patent term extension for the Forty Seven Patents, Ono Patents and Joint Patents in the Ono Territory. Forty Seven shall have the final decision-making authority with respect to applying for any such patent term extension for the Forty Seven Patents, Ono Patents and Joint Patents in the Forty Seven Territory. The Prosecuting Party of a Patent will act with reasonable promptness in light of the development stage of applicable Product(s) to apply for any such patent term extension of such Patent, where it so elects and will cooperate fully with the other Party in making such filings or actions, for example and without limitation, making available all required information and executing any required authorizations to apply for such patent term extension. All expenses incurred in connection with activities for patent term extensions pursuant to this Section shall be solely borne by the Patent owner.

10.8 **Infringement of Patents by Third Parties**.

10.8.1 **Notification**. Each Party shall promptly notify the other Party in writing of any actual or threatened infringement, unauthorized use or misappropriation of the Forty Seven Patents, Ono Patents or Joint Patents of which it becomes aware, and shall provide all evidence in such Party's possession demonstrating such infringement, unauthorized use or misappropriation.

10.8.2 Enforcement of Forty Seven Patents.

10.8.2.1 Forty Seven shall bring and control any suit or other action against any Person engaged in any infringement of a Forty Seven Patents Covering the Composition of Matter of a Licensed Antibody in the Ono Territory at its sole expense.

10.8.2.2 Forty Seven shall have the first right, but not the obligation, to bring and control any suit or other action against any Person engaged in any infringement of a Forty Seven Patent with respect to any matter other than the Composition of Matter of a Licensed Antibody in the Ono Territory at its sole expense. Forty Seven shall have a period of [***] after the first notice under Section 10.8.1 to elect to enforce such Forty Seven Patent in the Ono Territory against such Third Party infringement. If Forty Seven so elects, Forty Seven shall periodically inform Ono of all material steps (including, the status and progress) with regard to such suit or other action. If Forty Seven does not so elect, then Forty Seven shall so notify Ono in writing, and Ono shall have the right, but not the obligation, to commence a suit or take action to enforce the applicable Forty Seven Patent against such Third Party perpetrating such infringement in the Ono Territory.

10.8.2.3 Forty Seven shall have the sole right, but not the obligation, to bring and control any suit or other action against any Person engaged in the infringement of a Forty Seven Patent in the Forty Seven Territory at its sole expense.

10.8.3 **Enforcement of Ono Patents**.

10.8.3.1 Ono shall have the first right, but not the obligation, to bring and control an appropriate suit or other action against any Person engaged in the infringement of an Ono Patent in the Ono Territory at its sole expense, subject to the terms and conditions set forth in this Section 10.8.3. Ono shall have a period of [***] after the first notice under Section 10.8.1 to elect to enforce such Ono Patent in the Ono Territory against such Third Party infringement. If Ono so elects, Ono shall periodically inform Forty Seven of all material steps (including, the status and progress) with regard to such suit or other action. If Ono does not so elect, then Ono shall so notify Forty Seven in writing, and Forty Seven shall have the right, but not the obligation, to commence a suit or take action to enforce the applicable Ono Patent against such Third Party perpetrating such infringement in the Ono Territory.

10.8.3.2 Forty Seven shall have the first right, but not the obligation, to bring and control an appropriate suit or other action against any Person engaged in the infringement of an Ono Patent in the Forty Seven Territory at its sole expense, subject to the terms and conditions set forth in this Section 10.8.3. Forty Seven shall have a period of [***] after the first notice under Section 10.8.1 to elect to enforce such Ono Patent in the Forty Seven Territory against such Third Party infringement. If Forty Seven so elects, Forty Seven shall periodically inform Ono of all material steps (including, the status and progress) with regard to such suit or other action. If Forty Seven does not so elect, then Forty Seven shall so notify Ono in writing, and Ono shall have the right, but not the obligation, to commence a suit or take action to enforce the applicable Ono Patent against such Third Party perpetrating such infringement in the Forty Seven Territory.

10.8.4 **Enforcement of Joint Patents**.

10.8.4.1 Ono shall have the first right, but not the obligation, to bring and control an appropriate suit or other action against any Person engaged in the infringement of a Joint Patent in the Ono Territory at its sole expense, subject to the terms and conditions set forth in this Section 10.8.4. Ono shall have a period of [***] after the first notice under Section 10.8.1 to elect to enforce such Joint Patent in the Ono Territory against such Third Party infringement. If Ono so elects, Ono shall periodically inform Forty Seven of all material steps (including, the status and progress) with regard to such suit or other action. If Ono does not so elect, then Ono shall so notify Forty Seven in writing, and Forty Seven shall have the right, but not the obligation, to commence a suit or take action to enforce the applicable Joint Patent against such Third Party perpetrating such infringement in the Ono Territory.

10.8.4.2 Forty Seven shall have the first right, but not the obligation, to bring and control an appropriate suit or other action against any Person engaged in the infringement of a Joint Patent in the Forty Seven Territory at its sole expense, subject to the terms and conditions set forth in this Section 10.8.4. Forty Seven shall have a period of [***] after the first notice under Section 10.8.1 to elect to enforce such Joint Patent in the Forty Seven Territory against such Third Party infringement. If Forty Seven so elects, Forty Seven shall periodically inform Ono of all material steps (including, the status and progress) with regard to such suit or other action. If Forty Seven does not so elect, then Forty Seven shall so notify Ono in writing, and Ono shall have the right, but not the obligation, to commence a suit or take action to enforce the applicable Joint Patent against such Third Party perpetrating such infringement in the Forty Seven Territory.

10.8.5 **Enforcement Costs**. Subject to reimbursement as set forth in Section 10.8.6, each Party shall bear all of its own costs incurred in connection with its activities under this Section 10.8 with regard to any Forty Seven Patents, Ono Patents, and Joint Patents.

10.8.6 **Recoveries**. Any recovery by an enforcing Party shall be allocated first pro rata to the reimbursement of any expenses incurred by the Parties in the activities under this Section 10.8 (including reasonable expenses of outside counsel), and then:

[***]

10.8.7 **Cooperation.** Each Party shall provide to the other Party enforcing any such rights under this Section 10.8 reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Applicable Law to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, and shall seek consent of the other Party in any material aspects of such enforcement, including determination of litigation strategy and the filing of important papers to the competent court, which consent shall not be unreasonably withheld, conditioned, or delayed. The Party bringing the action shall have final decision-making authority with respect to such action, subject to Section 10.8.7.

10.9 **Infringement of Third Party Patents in the Ono Territory**.

10.9.1 **Notice**. If either Party becomes aware of any actual or threatened claim, suit, or proceeding by a Third Party alleging patent infringement by either Party (or its Affiliates or (sub)licensees), such Party will promptly notify the other Party thereof in writing and the Party shall discuss with the other Party the strategy for defending such claim, suit, or proceeding by the Third Party.

10.9.2 [***]

10.10 **Patent Marking**. Ono (or its Affiliate, Sublicensee, or distributor) shall mark Products marketed and sold by Ono (or its Affiliate, Sublicensee, or distributor) hereunder with appropriate patent numbers or indicia at Forty Seven's request; provided, however, that Ono shall only be required to so mark such Products to the extent such markings or such notices would impact recoveries of damages or equitable remedies available under Applicable Law with respect to infringements of Patents in the Ono Territory.

10.11 **Patent Oppositions and Other Proceedings**.

10.11.1 [***]

10.11.2 **Defense of Patent Rights**. If (a) a Forty Seven Patent becomes the subject of any proceeding commenced by a Third Party in the Ono Territory, (b) an Ono Patent becomes the subject of any proceeding commenced by a Third Party in any Territory, or (c) a Joint Patent becomes the subject of any proceeding commenced by a Third Party in any Territory, in each of case (a), (b) and (c), in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, invalidation action, interference, or other attack upon the validity, title, or enforceability thereof (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 10.8, in which case the provisions of Section 10.8 shall govern), the Parties shall promptly confer to determine whether to defend against such action in accordance with the following manner.

10.11.2.1 **Forty Seven Patents**. [***]. Forty Seven shall have a period of [***] after the first conference under Section 10.11.2 to notify the other Party of its decision to exercise its rights to control the defense of such Forty Seven Patent in the Forty Seven Territory in such proceeding commenced by a Third Party. If Forty Seven so elects, Forty Seven shall periodically inform Ono of all material steps (including, the status and progress) with regard to such defense and Ono shall have the right to participate and be represented in any such action by its own counsel at its own expense. If Forty Seven does not exercise such right, then Forty Seven shall so notify Ono in writing, and Ono shall have the right, but not the obligation, to control the defense against such action. Forty Seven shall permit Ono to participate in the proceeding to the extent permissible under Applicable Law, and to be represented by its own counsel in such proceeding, at Ono's expense.

10.11.2.2 **Ono Patents**. [***]

10.11.2.3 **Joint Patents**. In the case of controlling the defense against such action with respect to the Joint Patents in its respective Territory, the Parties shall promptly determine the appropriate course of action in good faith and the allocation of costs with respect thereto. In any case, the controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under Applicable Law, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense.

10.12 **Patent Challenge**.

10.12.1 Ono shall not, and Ono shall cause its Affiliates and their Sublicensees not to, directly or indirectly, initiate, engage in, file, finance, participate in, aid or otherwise assist in any re-examination, opposition, or other action or proceeding in any patent office, or court anywhere in the world whereby the ownership, validity, patentability, entitlement to, priority and/or enforceability of all or any of the Forty Seven Patents is challenged or otherwise disputed. Any breach of this Section 10.12.1 shall be deemed to be a material breach of this Agreement, subject to Section 10.12.2.

10.12.2 [***]

ARTICLE XI
CONFIDENTIALITY

Nondisclosure. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, during the Term and for [***] following the end of the Term, the receiving Party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other Party, and both Parties shall keep confidential and, subject to Sections 11.2, 11.3, and 11.4, shall not publish or otherwise disclose the terms of this Agreement. Notwithstanding the foregoing, [***]. Each Party may use the other Party's Confidential Information solely to the extent required to accomplish the purposes of this Agreement, including exercising such Party's rights or performing its obligations under this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but no less than reasonable care) to ensure that its employees, agents, consultants, contractors, and other representatives do not disclose or make any unauthorized use of the Confidential Information of the other Party. Each Party will promptly notify the other Party upon discovery of any unauthorized use or disclosure of the Confidential Information of the other Party.

11.1 **Authorized Disclosure**. The receiving Party may disclose Confidential Information belonging to the disclosing Party only to the extent such disclosure is reasonably necessary in the following instances:

11.1.1 filing or prosecuting Patents as permitted by this Agreement;

11.1.2 filing Regulatory Filings in order to obtain or maintain Regulatory Approvals;

11.1.3 prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;

11.1.4 complying with Applicable Laws or regulations (including regulations promulgated by securities exchanges) or court or administrative orders;

11.1.5 to its Affiliates, Sublicensees or prospective Sublicensees (in case of Ono), Forty Seven Partners or prospective Forty Seven Partners (in case of Forty Seven), subcontractors or prospective subcontractors, payors, consultants, agents, and advisors on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than those set forth in this ARTICLE XI; provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Third Party who receives Confidential Information pursuant to this Section 11.2 to treat such Confidential Information as required under this ARTICLE XI; or

11.1.6 to bona fide potential and actual investors, acquirors, merger partners, licensees, and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, or collaboration, in each case under written obligations of confidentiality and non-use at least as stringent as those herein, provided that the confidentiality term therefor shall not be less than [***].

11.1.7 Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Sections 11.2.2 through 11.2.4, it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure, reasonably consider the comments of the other Party with respect to limiting such disclosure, and use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the Parties agree to take reasonable actions to avoid the non-confidential disclosure of Confidential Information hereunder. Any information disclosed pursuant to Sections 11.2.2 through 11.2.4 shall remain the Confidential Information of the Disclosing Party and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this ARTICLE XI.

11.2 **Publications**.

11.2.1 During the Term, on a [***], each Party shall provide the JSC its proposed publication schedule for the subsequent [***]. Prior to public disclosure or submission for publication of a proposed publication describing the results of any scientific or clinical activity relating to a Licensed Antibody or Product, (a) Ono, and (b) upon Ono's reasonably request in good faith, Forty Seven (in each case, the "**Submitting Party**") shall send the other Party (the "**Responding Party**") a copy of the proposed publication to be submitted and shall allow the Responding Party a reasonable time period (but no less than [***]) for the Responding Party (i) to determine whether the proposed publication contains subject matter for which patent protection should be sought (prior to publication of such proposed publication) for the purpose of protecting an invention, (ii) to determine whether the proposed publication contains the Confidential Information of the Responding Party, or (iii) to provide the Submitting Party with its reasonable comments to such proposed publication, which the Submitting Party shall consider in good faith. Following the expiration of the applicable time period for review, the Submitting Party shall be free to submit such proposed publication for publication or otherwise disclose to the public such scientific or clinical results, subject to the procedures set forth in Section 11.3.2. For clarity, a Party shall not be obligated to delay disclosure or submission of such publication pursuant to the foregoing timelines with respect to publications that do not contain any patentable subject matter or any of the other Party's Confidential Information.

11.2.2 If the Responding Party believes that the subject matter of the proposed publication or other disclosure contains Confidential Information or a patentable invention of the Responding Party, then prior to the expiration of the applicable time period for review, the Responding Party shall notify the Submitting Party in writing of its determination that such proposed publication or other disclosure, as applicable, contains such information or subject matter for which patent protection should be sought. Upon receipt of such written notice from the Responding Party, the Submitting Party shall delay public disclosure of such information or submission of the proposed publication for an additional period of [***] (or such other time period mutually agreed by the Parties in writing) to permit preparation and filing of a patent application on the disclosed subject matter. The Submitting Party shall thereafter be free to publish or disclose such information, except that the Submitting Party may not disclose any Confidential Information of the Responding Party in violation of Section 11.1.

11.3 **Publicity**.

11.3.1 The Parties agree that the material terms of this Agreement are deemed to be the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth below in this Section 11.4 and in Section 11.2. The Parties have agreed to make a joint public announcement in English of the execution of this Agreement on or after the Effective Date. Ono shall be permitted to make a public announcement in Japanese of the execution of this Agreement substantially in the form and with the content of the English press release.

11.3.2 After release of such initial press release, if either Party desires to make a public announcement concerning the material terms of this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld or delayed. A Party commenting on such a proposed press release shall provide its comments, if any, within [***] after receiving the press release for review, or such shorter period as may be required in exigent circumstances. Where required by Applicable Law or by the regulations of the applicable securities exchange upon which a Party may be listed, such Party shall have the right to make a press release announcing the achievement of each milestone under this Agreement as it is achieved, the achievements of Regulatory Approvals as they occur, and other material events occurring pursuant to this Agreement, subject only to the review procedure set forth in the preceding sentence. In relation to each Party's review of such an announcement, such Party may make specific, reasonable comments on such proposed press release within the prescribed time for commentary, but shall not withhold its consent to disclosure of the information that the relevant milestone has been achieved and triggered a payment hereunder or is otherwise required to be disclosed by Applicable Laws or the rules of an applicable securities exchange. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 11.4.2, provided such information continues as of such time to be accurate.

11.3.3 The Parties acknowledge that Forty Seven will be obligated to file a copy of this Agreement with the U.S. Securities and Exchange Commission (the "**SEC**") or other applicable entity having regulatory authority over Forty Seven securities or the exchange thereof, as a material agreement of Forty Seven. Forty Seven shall be entitled to make such a required filing, provided that it requests confidential treatment of certain commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available to Forty Seven, and to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed. In the event of any such filing, Forty Seven will provide Ono with a copy of the Agreement marked to show provisions for which Forty Seven intends to seek confidential treatment and shall reasonably consider and incorporate Ono's comments thereon to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed. Ono will as promptly as practical provide any such comments. Ono recognizes that Applicable Laws and SEC policies and regulations to which Forty Seven is and may become subject to may require Forty Seven to publicly disclose certain terms of this Agreement that Ono may prefer not be disclosed, and that Forty Seven is in all cases entitled hereunder to make such required disclosures to the extent necessary to comply with such U.S. laws and SEC policies and regulations, as determined in good faith by Forty Seven's counsel.

ARTICLE XII
REPRESENTATIONS, WARRANTIES, & COVENANTS

12.1 **Mutual Representations and Warranties**. Each Party hereby represents and warrants to the other Party that as of the Effective Date:

12.1.1 **Corporate Existence and Power**. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

12.1.2 **Authority and Binding Agreement**. As of the Effective Date, (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

12.1.3 **No Conflict; Covenant**. It is not a party to any agreement that would materially prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement. During the Term of this Agreement, each Party covenants that it will not enter into any contractually binding agreement which would in any way materially impair its ability to perform its obligations under this Agreement in a timely fashion.

12.1.4 **No Debarment**. Neither Party shall use, during the term of this Agreement, any employee or consultant who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

12.1.5 **No Government Consent.** Neither the execution and delivery of this Agreement nor the performance hereof by such Party requires such Party to obtain any permit, authorization or consent from any Governmental Authority (except for any intellectual property rights, INDs, Regulatory Approvals, Manufacturing-related approvals or similar approvals necessary for Manufacture or having Manufactured in the Field for the Ono Territory, or Development, use or Commercialization in the Field in the Ono Territory, of the Licensed Product as set forth herein), or from any other Person.

12.2 **Forty Seven Representations and Warranties**. Forty Seven represents and warrants to Ono that, to Forty Seven's Knowledge as of the Effective Date:

12.2.1 Forty Seven is the sole and exclusive owner of, or otherwise Controls, the Forty Seven Technology and has the right to grant the licenses to the Forty Seven Technology to Ono pursuant to this Agreement.

12.2.2 Exhibit B is an accurate listing of all Forty Seven Patents owned or Controlled by Forty Seven as of the Effective Date that are necessary or useful for Manufacture or having Manufactured in the Field for the Ono Territory, or Development, use or Commercialization in the Field in the Ono Territory, of the Product.

12.2.3 All Forty Seven Technology is free and clear of any liens, charges or encumbrances that would impair Ono's exercise of its licenses under Section 2.1.1.

12.2.4 No Forty Seven Patent specified in Exhibit B is invalid or unenforceable in whole or in part or, as to a patent application, has lapsed, or in the case of a provisional patent application has been cancelled, withdrawn or abandoned without the possibility of revival.

12.2.5 There is no material infringement or misappropriation of any Forty Seven Technology by any Third Party in the Ono Territory.

12.2.6 Each Person who was an inventor of an invention Covered by any Forty Seven Patent, has executed and delivered to Forty Seven (or an entity that was obligated to assign such invention to Forty Seven) or its applicable Upstream Licensor an agreement assigning to Forty Seven or such entity all rights, titles and interests in and to such invention.

12.2.7 Forty Seven has [***]. Forty Seven has [***].

12.2.8 Forty Seven has [***].

12.2.9 There are [***].

12.2.10 There is [***].

12.2.11 The use, Development, Manufacture, having Manufactured or Commercialization by Ono (or its Sublicensees) of Hu5F9-G4 as contemplated hereunder will not infringe any issued patent of any Third Party and will not infringe the claims of any Third Party patent application that is published as of the Effective Date when and if such claims were to issue in their current form.

12.2.12 Forty Seven has [***].

12.2.13 [***].

12.2.14 With respect to each Upstream Agreement, (a) Forty Seven is not in material breach under such Upstream Agreement; (b) Forty Seven has not received any notice of material breach under such Upstream Agreement; and (c) Forty Seven has previously provided Ono with access to true and complete copies of such Upstream Agreement.

12.3 **Ono Representation, Warranty and Covenant**. Ono represents and warrants to Forty Seven that, as of the Effective Date, neither Ono nor any of its Affiliates Control any Patent that Covers the manufacture, use or sale of any Product in the Ono Territory or the Forty Seven Territory. Ono covenants that it will notify Forty Seven within [***] of acquiring Control of any Patent that Covers the manufacture, use or sale of any Product in the Ono Territory or the Forty Seven Territory (other than a Joint Patent) following the Effective Date.

12.4 **Limitation on Warranties; No Implied Warranties**. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, EACH PARTY MAKES NO AND EXPRESSLY DISCLAIMS ALL OTHER REPRESENTATIONS AND WARRANTIES WITH RESPECT TO THE PRODUCTS, FORTY SEVEN TECHNOLOGY, FORTY SEVEN PATENTS, DATA OR ANY OTHER SUBJECT MATTER OF THIS AGREEMENT, WHETHER EXPRESS, IMPLIED, OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS. EXCEPT TO THE EXTENT EXPRESSLY PROVIDED FOR HEREIN, NOTHING IN THIS AGREEMENT WILL BE CONSTRUED AS A REPRESENTATION OR WARRANTY BY FORTY SEVEN THAT THE FORTY SEVEN PATENTS OR THE FORTY SEVEN KNOW-HOW IS NOT INFRINGED BY ANY THIRD PARTY OR THAT THE PRACTICE OF SUCH RIGHTS DOES NOT INFRINGE ANY PUBLISHED INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

ARTICLE XIII
INDEMNIFICATION AND INSURANCE

13.1 **Indemnification by Forty Seven**. Forty Seven shall defend, indemnify, and hold Ono and its Affiliates, and Ono's and its Affiliates' officers, directors, employees, and agents (the "**Ono Indemnitees**") harmless from and against any and all Third Party claims, suits, proceedings, damages, expenses (including court costs and reasonable attorneys' fees and expenses), and recoveries (collectively, "**Claims**") to the extent that such Claims arise out of, are based on, or result from (a) the Development, Manufacture or Commercialization of, or the Medical Affairs Activities conducted with respect to, any Product by Forty Seven or its Affiliates, distributors, or licensees (other than Ono, its Affiliates and Sublicensees) (the "**Forty Seven Group**"); (b) a breach of any of Forty Seven's representations, warranties, covenants or obligations under this Agreement; (c) the intentional misconduct or negligent acts of any Forty Seven Indemnitee; or (d) [***] pursuant to and in accordance with this Agreement. The foregoing indemnity obligation shall not apply (i) to the extent that the Ono Indemnitees fail to comply with the indemnification procedures set forth in Section 13.3, solely to the extent Forty Seven's defense of the relevant Claims is prejudiced by such failure, or (ii) to the extent that any Claim arises from, is based on, or results from any activities set forth in Section 13.2 for which Ono is obligated to indemnify any Forty Seven Indemnitees.

13.2 **Indemnification by Ono**. Ono shall defend, indemnify, and hold Forty Seven, its Affiliates and Forty Seven's and its Affiliates' officers, directors, employees, and agents (the "**Forty Seven Indemnitees**") harmless from and against any and all Claims to the extent that such Claims arise out of, are based on, or result from (a) the Development, Manufacture or Commercialization of, or the Medical Affairs Activities conducted with respect to, any Product by Ono or its Affiliates, or its or their Sublicensees, contractors, or distributors (the "**Ono Group**"); (b) a breach of any of Ono's representations, warranties, covenants or obligations under this Agreement; or (c) the intentional misconduct or negligent acts of any Ono Indemnitee. The foregoing indemnity obligation shall not apply (i) to the extent that the Forty Seven Indemnitees fail to comply with the indemnification procedures set forth in Section 13.3, solely to the extent Ono's defense of the relevant Claims is prejudiced by such failure, or (ii) to the extent that any Claim arises from, is based on, or results from any activities set forth in Section 13.1 for which Forty Seven is obligated to indemnify any Ono Indemnitees.

13.3 **Indemnification Procedures**. The Party claiming indemnity under this ARTICLE XIII (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim and shall tender the defense of such Claim to the Indemnifying Party. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense. The Indemnifying Party shall not settle any claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, conditioned, or delayed, unless the settlement involves only the payment of money, and no admission of wrong-doing or fault by the Indemnified Party. The Indemnified Party shall not settle any such claim without the prior written consent of the Indemnifying Party.

13.4 **Non-Exclusive Remedy**. Neither Party shall be obligated to claim indemnification from the other Party under this Article XIII, and such injured Party retains all rights to defend itself against any such Claim and pursue in turn any claims against the other Party it may have in law or equity related to or arising from such Claim.

13.5 **Limitation of Liability**. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 13.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 13.1 OR 13.2, OR DAMAGES AVAILABLE FOR A BREACH OF THE EXCLUSIVITY OBLIGATIONS UNDER SECTION 2.10 OR BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE XI OR ARISING FROM A PARTY'S GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT.

13.6 **Insurance**. Each Party shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold by such Party. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this ARTICLE XIII. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [***] prior to the cancellation, non-renewal, or material change in such insurance or self-insurance which materially adversely affects the rights of the other Party hereunder.

ARTICLE XIV
TERM AND TERMINATION

14.1 **Term**.

14.1.1 This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this ARTICLE XIV, shall remain in effect until the expiration of all Royalty Terms in all countries in the Ono Territory (the "**Term**").

14.1.2 Following the expiration (but not earlier termination) of each Royalty Term with respect to a Product in country, Ono's license under Section 2.1.1 shall become fully paid-up with respect to such Product in such country.

14.1.3 Following the expiration (but not earlier termination) of all Royalty Terms with respect to all Products in all countries in the Ono Territory, Forty Seven's license under Section 2.4.1 shall become non-exclusive.

14.2 **Termination for Convenience**. Ono shall have the right to terminate this Agreement in its entirety or in any country in the Ono Territory, on a country-by-country basis, for any or no reason upon ninety (90) days' written notice to Forty Seven prior to the First Commercial Sale of the first Product hereunder, or upon one hundred and eighty (180) days' written notice following the First Commercial Sale of the first Product hereunder, provided that, upon such termination:

14.2.1 Where such termination is on a country-by-country basis, such country shall be excluded from the Ono Territory;

14.2.2 Ono shall not, during the notice period for such termination, take any action that could reasonably be expected to have a material adverse impact on the further Development and Commercialization of the Product; provided, however, that Ono shall have the right to take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems;

14.2.3 Ono shall be required to perform any outstanding obligations of Ono that existed or accrued prior to the effective date of such termination; and

14.2.4 the JSC shall coordinate the wind-down of Ono's efforts under this Agreement and the provisions of Section 14.5 shall apply.

14.3 **Termination for Breach**. Forty Seven shall have the right to terminate this Agreement upon written notice to Ono if Ono, after receiving written notice from Forty Seven identifying such material breach by Ono, fails to cure such breach within [***] from the date of such notice (or within [***] notice in the event such breach is solely based upon Ono's failure to pay any amounts due Forty Seven hereunder). Ono shall have the right to terminate this Agreement upon written notice to Forty Seven if Forty Seven, after receiving written notice identifying a material breach by Forty Seven of its obligations under this Agreement, fails to cure such breach within [***] from the date of such notice (or within [***] notice in the event such breach is solely based upon Forty Seven's failure to pay any amounts due Ono hereunder). If (a) any material breach in question takes place with respect only to a certain country in the Ono Territory, other than Japan, and (b) such material breach does not jeopardize the non-breaching Party's rights and benefits in other country(ies), the non-breaching Party's right to terminate this Agreement shall be limited to such Product in such country. For clarity, (i) Forty Seven shall have the right to terminate this Agreement in its entirety if there is any material breach by Ono that relates to Japan that is not cured within the time periods set forth above, and (ii) the non-breaching Party shall not be obligated to terminate this Agreement for any breach as permitted above and, irrespective of whether such Party terminates this Agreement, shall be entitled to seek all available remedies and damages for such breach in accordance with Section 15.3.

14.4 **Termination for Insolvency**. Forty Seven shall have the right to terminate this Agreement upon written notice to Ono if Ono makes a general assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not dismissed, discharged, bonded or stayed within [***] after the filing thereof. Ono shall have the right to terminate this Agreement upon written notice to Forty Seven if Forty Seven makes a general assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not dismissed, discharged, bonded or stayed within [***] after the filing thereof.

14.5 **Forty Seven Rights upon Termination of the Agreement**. Upon the early termination of this Agreement under Section 14.2, Section 14.3, Section 14.4, or Section 16.3, the following shall apply (in addition to any other rights and obligations under Section 14.2 or otherwise under this Agreement with respect to such termination); provided that in the event of a termination under Section 14.2, the following shall apply only with respect to the country(ies) to which such termination applies:

14.5.1 **Licenses**.

14.5.1.1 Upon termination by Ono under Section 14.2 or by Forty Seven under Section 14.3, Section 14.4 or Section 16.3, Ono hereby grants to Forty Seven (effective as of the effective date of such termination) an exclusive (even as to Ono and its Affiliates), fully paid-up license, with the right to grant multiple tiers of sublicenses, under any Ono Technology to Develop, Manufacture, have Manufactured, use, Commercialize, import, export and otherwise exploit any and all Licensed Antibodies and Products, effective upon the date of such termination, (a) if this Agreement is only terminated in some but not all countries in the Ono Territory, in (i) any such terminated country(ies) in the Ono Territory and (ii) the Forty Seven Territory, and (b) if this Agreement is terminated in its entirety, worldwide.

14.5.1.2 Upon termination by Ono under Section 14.3, Section 14.4 or Section 16.3, Ono hereby grants to Forty Seven (effective as of the effective date of such termination) an exclusive (even as to Ono and its Affiliates), royalty-bearing license, with the right to grant multiple tiers of sublicenses, under any Ono Technology to Develop, Manufacture, have Manufactured, use, Commercialize, import, export and otherwise exploit any and all Licensed Antibodies and Products (a) if the Agreement is only terminated in some but not all countries in the Ono Territory, (i) in any such terminated country(ies) in the Ono Territory and (ii) the Forty Seven Territory, and (b) if the Agreement is terminated as set forth above in its entirety, worldwide. Such royalty shall be established in accordance with Section 14.5.6.

14.5.2 **Regulatory Materials; Data**. To the extent permitted by Applicable Laws, Ono shall transfer and assign to Forty Seven all Regulatory Filings and Regulatory Approvals for the Products in any terminated country(ies) in the Ono Territory, and all Data from all preclinical, non-clinical, and clinical studies of Products conducted by or on behalf of Ono, its Affiliates, or Sublicensees, and all pharmacovigilance data (including all Adverse Event Data), free and clear of any liens or encumbrances; provided that, to the extent the foregoing assignment is not permitted by Applicable Laws, Ono hereby grants to Forty Seven, effective as of the effective date of such termination, an exclusive (even as to Ono and its Affiliates) license, with the right to grant multiple tiers of sublicenses, under such Regulatory Filings, Regulatory Approvals and Data to research, Develop, Manufacture, have Manufactured, use, Commercialize, import, export and otherwise exploit any and all Licensed Antibodies and Products worldwide. If this Agreement is terminated by Ono pursuant to Sections 14.3 or 14.4, such transfer, assignment or license shall be royalty-bearing in accordance with Section 14.5.6. If this Agreement is terminated other than by Ono pursuant to Sections 14.3 or 14.4, the consideration for such transfer, assignment or license mentioned above shall be zero (0).

14.5.3 **Trademarks**. Except if this Agreement is terminated by Ono pursuant to Sections 14.3 or 14.4, upon Forty Seven's written request, Ono shall assign to Forty Seven its rights to the Product Trademark in the Ono Territory (if any), at Ono's sole cost and expense.

14.5.4 **Transition Assistance**. Up to [***] from the effective date of such termination, Ono shall provide such assistance as may be reasonably necessary to transfer or transition over a reasonable period of time to Forty Seven all Ono Know-How and Joint Know-How, or then-existing commercial contractual arrangements (if permitted by the terms of such contracts) that are necessary or useful for Forty Seven to commence or continue Developing, conduct Manufacturing of, or Commercializing Products in the terminated country, to the extent Ono is then performing or having performed such activities, (a) if this Agreement is terminated by Ono under Section 14.3, at Forty Seven's cost, or (b) if this Agreement is terminated by Ono under Section 14.2 or by Forty Seven under Section 14.3, at Ono's cost. Ono shall use Commercially Reasonable Efforts, upon request of Forty Seven, to transfer any agreements or arrangements with Third Party suppliers or vendors to supply or sell Products in the terminated country. To the extent that any contract between Ono and a Third Party for the supply of a Product for the Ono Territory is not assignable to Forty Seven, then Ono shall reasonably cooperate with Forty Seven, at Forty Seven's cost, to arrange to continue to obtain such supply from such entity.

14.5.5 **Remaining Inventories**. Forty Seven shall have the right to purchase from Ono all of the inventory of Products held by Ono as of the effective date of such termination at a price equal to [***] for such Product (which, for Product purchased by Ono from Forty Seven shall be [***]). Forty Seven shall notify Ono whether Forty Seven elects to exercise such right within [***] after receiving notice from Ono reporting such inventory as of the date of such termination. If Forty Seven does not exercise such right, Ono shall have the right to sell in the Ono Territory any such remaining inventory in accordance with Applicable Laws over a period of no greater than [***] after the effective date of such termination.

14.5.6 [***]

14.6 **Survival**. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the following provisions shall survive any expiration or termination of this Agreement: ARTICLES I, XIII, XV and XVI (excluding Section 16.14), and Sections 2.2.1(b), 2.5, 2.8.1, 2.11, 2.12, 9.3 and 9.4 (solely with respect to sales occurring prior to the effective date of expiration or termination), 9.5 (solely with respect to Global Common Costs, Manufacturing Costs and other reimbursements occurring, or that are committed to and non-cancellable, prior to the effective date of expiration or termination), 9.6, 9.7, 9.8, 9.9, 10.2, 10.4, 10.5, 11.1, 11.2, 11.4, 12.4, 14.5 and 14.6. In addition, the following Sections shall survive expiration (but not earlier termination) of this Agreement: Sections 2.3, 14.1.2 and 14.1.3.

ARTICLE XV
DISPUTE RESOLUTION

15.1 **Disputes**. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the Parties' objective to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this ARTICLE XV to resolve any controversy or claim arising out of, relating to, or in connection with any provision of this Agreement if and when a dispute arises under this Agreement.

15.2 **Arising Between the Parties**. Except as otherwise provided in Section 3.3, with respect to all disputes arising between the Parties, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, or any question regarding its existence, validity or termination, if the Parties are unable to resolve such dispute within [***] after such dispute is first identified by either Party in writing to the other Party, the Parties shall refer such dispute to the Executive Officers for attempted resolution by good faith negotiations within [***] after such notice is received.

15.3 **Binding Arbitration**. If the Executive Officers are not able to resolve a dispute referred to them under Section 15.2 (other than a dispute of the JSC pursuant to Section 3.3.1, which shall be subject to Section 3.3.2) within such [***] period, and subject to Section 15.4, such dispute shall be finally resolved through binding arbitration, which arbitration may be initiated by either Party at any time after the conclusion of such period, on the following basis:

15.3.1 The seat, or legal place, of arbitration shall be [***]. The language of the arbitration shall be English.

15.3.2 The arbitration shall be made in accordance with the current Rules of Arbitration of International Chamber of Commerce (ICC) by three (3) arbitrators appointed in accordance with the said Rules. Each Party shall nominate one (1) arbitrator, and the two (2) arbitrators so nominated shall nominate a third (3rd) arbitrator, who shall act as the chairperson.

15.3.3 Judgment upon the award rendered by such arbitrator shall be binding on the Parties and may be entered by any court or forum having jurisdiction.

15.3.4 Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Further, either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of such Party pending the arbitration award.

15.3.5 The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. [***].

15.3.6 The tribunal may include in its award an allocation to any Party of costs and expenses relating to the arbitration, excluding lawyers' fee, as the tribunal deems reasonable. Each Party shall bear its own cost and expenses for its own lawyers.

15.3.7 If the tribunal orders production of documents, the tribunal shall take guidance from the IBA Rules on the Taking of Evidence in International Arbitration as current on the date of the commencement of the arbitration. The existence and content of the arbitral proceedings, any information exchanged between Parties during the arbitral proceedings and any rulings or award shall be kept confidential by the Parties and members of the tribunal except (a) to the extent that disclosure may be required of a Party to fulfill a legal duty, protect or pursue a legal right, or enforce an award in bona fide legal proceedings before a court or other judicial authority, (b) with the written consent of the Parties, (c) where necessary for the preparation or presentation of a claim or defense in such arbitration, (d) where such information is already in the public domain other than as a result of a breach of this clause, or (e) by order of the tribunal upon application of a Party.

15.3.8 In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy, or claim would be barred by the applicable statute of limitations.

15.4 **Patent and Trademark Dispute Resolution**. Any dispute, controversy, or claim relating to the scope, validity, enforceability, or infringement of any patent rights covering the manufacture, use, or sale of any Product or of any trademark rights relating to any Licensed Antibody or Product shall be submitted to a court of competent jurisdiction in the country or jurisdiction in which such patent or trademark rights were granted or arose.

ARTICLE XVI
OTHER PROVISIONS

16.1 **Governing Law**. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, United States, without reference to its conflicts of law principles. The Parties hereby agree to exclude the application of the United Nations Convention on Contracts for the International Sale of Goods.

16.2 **Performance Through Affiliates**. Each Party may discharge any obligation and exercise any right hereunder through any of its Affiliates (without an assignment of this Agreement), subject to Section 2.2. Each Party shall remain directly liable the other Party with respect to the performance of any of its Affiliates.

16.3 **Force Majeure**. Both Parties will be excused from the performance of their obligations under this Agreement, other than the obligation to make monetary payments, and neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice thereof to the other Party. The Parties shall attempt to seek a mutually acceptable solution within the spirit and intent of this Agreement. If (i) such inability to perform continues for a period more than [***], (ii) the Parties fail to find a mutually acceptable solution as above mentioned and (iii) nonperforming Party fails to uses Commercially Reasonable Efforts to remedy its inability to perform and to mitigate the effects of the circumstance of force majeure, then the other Party may terminate this Agreement upon [***] prior written notice to the nonperforming Party. For purposes of this Agreement, a force majeure event will include conditions beyond the reasonable control and without the fault of a Party, such as an act of God, voluntary or involuntary compliance with any regulation, law, or order of any government, war, an act of terrorism, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm, or like catastrophe; provided, however, the payment of amounts due and owing hereunder may not be delayed by the payor because of a force majeure affecting the payor.

16.4 **Assignment**.

16.4.1 Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the prior written consent of the other Party; provided, however, that either Party may, without the other Party's written consent, assign this Agreement and its rights and obligations hereunder in its entirety to (a) any of its Affiliates, or (b) any purchaser of all, or substantially all, of its assets to which this Agreement relates, or (c) any successor corporation resulting from any merger, consolidation, share exchange, or other similar transaction, provided that any such successor corporation shall assume all obligations of its assignor under this Agreement and provided further that either Party may assign or sell its rights to receive any amounts due hereunder (and the other Party shall cooperate reasonably with such Party in connection therewith). This Agreement will inure to the benefit of Ono and Forty Seven and their respective successors and permitted assigns. Any assignment of this Agreement that is not made in accordance with this Section 16.4 shall be null and void and of no legal force or effect.

16.4.2 Notwithstanding anything herein to the contrary, in the event of (a) a transaction by a Party described in Section 16.4.1(b) or (c), or (b) the acquisition by a Party or any of its Affiliates of all or substantially all of the business of a Third Party (such Third Party, an "**Acquiree**"), whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise, the intellectual property of the acquiring entity or the Acquiree, as applicable, and their respective Affiliates, as such intellectual property exists immediately prior to the consummation of such transaction or is developed or acquired thereafter without use of the other Party's Confidential Information, Know-How or Patents, shall not be included in the intellectual property licensed hereunder or otherwise subject to this Agreement.

16.5 **Severability**. In the event any one or more of the provisions contained in this Agreement should be held invalid, illegal, or unenforceable in any respect, the validity, legality, and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby. The Parties will in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal, and enforceable provision(s) that implement the purposes of this Agreement.

16.6 **Notices**. Any notice to be given under this Agreement must be in writing and delivered either in person, or by (a) air mail (postage prepaid) requiring return receipt, (b) overnight courier, or (c) facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at its address(es) given below, or at any address such Party may designate by prior written notice to the other Party in accordance with this Section 16.6. Notice shall be deemed sufficiently given for all purposes upon the (i) date of actual receipt; or (ii) if sent by facsimile, the date of confirmation of receipt if during the recipient's normal business hours, otherwise the next business day.

If to Forty Seven, notices must be addressed to:

Forty Seven, Inc.
1490 O'Brien Drive, Suite A
Menlo Park, CA 94025, United States
Attention: [***]
Fax: [***]

If to Ono, notices must be addressed to:

Ono Pharmaceutical Co., Ltd.
8-2, Kyutaromachi 1-chome,
Chuo-ku
Osaka 541-8564, Japan
Attention: [***]
Fax: [***]

16.7 **Time of the Essence**. Each Party depends upon the other Party's timely performance of its obligations hereunder and, therefore, time is of the essence with regard to the other Party's performance hereunder.

16.8 **Entire Agreement; Amendments**. This Agreement, including the schedules, contains the entire understanding of the Parties with respect to the subject matter herein. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written, or otherwise, concerning any and all matters contained herein, including the Confidentiality Agreements. Except as expressly set forth herein, this Agreement may be amended or modified only by a written instrument duly executed by both Parties.

16.9 **Relationship of the Parties**. It is expressly agreed that Forty Seven and Ono are independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture, or agency. Neither Forty Seven nor Ono will have the authority to make any statements, representations, or commitments of any kind, or to take any action, which will be binding on the other Party, without the prior written consent of the other Party. Nothing contained in this Agreement shall be deemed to make any member of the JSC or any subcommittee (or any other committees or working groups) a partner, agent, or legal representative of the other Party, or to create any fiduciary relationship for any purpose whatsoever. Except as may be explicitly provided this Agreement, no member of the JSC or any subcommittee (or any other committee or working group) will have any authority to act for, or to assume any obligation or responsibility on behalf of, any other member of the JSC or any subcommittee (or any other committee or working group) of the other Party.

16.10 **Waiver**. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. Any waiver by a Party of a particular term or condition will be effective only if set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition.

16.11 **Third Party Beneficiaries**. Except as otherwise expressly provided in this Agreement, nothing herein expressed or implied is intended or will be construed to confer upon or to give to any Third Party any rights or remedies by reason of this Agreement. Except as otherwise expressly provided in this Agreement, there are no intended Third Party beneficiaries under or by reason of this Agreement.

16.12 **Further Assurances**. Upon the other Party's request, each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be reasonably agreed by the Parties as necessary or appropriate to carry out the purposes and intent of this Agreement.

16.13 **Counterparts**. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

16.14 **Anti-Bribery and Anti-Corruption**. The Parties shall acknowledge and agree that there are anti-bribery and anti-corruption laws, including US Foreign Corrupt Practices Act, the UK Bribery Act 2010, Japan Unfair Competition Prevention Act and China Anti Commercial Bribery Laws, that prohibit the payment, offering, and/or receiving, as the case may be, of anything of value to or from, a government employee, official, or private individual, for the purpose of (i) inducing or influencing any governmental act, or decision affecting one Party, (ii) helping one Party obtain or retain any business, or (iii) giving otherwise improperly benefit of one Party's business activities, and such laws prohibit a Party from being involved with clients, contractors, agents, consultants, advisors or other third parties involved in such activity. Each Party shall agree to refrain from any activity that would constitute a violation of such laws in connection with this Agreement. Each Party shall further ensure that its and/or its Affiliates' directors, officers, employees, agents, and Sublicensee shall follow and observe all relevant obligations and responsibilities in compliance with anti-bribery and anti-corruption laws in its performance under this Agreement. Each Party shall indemnify the other Party and its directors, officers, employees, agents, and Sublicensee against any and all liabilities, losses and expenses, including any civil or criminal fines imposed by any relevant government or regulatory authority and any legal fees, costs and expenses, which the other Party and its directors, officers, employees and agents may incur as a result of its breach of this Section 16.14. Breach of anti-bribery and anti-corruption laws by one Party, its Affiliates, its and their directors, officers, employees, agents, and Sublicensee shall entitle the other Party to terminate this Agreement upon ten (10) days' prior written notice to such other Party.

16.15 **Interpretation**. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections, and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The word "will" shall be construed to have the same meaning and effect as the word "shall". The words "herein," "hereof," and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language.

{Signature Page Follows}

IN WITNESS WHEREOF, the Parties have executed this Exclusive License and Collaboration Agreement to be effective as of the Effective Date.

FORTY SEVEN, INC.

By:
Name: [***]
Title: [***]

ONO PHARMACEUTICAL CO., LTD.

By:
Name: [***]
Title: [***]

EXHIBIT A

[***]

EXHIBIT B
Forty Seven Patents

[***]

EXHIBIT C
Hu5F9-G4

[***]

EXHIBIT D
Upstream Agreements

1. [***]

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: November 12, 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: November 12, 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 September 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 my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 12, 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 September 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 my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 12, 2019

By: /s/ Ann D. Rhoads

Ann D. Rhoads
Chief Financial Officer