

**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: 001-38753



Moderna, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

81-3467528
(IRS Employer
Identification No.)

**200 Technology Square
Cambridge, Massachusetts**
(Address of Principal Executive
Offices)

02139
(Zip Code)

(617) 714-6500
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	MRNA	The NASDAQ Stock Market LLC

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ 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 Act). **Yes** ☐ **No** ☒

As of October 31, 2019, there were 333,250,115 shares of the registrant's common stock, par value \$0.0001 per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Form 10-Q"), including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Form 10-Q include, but are not limited to, statements about:

- the initiation, timing, progress, results, safety and efficacy, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
 - our anticipated next steps for our development candidates and investigational medicines;
 - our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop development candidates and investigational medicines, including by applying learnings from one program to our other programs and from one modality to our other modalities;
 - our ability and the potential to successfully manufacture our drug substances, delivery vehicles, development candidates, and investigational medicines for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;
 - the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and investigational medicines;
 - our ability to obtain funding for our operations necessary to complete further development and commercialization of our investigational medicines;
 - our ability to obtain and maintain regulatory approval of our investigational medicines;
 - our ability to commercialize our products, if approved;
 - the pricing and reimbursement of our investigational medicines, if approved;
 - the implementation of our business model, and strategic plans for our business, investigational medicines, and technology;
 - the scope of protection we are able to establish and maintain for intellectual property rights covering our investigational medicines and technology;
 - estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;
 - the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory, and commercialization expertise;
 - future agreements with third parties in connection with the commercialization of our investigational medicines, if approved;
 - the size and growth potential of the markets for our investigational medicines, and our ability to serve those markets;
 - our financial performance;
 - the rate and degree of market acceptance of our investigational medicines;
 - regulatory developments in the United States and foreign countries;
 - our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
 - our ability to produce our products or investigational medicines with advantages in turnaround times or manufacturing cost;
 - the success of competing therapies that are or may become available;
 - our ability to attract and retain key scientific or management personnel;
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- the impact of laws and regulations;
- developments relating to our competitors and our industry; and
- other risks and uncertainties, including those discussed in Part II, Item 1A - Risk Factors in this Form 10-Q.

In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled “Risk Factors” and elsewhere in this Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those expressed or implied by the forward-looking statements. No forward-looking statement is a guarantee of future performance.

The forward-looking statements in this Form 10-Q represent our views as of the date of this Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Form 10-Q.

This Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We have not independently verified the information contained in such sources.

NOTE REGARDING COMPANY REFERENCES

Unless the context otherwise requires, the terms “Moderna,” “the Company,” “we,” “us,” and “our” in this Form 10-Q refer to Moderna, Inc. and its consolidated subsidiaries.

Table of Contents

	Page
PART I.	
Item 1.	Financial Statements (Unaudited) 5
	Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018 5
	Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2019 and 2018 6
	Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2019 and 2018 7
	Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the three and nine months ended September 30, 2019 and 2018 8
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018 10
	Notes to Condensed Consolidated Financial Statements 11
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations 42
Item 3.	Quantitative and Qualitative Disclosures about Market Risk 55
Item 4.	Controls and Procedures 55
PART II.	
Item 1.	Legal Proceedings 56
Item 1A.	Risk Factors 56
Item 2	Unregistered Sales of Equity Securities and Use of Proceeds 56
Item 6.	Exhibits 56
SIGNATURES	

Item 1. Financial Statements

MODERNA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in thousands, except share and per share data)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 173,711	\$ 658,364
Investments	884,829	863,063
Accounts receivable	2,800	11,686
Accounts receivable from related party	5,416	899
Prepaid expenses and other current assets	26,678	28,399
Restricted cash	1,032	595
Total current assets	1,094,466	1,563,006
Investments, non-current	279,860	172,990
Property and equipment, net	203,688	211,977
Restricted cash, non-current	10,791	11,532
Other non-current assets	2,094	2,644
Total assets	\$ 1,590,899	\$ 1,962,149
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 11,737	\$ 31,210
Accrued liabilities	60,079	79,073
Deferred revenue	70,191	109,056
Other current liabilities	5,835	3,464
Total current liabilities	147,842	222,803
Deferred revenue, non-current	143,438	165,352
Deferred lease obligation, non-current	13,850	10,006
Lease financing obligation	33,801	33,489
Other non-current liabilities	161	258
Total liabilities	339,092	431,908
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, par value \$0.0001; 162,000,000 shares authorized as of September 30, 2019 and December 31, 2018; no shares issued or outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, par value \$0.0001; 1,600,000,000 shares authorized as of September 30, 2019 and December 31, 2018; 332,494,777 and 328,798,904 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	33	33
Additional paid-in capital	2,618,492	2,538,155
Accumulated other comprehensive income (loss)	2,830	(1,320)
Accumulated deficit	(1,369,548)	(1,006,627)
Total stockholders' equity	1,251,807	1,530,241
Total liabilities and stockholders' equity	\$ 1,590,899	\$ 1,962,149

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

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Collaboration revenue	\$ 9,614	\$ 16,935	\$ 32,757	\$ 56,530
Collaboration revenue from related party	3,724	19,727	4,726	33,166
Grant revenue	3,708	5,095	8,671	9,951
Total revenue	17,046	41,757	46,154	99,647
Operating expenses:				
Research and development	119,715	109,050	378,786	303,653
General and administrative	28,188	18,525	83,994	56,229
Total operating expenses	147,903	127,575	462,780	359,882
Loss from operations	(130,857)	(85,818)	(416,626)	(260,235)
Interest income	9,252	6,519	30,546	18,129
Other expense, net	(1,767)	(1,032)	(5,351)	(1,044)
Loss before income taxes	(123,372)	(80,331)	(391,431)	(243,150)
(Benefit from) provision for income taxes	(178)	—	(526)	158
Net loss	\$ (123,194)	\$ (80,331)	\$ (390,905)	\$ (243,308)
Net loss attributable to common stockholders (Note 11)	\$ (123,194)	\$ (87,819)	\$ (390,905)	\$ (257,758)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.37)	\$ (1.32)	\$ (1.19)	\$ (3.91)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	330,769,341	66,283,040	329,592,322	65,887,511

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

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited, in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	\$ (123,194)	\$ (80,331)	\$ (390,905)	\$ (243,308)
Other comprehensive income (loss):				
Unrealized gain on available-for-sale debt securities, net of tax, \$25 and \$0, for three months ended September 30, 2019 and 2018, respectively, and net of tax, \$1,173 and \$0, for nine months ended September 30, 2019 and 2018, respectively	168	458	4,243	197
Less: amounts recognized for net realized (gain)/loss included in net loss	(79)	629	(93)	38
Total other comprehensive income	89	1,087	4,150	235
Comprehensive loss	<u>\$ (123,105)</u>	<u>\$ (79,244)</u>	<u>\$ (386,755)</u>	<u>\$ (243,073)</u>

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

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2019
(Unaudited, in thousands except share data)

	Three Months Ended September 30, 2019							
	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at June 30, 2019	—	\$ —	329,958,172	\$ 33	\$ 2,582,134	\$ 2,741	\$ (1,246,354)	\$ 1,338,554
Vesting of restricted common stock	—	—	33,678	—	—	—	—	—
Exercise of options to purchase common stock, net	—	—	2,502,927	—	15,554	—	—	15,554
Stock-based compensation	—	—	—	—	20,804	—	—	20,804
Unrealized gain on marketable securities	—	—	—	—	—	89	—	89
Net loss	—	—	—	—	—	—	(123,194)	(123,194)
Balance at September 30, 2019	—	\$ —	332,494,777	\$ 33	\$ 2,618,492	\$ 2,830	\$ (1,369,548)	\$ 1,251,807

	Three Months Ended September 30, 2018							
	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at June 30, 2018	509,352,795	\$1,837,620	66,204,796	\$ 6	\$ 98,105	\$ (2,009)	\$ (784,870)	\$ (688,768)
Vesting of restricted common stock	—	—	103,798	—	—	—	—	—
Exercise of options to purchase common stock, net	—	—	44,307	—	290	—	—	290
Repurchase of Series D redeemable convertible preferred stock	(269,180)	(704)	—	—	(2,009)	—	—	(2,009)
Repurchase of Series E redeemable convertible preferred stock	(544,100)	(3,355)	—	—	(2,118)	—	—	(2,118)
Stock-based compensation	—	—	—	—	14,720	—	—	14,720
Unrealized gain on marketable securities	—	—	—	—	—	1,087	—	1,087
Net loss	—	—	—	—	—	—	(80,331)	(80,331)
Balance at September 30, 2018	508,539,515	\$1,833,561	66,352,901	\$ 6	\$ 108,988	\$ (922)	\$ (865,201)	\$ (757,129)

Nine Months Ended September 30, 2019									
	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity	
	Shares	Amount	Shares	Amount					
Balance at December 31, 2018	—	\$ —	328,798,904	\$ 33	\$ 2,538,155	\$ (1,320)	\$ (1,006,627)	\$ 1,530,241	
Transition adjustment from adoption of ASU Topic 606 (Note 2)			—	—	—	—	27,984	27,984	
Vesting of restricted common stock	—	—	141,153	—	—	—	—	—	
Exercise of options to purchase common stock, net	—	—	3,554,720	—	19,541	—	—	19,541	
Stock-based compensation	—	—	—	—	60,796	—	—	60,796	
Unrealized gain on marketable securities	—	—	—	—	—	4,150	—	4,150	
Net loss	—	—	—	—	—	—	(390,905)	(390,905)	
Balance at September 30, 2019	—	\$ —	332,494,777	\$ 33	\$ 2,618,492	\$ 2,830	\$ (1,369,548)	\$ 1,251,807	

Nine Months Ended September 30, 2018									
	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit	
	Shares	Amount	Shares	Amount					
Balance at December 31, 2017	448,686,791	\$1,176,661	65,206,999	\$ 6	\$ 71,679	\$ (1,157)	\$ (621,893)	\$ (551,365)	
Vesting of restricted common stock	—	—	754,127	—	—	—	—	—	
Issuance of Series G redeemable convertible preferred stock, net of issuance costs of \$10,517	55,666,004	549,413	—	—	152	—	—	152	
Issuance of Series H redeemable convertible preferred stock, net of issuance costs of \$474	5,000,000	111,546	—	—	—	—	—	—	
Repurchase of Series D redeemable convertible preferred stock	(269,180)	(704)	—	—	(2,009)	—	—	(2,009)	
Repurchase of Series E redeemable convertible preferred stock	(544,100)	(3,355)	—	—	(2,118)	—	—	(2,118)	
Exercise of options to purchase common stock, net	—	—	391,775	—	360	—	—	360	
Stock-based compensation	—	—	—	—	40,924	—	—	40,924	
Unrealized loss on marketable securities	—	—	—	—	—	235	—	235	
Net loss	—	—	—	—	—	—	(243,308)	(243,308)	
Balance at September 30, 2018	508,539,515	\$1,833,561	66,352,901	\$ 6	\$ 108,988	\$ (922)	\$ (865,201)	\$ (757,129)	

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Nine Months Ended September 30,	
	2019	2018
Operating activities		
Net loss	\$ (390,905)	\$ (243,308)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	60,796	40,924
Depreciation and amortization	22,082	17,512
Amortization/accretion of investments	(3,428)	(1,103)
Loss on disposal of property and equipment	70	—
Changes in assets and liabilities:		
Accounts receivable	8,886	2,036
Accounts receivable from related party	(4,517)	(176)
Prepaid expenses and other assets	(1,407)	(5,246)
Accounts payable	(19,185)	718
Accrued liabilities	(8,253)	(17,190)
Deferred revenue	(32,795)	(37,103)
Deferred lease obligation	3,844	2,237
Other liabilities	1,617	854
Net cash used in operating activities	<u>(363,195)</u>	<u>(239,845)</u>
Investing activities		
Purchases of marketable securities	(949,277)	(951,194)
Proceeds from maturities of marketable securities	747,846	493,525
Proceeds from sales of marketable securities	81,030	170,531
Purchases of property and equipment	(24,892)	(92,129)
Net cash used in investing activities	<u>(145,293)</u>	<u>(379,267)</u>
Financing activities		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	661,111
Repurchases of redeemable convertible preferred stock	—	(8,182)
Proceeds from issuance of common stock through equity plans, net	19,541	360
Reimbursement of assets under lease financing obligation	3,678	1,747
Payments on financing lease obligation	312	(4,109)
Net cash provided by financing activities	<u>23,531</u>	<u>650,927</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>(484,957)</u>	<u>31,815</u>
Cash, cash equivalents and restricted cash, beginning of year	670,491	147,608
Cash, cash equivalents and restricted cash, end of period	<u>\$ 185,534</u>	<u>\$ 179,423</u>
Non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	<u>\$ 1,863</u>	<u>\$ 12,768</u>
Leasehold improvements included in prepaid and other current assets	<u>\$ 6,310</u>	<u>\$ 13,567</u>
Lease financing obligation	<u>\$ —</u>	<u>\$ 13,567</u>

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

MODERNA, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Description of the Business

Moderna, Inc. is a Delaware corporation, incorporated under the laws of the State of Delaware on July 22, 2016 (collectively, with its consolidated subsidiaries, any of Moderna, Company, we, us or our). In August 2018, we changed our name from Moderna Therapeutics, Inc. to Moderna, Inc. We are the successor in interest to Moderna LLC, a limited liability company formed under the laws of the State of Delaware in 2013. We are creating a new generation of potentially transformative medicines based on messenger RNA (mRNA), to improve the lives of patients. Since inception, we have incurred significant net losses. We expect to continue to incur significant expenses and operating losses for the foreseeable future. In addition, we anticipate that our expenses will increase significantly in connection with our ongoing activities to support our platform research, drug discovery and clinical development, infrastructure and Research Engine and Early Development engine, digital infrastructure, creation of a portfolio of intellectual property, and administrative support.

We do not expect to generate significant revenue from sales of potential mRNA medicines unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our investigational medicines. If we seek to obtain regulatory approval for any of our investigational medicines, we expect to incur significant commercialization expenses.

As a result, we will need substantial additional funding to support our continued operations and pursue our growth strategy. Until we can generate significant revenue from potential mRNA medicines, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings, government funding arrangements, strategic alliances and marketing, distribution and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our programs. We believe that our cash, cash equivalents, and investments as of September 30, 2019 will be sufficient to enable us to fund our projected operations through at least the next 12 months from the issuance of our financial statements.

Because of the numerous risks and uncertainties associated with pharmaceutical development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our medicines, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

2. Summary of Basis of Presentation and Recent Accounting Standards

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements that accompany these notes have been prepared in conformity with U.S. generally accepted accounting principles (GAAP) and applicable rules and regulations of the Securities and Exchange Commission (SEC) for interim financial reporting, consistent in all material respects with those applied in our Annual Report on Form 10-K for the year ended December 31, 2018 (2018 Form 10-K), except for changes associated with recent accounting standards for revenue recognition as detailed in "Note 2 - Recent Accounting Standards and Accounting Policies." This report should be read in conjunction with the consolidated financial statements in our 2018 Form 10-K.

We have made estimates and judgments affecting the amounts reported in our condensed consolidated financial statements and the accompanying notes. On an ongoing basis, we evaluate our estimates, including critical accounting policies or estimates related to revenue recognition, research and development expense, income tax provisions, stock-based compensation, and useful lives of long-lived assets. We base our estimates on historical experience and on various relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. The actual results that we experience may differ materially from our estimates. The condensed consolidated financial statements reflect all normal recurring adjustments necessary to present fairly the financial position, results of operations, and cash flows for the interim periods, but are not necessarily indicative of the results of operations to be anticipated for the full year ending December 31, 2019.

Recent Accounting Standards and Accounting Policies

Revenue Recognition

On January 1, 2019, we adopted Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (ASC 606), using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2019. We recognized the cumulative effect of the adoption as an adjustment to the opening balance of accumulated deficit in the current period condensed consolidated balance sheet. Results for reporting periods beginning after January 1, 2019 are presented under ASC 606, while prior period amounts have not been adjusted and continue to be reported in accordance with our historic accounting under ASC Topic 605, *Revenue Recognition* (ASC 605). ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

Our revenue is primarily generated through collaboration arrangements and grants from government-sponsored and private organizations. Our collaboration arrangements typically contain multiple promises, including licenses to our intellectual property, options to obtain development and commercialization rights, research and development services, and obligations to develop and manufacture preclinical and clinical material. Such arrangements provide for various types of payments to us, including upfront payments, funding of research and development activities, funding for the purchase of preclinical and clinical material, development, regulatory and commercial milestone payments, licensing fees, option exercise payments, and royalties based on product sales. We have received grants from various government-sponsored and private organizations for research and related activities that provide for payments for reimbursed costs, which may include overhead and general and administrative costs as well as a related profit margin.

We analyze our collaboration arrangements to assess whether they are within the scope of ASC Topic 808, *Collaborative Arrangements* (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 that are dependent on the commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, we assess whether aspects of the arrangement between us and our collaboration partner are within the scope of other accounting literature. If we conclude that some or all aspects of the arrangement represent a transaction with a customer, we account for those aspects of the arrangement within the scope of ASC 606. If we conclude that some or all aspects of the arrangement are within the scope of ASC 808 and do not represent a transaction with a customer, we recognize our allocation of the shared costs incurred with respect to the jointly conducted activities as a component of the related expense in the period incurred. Pursuant to ASC 606, a customer is a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. If we conclude a counter-party to a transaction is not a customer or otherwise not within the scope of ASC 606 or ASC 808, we consider the guidance in other accounting literature as applicable or by analogy to account for such transaction. We also consider the guidance in ASC 606 with respect to principal versus agent considerations, in determining the appropriate treatment for the transactions between us and the strategic collaborator and the transactions between us and other third parties. The classification of transactions under our arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Any consideration related to activities in which we are considered the principal, which includes being in control of the good or service before such good or service is transferred to the customer, are accounted for as gross revenue.

We receive payments from our customers based on billing schedules established in each contract. Upfront payments and fees are recorded as contract liabilities upon receipt or when due and may require deferral of revenue recognition to a future period when we perform our obligations under the arrangement. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current liabilities on our condensed consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as non-current liabilities on our condensed consolidated balance sheets. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less or the amount is immaterial. As of September 30, 2019, we had not capitalized any costs to obtain any of our contracts.

Collaboration Revenue

To determine the appropriate amount of revenue to be recognized for arrangements that we determine are within the scope of ASC 606, we perform the following steps: (i) identify the contract(s) with the customer; (ii) identify the performance obligations in the

contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) each performance obligation is satisfied.

We account for a contract with a customer that is within the scope of ASC 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations; (ii) each party's rights regarding the goods and/or services to be transferred can be identified; (iii) the payment terms for the goods and/or services to be transferred can be identified; (iv) the arrangement has commercial substance; and (v) collection of substantially all of the consideration to which we will be entitled in exchange for the goods and/or services that will be transferred to the customer is probable. We also determine the term of the contract based on the period in which we and our customer have present and enforceable rights and obligations for purposes of identifying the performance obligations and determining the transaction price.

We evaluate contracts that contain multiple promises to determine which promises are distinct. Promises are considered to be distinct and therefore, accounted for as separate performance obligations, provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and (ii) the promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. In assessing whether a promise is distinct, we consider factors such as whether: (i) we provide a significant service of integrating goods and/or services with other goods and/or services promised in the contract; (ii) one or more of the goods and/or services significantly modifies or customizes, or are significantly modified or customized by one or more of the other goods and/or services promised in the contract; and (iii) the goods and/or services are highly interdependent or highly interrelated. Individual goods or services (or bundles of goods and/or services) that meet both criteria for being distinct are accounted for as separate performance obligations. Promises that are not distinct at contract inception are combined and accounted for as a single performance obligation. Options to acquire additional goods and/or services are evaluated to determine if such option provides a material right to the customer that it would not have received without entering into the contract. If so, the option is accounted for as a separate performance obligation. If not, the option is considered a marketing offer which would be accounted for as a separate contract upon the customer's election.

The transaction price is generally comprised of an upfront payment due at contract inception and variable consideration in the form of payments for our services and materials and milestone payments due upon the achievement of specified events. Other payments the Company could be entitled to include tiered royalties earned when customers recognize net sales of licensed products. We consider the existence of any significant financing component within our arrangements and have determined that a significant financing component does not exist in our arrangements as substantive business purposes exist to support the payment structure other than to provide a significant benefit of financing. We measure the transaction price based on the amount of consideration we expect to be entitled in exchange for transferring the promised goods and/or services to the customer. We utilize either the expected value method or the most likely amount method to estimate the amount of variable consideration, depending on which method is expected to better predict the amount of consideration to which we will be entitled. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. With respect to arrangements that include payments for a development or regulatory milestone payment, we evaluate whether the associated event is considered probable of achievement and estimate the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within our control or the licensee, such as those dependent upon receipt of regulatory approval, are not considered to be probable of achievement until the triggering event occurs. At the end of each reporting period, we re-evaluate the probability of achievement of each milestone and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment. For arrangements that include sales-based royalties, including milestone payments based upon the achievement of a certain level of product sales, wherein the license is deemed to be the sole or predominant item to which the payments relate, we recognize revenue upon the later of: (i) when the related sales occur or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied (or partially satisfied). Consideration that would be received for optional goods and/or services is excluded from the transaction price at contract inception.

We generally allocate the transaction price to each performance obligation based on a relative standalone selling price basis. We develop assumptions that require judgment to determine the standalone selling price for each performance obligation in consideration of applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated research and development costs. However, in certain instances, we allocate variable consideration entirely to one or more performance obligation if the terms of the variable consideration relate to the satisfaction of the respective performance obligation and the amount allocated is consistent with the amount we would expect to receive for the satisfaction of the respective performance obligation.

We recognize revenue based on the amount of the transaction price that is allocated to each respective performance obligation when or as the performance obligation is satisfied by transferring a promised good or service to the customer. For performance obligations that are satisfied at a point in time, we recognize revenue when control of the goods and/or services is transferred to the customer. For performance obligations that are satisfied over time, we recognize revenue by measuring the progress toward complete satisfaction of the performance obligation using a single method of measuring progress which depicts the performance in transferring control of the associated goods and/or services to the customer. We generally use input methods to measure the progress toward the complete satisfaction of performance obligations satisfied over time. With respect to arrangements containing a license to our intellectual property that is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from amounts allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

Grant Revenue

We have contracts with the U.S. government's Defense Advanced Research Projects Agency (DARPA), Biomedical Advanced Research (BARDA), and the Bill & Melinda Gates Foundation (Gates Foundation). We recognize revenue from these contracts as we perform services under these arrangements when the funding is committed. Revenues and related expenses are presented gross in the condensed consolidated statements of operations as we have determined we are the primary obligor under the arrangements relative to the research and development services we perform as lead technical expert.

Comprehensive Loss

Comprehensive loss includes net loss and other comprehensive income (loss) for the period. Other comprehensive income (loss) consists of unrealized gains and losses on our investments. Total comprehensive loss for all periods presented has been disclosed in the condensed consolidated statements of comprehensive loss.

The components of accumulated other comprehensive income for the three and nine months ended September 30, 2019 are as follows (in thousands):

	Unrealized Gain on Available-for-Sale Debt Securities
	September 30, 2019
Accumulated other comprehensive loss, balance at December 31, 2018	\$ (1,320)
Other comprehensive income	1,911
Accumulated other comprehensive income, balance at March 31, 2019	591
Other comprehensive income	2,150
Accumulated other comprehensive income, balance at June 30, 2019	2,741
Other comprehensive income	89
Accumulated other comprehensive income, balance at September 30, 2019	\$ 2,830

Emerging Growth Company Status

We are an "emerging growth company," (EGC) as defined in the Jumpstart Our Business Startups Act, (JOBS Act), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. We may take advantage of these exemptions until we are no longer an EGC under Section 107 of the JOBS Act, which provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards, and as a result of this election, our condensed consolidated financial statements may not be comparable to companies that comply with

public company FASB standards' effective dates. As of June 30, 2019, we determined that we will become a large accelerated filer under the rules of the SEC and we will no longer be classified as an EGC as of December 31, 2019.

Recently Adopted Accounting Standards

ASU No. 2014-09, Revenue from Contracts with Customers

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes all existing revenue recognition requirements in ASC 605 and most industry specific guidance. ASC 606 provides a single comprehensive model for use in accounting for revenue arising from contracts with customers. We adopted the new revenue standard on January 1, 2019 using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2019. We recognized the cumulative effect of the adoption as an adjustment to the opening balance of accumulated deficit in the first quarter of 2019. We have elected to use the practical expedient to aggregate the impact of all contract modifications that occurred prior to the ASC 606 adoption with respect to (i) identification of the satisfied and unsatisfied performance obligations, (ii) determination of the transaction price and (iii) allocation of the transaction price to the satisfied and unsatisfied performance obligations.

ASC 606 requires significant judgment and estimates and results in changes to, but not limited to: (i) the determination of the transaction price, including estimates of variable consideration, (ii) the allocation of the transaction price, including the determination of estimated selling price, and (iii) the pattern of recognition, including the application of proportional performance as a measure of progress on service-related promises and application of point-in-time recognition for supply-related promises. We recorded the cumulative-effect adjustment of \$28.0 million to the opening balance of accumulated deficit as of January 1, 2019 with a corresponding decrease to deferred revenue. The effect of the adoption of ASC 606 on our condensed consolidated balance sheet is as follows (in thousands):

Condensed Consolidated Balance Sheet	Balance at December 31, 2018	Adjustments	Balance at January 1, 2019
Deferred revenue, current	\$ 109,056	\$ (27,281)	\$ 81,775
Deferred revenue, non-current	165,352	(3,441)	161,911
Accounts receivable	11,686	(2,738)	8,948
Accumulated deficit	(1,006,627)	27,984	(978,643)

The cumulative-effect adjustment is primarily due to the application of ASC 606 to our strategic collaboration agreements, particularly our Combined 2018 AZ Agreements, 2016 VEGF Exercise and Merck PCV/SAV Agreement (see Note 3). In addition, as a result of the cumulative decrease in deferred revenue, our corresponding deferred tax asset was decreased by \$8.4 million, which was offset by a corresponding decrease to our valuation allowance.

A substantial portion of the \$28.0 million cumulative-effect adjustment is the result of the application of ASC 606 regarding the allocation of the transaction price and the measurement of progress in satisfying performance obligations. In particular, for the Combined 2018 AZ Agreements, the adoption of ASC 606 resulted in the decrease of previously deferred revenue of \$39.9 million. For the Merck PCV/SAV Agreement, the adoption of ASC 606 resulted in a reversal of previously recognized revenue and an increase in deferred revenue of \$13.9 million. These adjustments are due to the change in the way we allocate the transaction price to each performance obligation and measure our performance under each agreement from a straight-line method to a proportional performance model. In addition, the adoption of ASC 606 resulted in the decrease of \$4.3 million of previously deferred revenue relating to the 2016 VEGF Exercise. Under ASC 605, the product option fee and the clinical milestone payment we received pursuant to the VEGF Exercise were deferred until the consideration pertaining to the clinical supply of mRNA can be reasonably estimated. Under ASC 606, we are required to estimate the total variable consideration to determine the total consideration and recognize the revenue as clinical supply is shipped to the customer based on the proportionate amount of the transaction price. As a result, the balance of remaining deferred revenues at January 1, 2019 was \$75.7 million, \$37.1 million and \$125.2 million related to the Combined 2018 AZ Agreements, 2016 VEGF Exercise and the Merck PCV/SAV Agreement, respectively.

The following tables summarize the effects of adopting ASC 606 on our condensed consolidated financial statements at September 30, 2019, and for the three and nine months ended September 30, 2019 (in thousands, except per share data):

Condensed Consolidated Balance Sheet	September 30, 2019		
	As reported under ASC 606	Adjustments	Balance without adoption of ASC 606
Deferred revenue, current	\$ 70,191	\$ (16,549)	\$ 53,642
Deferred revenue, non-current	143,438	11,259	154,697
Accumulated deficit	(1,369,548)	6,081	(1,363,467)

Condensed Consolidated Statement of Operations	Three Months Ended September 30, 2019		
	As reported under ASC 606	Adjustments	Amount without adoption of ASC 606
Revenue:			
Collaboration revenue	\$ 9,614	\$ 676	\$ 10,290
Collaboration revenue from related party	3,724	7,000	10,724
Total revenue	17,046	7,676	24,722
Loss from operations	(130,857)	7,676	(123,181)
Loss before income taxes	(123,372)	7,676	(115,696)
Net loss	(123,194)	7,676	(115,518)
Net loss per share - basic and diluted	(0.37)	0.02	(0.35)

Condensed Consolidated Statement of Operations	Nine Months Ended September 30, 2019		
	As reported under ASC 606	Adjustments	Amount without adoption of ASC 606
Revenue:			
Collaboration revenue	\$ 32,757	\$ 2,045	\$ 34,802
Collaboration revenue from related party	4,726	32,019	36,745
Total revenue	46,154	34,064	80,218
Loss from operations	(416,626)	34,064	(382,562)
Loss before income taxes	(391,431)	34,064	(357,367)
Net loss	(390,905)	34,064	(356,841)
Net loss per share - basic and diluted	(1.19)	0.11	(1.08)

ASU No. 2016-18, Statement of Cash Flows: Restricted Cash

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires the statement of cash flows to explain the change during the period in the total of cash, cash equivalents and restricted cash. When cash, cash equivalents and restricted cash are presented in more than one line item on the balance sheet, the new standard requires a reconciliation of the totals in the statement of cash flows to the related captions in the balance sheet. This reconciliation can be presented either on the face of the statement of cash flows or in the notes to the financial statements. The new standard became effective for us on January 1, 2019. As a result of adopting this new standard using a retrospective transition method for each period presented, we include our restricted cash balance in the cash, cash equivalents and restricted cash reconciliation of operating, investing and financing activities in the condensed consolidated statements of cash flows.

The following table provides a reconciliation of cash, cash equivalents and restricted cash in the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows (in thousands):

	As of September 30,	
	2019	2018
Cash and cash equivalents	\$ 173,711	\$ 167,060
Restricted cash	1,032	831
Restricted cash, non-current	10,791	11,532
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	\$ 185,534	\$ 179,423

ASU No. 2018-07, Compensation - Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting

In June 2018, the FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance generally consistent with the accounting for employee share-based compensation. The new standard will be effective for us on January 1, 2020, with early adoption permitted. We early adopted this standard in the first quarter of 2019. The adoption of this standard did not have a material impact on our condensed consolidated financial statements and disclosure.

ASU No. 2018-18, Collaborative Arrangements: Clarifying the Interaction between Topic 808 and Topic 606

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies the interaction between Topic 808 and Topic 606, *Revenue from Contracts with Customers*. Currently, Topic 808 does not provide comprehensive recognition or measurement guidance for collaborative arrangements, and the accounting for those arrangements is often based on an analogy to other accounting literature or an accounting policy election. Similarly, aspects of Topic 606 have resulted in diversity in practice on the effect of the revenue standard on the accounting for collaborative arrangements. The standard will become effective for us beginning on January 1, 2021, with early adoption permitted. We early adopted this standard in connection with the adoption of ASC 606 in the first quarter of 2019. The adoption of this standard did not have a material impact on our condensed consolidated financial statements and disclosure.

Recently Issued Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our condensed consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which supersedes all existing lease guidance. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. The new standard requires lessees to recognize an operating lease with a term greater than one year on their balance sheets as a right-of-use asset and corresponding lease liability, measured at the present value of the lease payments. Lessees are required to classify leases as either finance or operating leases. If the lease is effectively a financed-purchase by the lessee, it is classified as a financing lease, otherwise it is classified as an operating lease. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. ASC 842 provides accounting guidance for transactions that meet specific criteria for a leaseback transaction. If the criteria are not met, the transaction is considered a “failed sale” and the transaction must be accounted for as a financing arrangement. The new standard will be effective for us on December 31, 2019. Upon adoption, the new standard, as amended, allows lessees to apply the transition requirements either (1) retrospectively to each prior reporting period presented in the financial statements with the cumulative effect of applying the new rules recognized at the beginning of the earliest comparative period presented, or (2) retrospectively at the beginning of the period of adoption with the cumulative effect of applying the new rules recognized then. We plan to apply the second adoption methodology and are currently evaluating the impact of this new standard on our consolidated financial statements and disclosures. Our assessment includes, but is not limited to, evaluating the impact this standard has on the lease of our corporate headquarters at 200 Technology Square in Cambridge, MA, the lease of our office and laboratory space at 500 Technology Square, Cambridge, MA and our manufacturing and additional facilities in Norwood, MA, (see Note 7), and the identification of any embedded leases. We expect that most of our lease commitments will be subject to the new standard and recognized as lease liabilities and right-of-use assets upon adoption, which will increase our total assets and total liabilities.

In June 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments* (ASU 2016-13). ASU 2016-13 will change how companies account for credit losses for most financial assets and certain other instruments. For trade receivables, loans and held-to-maturity debt securities, companies will be required to recognize an allowance for credit losses rather than reducing the carrying value of the asset. ASU 2016-13 will be effective for us on January 1, 2020, including interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the potential impact this standard may have on our condensed consolidated financial statements and results of operations.

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Topic 350): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. This standard requires capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This standard should be applied either retrospectively or prospectively, and will be effective for us on January 1, 2020, with early adoption permitted. We are currently evaluating the potential impact this standard may have on our condensed consolidated financial statements and results of operations upon adoption.

3. Collaboration Agreements

The following table summarizes our total consolidated net revenue from our strategic collaborators for the periods presented (in thousands):

	Three Months Ended		
	September 30, 2019 as reported (under ASU 606)	September 30, 2019 without adoption of 606 (under ASC 605)	September 30, 2018 as reported (under ASC 605)
Collaboration Revenue by Strategic Collaborator:			
Merck	\$ 9,110	\$ 9,786	\$ 14,475
AstraZeneca	3,724	10,724	19,727
Vertex	504	504	2,460
Total collaboration revenue	\$ 13,338	\$ 21,014	\$ 36,662
	Nine Months Ended		
	September 30, 2019 as reported (under ASU 606)	September 30, 2019 without adoption of 606 (under ASC 605)	September 30, 2018 as reported (under ASC 605)
Collaboration Revenue by Strategic Collaborator:			
Merck	\$ 28,456	\$ 30,103	\$ 47,537
AstraZeneca	4,726	36,745	33,166
Vertex	4,301	4,699	8,993
Total collaboration revenue	\$ 37,483	\$ 71,547	\$ 89,696

The following table presents changes in the balances of our receivables and contract liabilities related to our strategic collaboration agreements during the nine months ended September 30, 2019 (in thousands):

	January 1, 2019	Additions	Deductions	September 30, 2019
Contract Assets:				
Accounts receivable	\$ 4,612	\$ 12,118	\$ (8,514)	\$ 8,216
Contract Liabilities:				
Deferred revenue	\$ 240,924	\$ 9,774	\$ (40,245)	\$ 210,453

During the three and nine months ended September 30, 2019, we recognized the following revenue as a result of the change in the contract liability balances related to our collaboration agreements (in thousands):

Revenue recognized in the period from:	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Amounts included in contract liabilities at the beginning of the period ⁽¹⁾	\$ 15,080	\$ 40,245

⁽¹⁾ We first allocate revenue to the individual contract liability balance outstanding at the beginning of the period until the revenue exceeds that balance. If additional consideration is received on those contracts in subsequent periods, we assume all revenue recognized in the reporting period first applies to the beginning contract liability.

As of September 30, 2019, the aggregated amount of the transaction price allocated to performance obligations under our collaboration agreements that are unsatisfied or partially unsatisfied was \$261.0 million.

AstraZeneca – Strategic Alliances in Cardiovascular and Oncology

2013 Option Agreement and Services and Collaboration Agreement

In March 2013, we entered into an Option Agreement, the AZ Option Agreement, and a related Services and Collaboration Agreement, the AZ Services Agreement, with AstraZeneca, which were amended and restated in June 2018. We refer to these agreements in the forms that existed prior to the 2018 amendment and restatement as the 2013 AZ Agreements. Under the 2013 AZ Agreements, we granted AstraZeneca certain exclusive rights and licenses, and options to obtain exclusive rights to develop and commercialize potential therapeutic mRNA medicines directed at certain targets for the treatment of cardiovascular and cardiometabolic diseases and cancer, and agreed to provide related services to AstraZeneca. Pursuant to the 2013 AZ Agreements, AstraZeneca was responsible for all research, development and commercialization activities, while we provided specified research and manufacturing services during a research and evaluation period, as described below, to further AstraZeneca's activities pursuant to an agreed upon services plan. Under the 2013 AZ Agreements, AstraZeneca could have requested we provide additional services, at AstraZeneca's expense. Subject to customary "back-up" supply rights granted to AstraZeneca, we exclusively manufactured (or had manufactured) mRNA for all research, development and commercialization purposes under the 2013 AZ Agreements until, on a product-by-product basis, the expiration of the time period for which we are entitled to receive earn-out payments with respect to such product pursuant to the 2013 AZ Agreements.

As of the effective date of the 2013 AZ Agreements, AstraZeneca acquired forty options that it may exercise to obtain exclusive rights to clinically develop and commercialize identified development candidates (and related back-up candidates) directed to specified targets that arise during the research and evaluation period. During the research and evaluation period for research candidates under the 2013 AZ Agreements, AstraZeneca could have elected to designate a limited number of research candidates as development candidates in order to continue preclinical development on such development candidates (and related back-up candidates). From such pool of development candidates designated by AstraZeneca, during a specified option exercise period, AstraZeneca could have then exercised one of its options to obtain exclusive rights to clinically develop and commercialize an identified development candidate (and related back-up candidates). If AstraZeneca did not exercise one of its options to acquire exclusive rights to clinically develop and commercialize a particular development candidate during the defined option exercise period for such development candidate, AstraZeneca's rights to exercise an option and other rights granted under the 2013 AZ Agreements with respect to such development candidate (and related back-up candidates) would terminate, all rights to exploit such development candidate (and related back-up candidates) would be returned to us and all data and results generated by AstraZeneca with respect to such development candidate (and related back-up candidates) would be either assigned or licensed to us. Upon the earlier of termination of the 2013 AZ Agreements for any reason and a specified anniversary of the effective date of the 2013 AZ Agreements, all unexercised options, and the right to exercise any and all options if not previously exercised by AstraZeneca, would automatically terminate. On a target-by-target basis, we and AstraZeneca agreed to certain defined exclusivity obligations under the 2013 AZ Agreements with respect to the research, development and commercialization of mRNA medicines for such target.

As of the effective date of the 2013 AZ Agreements, AstraZeneca made upfront cash payments to us totaling \$240.0 million. Under the 2013 AZ Agreements, we were entitled to receive payments that are not related to any specific program of up to \$180.0 million in the aggregate for the achievement of three technical milestones relating to toxicity, delivery, and competition criteria. We achieved the toxicity and competition milestones in the year ended December 31, 2015. The delivery milestone has expired. Under the 2013 AZ Agreements, AstraZeneca was obligated to pay us a \$10.0 million option exercise fee with respect to each development candidate (and related back-up candidates) for which it exercised an option. In addition, upon AstraZeneca's exercise of each option, we were eligible to receive certain payments contingent upon the achievement of specified clinical, regulatory, and commercial events. For any product candidate optioned by AstraZeneca, we were eligible to receive, per product candidate, up to \$100.0 million in payments for achievement of development milestones, up to \$100.0 million payments for achievement of regulatory milestones, and up to \$200.0 million payments for achievement of commercial milestones. Additionally, under the 2013 AZ Agreements, we were entitled to

receive, on a product-by-product basis, earn-out payments on worldwide net sales of products ranging from a high-single digit percentage to 12%, subject to certain reductions, with an aggregate minimum floor.

We received from AstraZeneca under the 2013 AZ Agreements an option exercise payment of \$10.0 million in the year ended December 31, 2016, and a clinical milestone payment of \$30.0 million with respect to AstraZeneca's VEGF-A product (AZD8601) during the year ended December 31, 2018, that is currently being developed in a Phase 2 clinical trial in certain fields. Unless earlier terminated, the 2013 AZ Agreements would have continued until the expiration of AstraZeneca's earn-out and contingent option exercise payment obligations for optioned product candidates. Either party had the right to terminate the 2013 AZ Agreements upon the other party's material breach, either in its entirety or in certain circumstances, with respect to relevant candidates, subject to a defined materiality threshold and specified notice and cure provisions. If AstraZeneca had the right to terminate the 2013 AZ Agreements for our material breach, then AstraZeneca could have elected, in lieu of terminating the 2013 AZ Agreements, in their entirety or with respect to such candidates, to have the 2013 AZ Agreements remain in effect, subject to reductions in certain payments we were eligible to receive and certain adjustments to AstraZeneca's obligations under the 2013 AZ Agreements. AstraZeneca had the right to terminate the 2013 AZ Agreements in full, without cause, upon 90-days' prior notice to us.

2016 Strategic Alliance with AstraZeneca – IL12

In January 2016, we entered into a new Strategic Drug Development Collaboration and License Agreement, which we refer to as the 2016 AZ Agreement, with AstraZeneca to discover, develop and commercialize potential mRNA medicines for the treatment of a range of cancers.

Under the terms of the 2016 AZ Agreement, we and AstraZeneca have agreed to work together on an immuno-oncology program focused on the intratumoral delivery of a potential mRNA medicine to make the IL12 protein. The 2016 AZ Agreement initially included research activities with respect to a second discovery program. During a limited period of time, each party had an opportunity to propose additional discovery programs to be conducted under the 2016 AZ Agreement. We are responsible for conducting and funding all discovery and preclinical development activities under the 2016 AZ Agreement in accordance with an agreed upon discovery program plan for the IL12 program and any other discovery program the parties agree to conduct under the 2016 AZ Agreement. For the IL12 program and any other discovery program the parties agree to conduct under the 2016 AZ Agreement, during a defined election period that commenced as of the effective date of the 2016 AZ Agreement (for the IL12 program) and otherwise will commence on initiation of any such new discovery program, AstraZeneca may elect to participate in the clinical development of a development candidate arising under the 2016 AZ Agreement from such program. If AstraZeneca so elects (as it has for the IL12 program), AstraZeneca will lead clinical development activities worldwide and we will be responsible for certain activities, including being solely responsible for manufacturing activities, all in accordance with an agreed upon development plan. AstraZeneca will be responsible for funding all Phase 1 clinical development activities (including costs associated with our manufacture of clinical materials in accordance with the development plan), and Phase 2 clinical development activities (including costs associated with our manufacture of clinical materials in accordance with the development plan) up to a defined dollar threshold. We and AstraZeneca will equally share the costs of Phase 2 clinical development activities in excess of such dollar threshold, all Phase 3 clinical development activities and certain other costs of late-stage clinical development activities, unless we elect not to participate in further development and commercialization activities and instead receive tiered royalties, as described below.

We and AstraZeneca will co-commercialize products in the U.S. in accordance with an agreed upon commercialization plan and budget, and on a product-by-product basis will equally share the U.S. profits or losses arising from such commercialization. Notwithstanding, on a product-by-product basis, prior to a specified stage of development of a given product, we have the right to elect not to participate in the further development and commercialization activities for such product. If we make such election, instead of participating in the U.S. profits and losses share with respect to such product, we are obligated to discuss future financial terms with AstraZeneca. If we are unable to agree on future financial terms within a short, defined period of time, we are entitled to receive tiered royalties at default rates set forth in the 2016 AZ Agreement, ranging from percentages in the mid-single digits to 20% on worldwide net sales of products, subject to certain reductions with an aggregate minimum floor. AstraZeneca has sole and exclusive responsibility for all ex-U.S. commercialization efforts. Unless we have elected to not to participate in further development (in which case royalties on ex-U.S. net sales will be at the default rates as described above, unless otherwise agreed by the parties), we are entitled to tiered royalties at rates ranging from 10% to 30% on ex-U.S. net sales of the products, subject to certain reductions with an aggregate minimum floor. Subject to customary "back-up" supply rights granted to AstraZeneca, we exclusively manufacture (or have manufactured) products for all development and commercialization purposes. We and AstraZeneca have agreed to certain defined exclusivity obligations with each other under the 2016 AZ Agreement with respect to the development and commercialization of mRNA medicines for IL12.

Unless earlier terminated, our strategic alliance under the 2016 AZ Agreement will continue on a product-by-product basis (i) until both parties cease developing and commercializing such product without the intention to resume, if we have not elected our right not to participate in further development and commercialization of such product or (ii) on a country-by-country basis, until the end of the applicable royalty term for such product in such country, if we have elected our right not to participate in further development and commercialization of such product.

Either party may terminate the 2016 AZ Agreement upon the other party's material breach, subject to specified notice and cure provisions. Each party may also terminate the 2016 AZ Agreement in the event the other party challenges such party's patent rights, subject to certain defined exceptions. AstraZeneca has the right to terminate the 2016 AZ Agreement in full or with respect to any program for scientific, technical, regulatory or commercial reasons at any time upon 90 days' prior written notice to us. On a product-by-product basis, we have the right to terminate the 2016 AZ Agreement in certain cases if AstraZeneca has suspended or is no longer proceeding with the development or commercialization of such product for a period of twelve consecutive months, subject to specified exceptions, including tolling for events outside of AstraZeneca's control. On a product-by-product basis, if the 2016 AZ Agreement is terminated with respect to a given product, AstraZeneca's rights in such product will terminate and, to the extent we terminated for AstraZeneca's breach, patent challenge or cessation of development or AstraZeneca terminated in its discretion, AstraZeneca will grant us reversion licenses and take certain other actions so as to enable us to continue developing and commercializing such product in the oncology field.

If we continue developing and commercializing a given product following termination of the 2016 AZ Agreement by AstraZeneca in its discretion with respect to such product, AstraZeneca is entitled to receive a mid-single digit royalty on our worldwide net sales of such product and a high-single digit percentage of the amounts received by us from a third party in consideration of a license to such third party to exploit such product, in each case, until AstraZeneca recovers an amount equal to specified development costs incurred by AstraZeneca under the 2016 AZ Agreement with respect to such product prior to such termination. Such percentages increase by a low to mid-single digit amount to the extent such termination occurs after such product achieves a specified stage of development.

2017 Strategic Alliance with AstraZeneca – Relaxin

In October 2017, we entered a new Collaboration and License Agreement, which we refer to as the 2017 AZ Agreement, under which AstraZeneca may clinically develop and commercialize a development candidate, now known as AZD7970, which is comprised of an mRNA construct for the relaxin protein designed by us and encapsulated in one of our proprietary lipid nanoparticles ("LNP"). We discovered and performed preclinical development activities for AZD7970 prior to the initiation of the strategic alliance with AstraZeneca under the 2017 AZ Agreement.

Under the terms of the 2017 AZ Agreement, we will fund and be responsible for conducting preclinical development activities for AZD7970 through completion of IND-enabling GLP toxicology studies and AstraZeneca will lead pharmacological studies, each in accordance with an agreed upon discovery program plan. During a defined election period that commences as of the effective date of the 2017 AZ Agreement, AstraZeneca may elect to participate in further development and commercialization of AZD7970. Upon such election, AstraZeneca will lead clinical development activities for AZD7970 worldwide and we will be responsible for manufacturing AZD7970, certain regulatory matters and any other development activities that we agree to perform and that are set forth in an agreed upon development plan. AstraZeneca will be responsible for funding Phase 1 clinical development activities (including costs associated with our manufacture of clinical materials in accordance with the development plan, up to a cap above which such costs are shared), and Phase 2 clinical development activities (including costs associated with our manufacture of clinical materials in accordance with the development plan, up to a cap above which such costs are shared) up to a defined dollar threshold. Thereafter, we and AstraZeneca will equally share the costs of Phase 2 clinical development activities in excess of such defined dollar threshold, all Phase 3 clinical development activities and certain other costs of late-stage clinical development activities, unless we elect not to participate in further development and co-commercialization activities and instead receive tiered royalties as described below. If the development candidate is determined to be IND-ready, and AstraZeneca does not timely elect to participate in the clinical development of AZD7970, AstraZeneca is obligated to reimburse us for certain costs we incurred in the manufacture and development of AZD7970, since execution of the 2017 AZ Agreement.

We and AstraZeneca will co-commercialize AZD7970 in the United States in accordance with an agreed upon commercialization plan and budget, and will equally share U.S. profits or losses arising from such commercialization. Notwithstanding, prior to a specified stage of development of AZD7970, we have the right to elect not to participate in the further development and commercialization activities for AZD7970. If we make such election, instead of participating in the U.S. profits and losses share with respect to AZD7970, we are obligated to discuss future financial terms with AstraZeneca. If we are unable to agree on future financial terms within a short, defined period of time, we are entitled to receive tiered royalties at default rates set forth in the 2017 AZ Agreement, ranging from percentages in the mid-single digits to the low 20s on worldwide net sales by AstraZeneca of AZD7970, subject to

certain reductions, with an aggregate minimum floor. AstraZeneca has sole and exclusive responsibility for all ex-U.S. commercialization efforts. Unless we have elected not to participate in further development (in which case royalties on ex-U.S. net sales will be at the default rates as described above, unless otherwise agreed by the parties), we are entitled to receive tiered royalties at rates ranging from 10% to 30% on annual ex-U.S. net sales of AZD7970, subject to certain reductions with an aggregate minimum floor. Subject to customary “back-up” supply rights granted to AstraZeneca, we exclusively manufacture (or have manufactured) products for all development and commercialization purposes. Additionally, we and AstraZeneca have agreed to certain defined exclusivity obligations under the 2017 AZ Agreement with respect to the development and commercialization of mRNA medicines for Relaxin.

Unless earlier terminated, our strategic alliance under the 2017 AZ Agreement will continue (i) until the expiration of AstraZeneca’s election period, if it does not elect to participate in the clinical development of AZD7970, (ii) until both parties cease developing and commercializing AZD7970 without the intention to resume, if we have not elected our right not to participate in further development and commercialization of AZD7970, (iii) on a country-by-country basis, until the end of the applicable royalty term for AZD7970 in such country, if we have elected our right not to participate in further development and commercialization of AZD7970 or (iv) following completion of IND-enabling studies with respect to AZD7970, if we provide AstraZeneca with written notice that we do not reasonably believe that the product is IND-ready.

Either party may terminate the 2017 AZ Agreement upon the other party’s material breach, subject to specified notice and cure provisions. Each party may also terminate the 2017 AZ Agreement in the event the other party challenges the validity or enforceability of such party’s patent rights, subject to certain defined exceptions. AstraZeneca has the right to terminate the 2017 AZ Agreement in full for scientific, technical, regulatory or commercial reasons at any time upon 90 days’ prior written notice to us. We have the right to terminate the 2017 AZ Agreement in certain cases if AstraZeneca has suspended or is no longer proceeding with the development or commercialization of AZD7970 for a period of twelve consecutive months, subject to specified exceptions, including tolling for events outside of AstraZeneca’s control. If AstraZeneca does not timely elect to participate in clinical development of AZD7970, or the Agreement is terminated, AstraZeneca’s rights in AZD7970 will terminate and, to the extent we terminated for AstraZeneca’s breach, patent challenge or cessation of development or AstraZeneca terminated in its discretion, AstraZeneca will grant us reversion licenses and take certain other actions so as to enable us to continue developing and commercializing AZD7970 in the cardiovascular and cardiometabolic fields.

If we continue developing and commercializing AZD7970 following a termination of the 2017 AZ Agreement by AstraZeneca in its discretion, AstraZeneca is entitled to receive a mid-single digit royalty on our worldwide net sales of AZD7970 and a high-single digit percentage of the amounts received by us from a third party in consideration for a license to such third party to exploit AZD7970, in each case until AstraZeneca recovers an amount equal to specified development costs incurred by AstraZeneca under the 2017 AZ Agreement with respect to AZD7970 prior to such termination. Such percentages increase by a low to mid-single digit amount to the extent such termination occurs after such product achieves a specified stage of development.

2013 Agreements with AstraZeneca, amended and restated in 2018

In June 2018, we entered into an Amended and Restated Option Agreement and a related Amended and Restated Services and Collaboration Agreement with AstraZeneca, or the 2018 A&R Agreements, which amended and restated the 2013 AZ Agreements. Under the 2018 A&R Agreements, we granted AstraZeneca certain exclusive rights and licenses to research, develop and commercialize potential therapeutic mRNA medicines directed at certain targets for the treatment of cardiovascular and cardiometabolic diseases and cancer, and agreed to provide related services to AstraZeneca. The activities to be performed by the parties under the 2018 A&R Agreements are limited to defined biological targets in the cardiovascular and cardiometabolic fields and one defined target in the cancer field.

Pursuant to the 2018 A&R Agreements, AstraZeneca is responsible for all research, development and commercialization activities and associated costs, while we provide specified research and manufacturing services during a research and evaluation period, as described below, to further AstraZeneca’s activities conducted pursuant to an agreed upon services plan. During this research and evaluation period, these research services, and manufacturing services in excess of a specified threshold, are provided at AstraZeneca’s expense, and manufacturing services below the specified threshold are provided at no additional expense to AstraZeneca. AstraZeneca may request we provide additional research and manufacturing services, at AstraZeneca’s expense, following the end of the research and evaluation period. Subject to customary “back-up” supply rights granted to AstraZeneca, we exclusively manufacture (or have manufactured) mRNA for all research, development and commercialization purposes under the 2018 A&R Agreements until, on a product-by-product basis, the expiration of the time period for which we are entitled to receive earn-out payments with respect to such product pursuant to the 2018 A&R Agreements.

As of the effective date of the 2013 AZ Agreements, and as further reflected in the 2018 A&R Agreements, AstraZeneca acquired forty options that it may exercise to obtain exclusive rights to clinically develop and commercialize identified development candidates (and related back-up candidates) directed to specified targets that arise during the research and evaluation period. During the research and evaluation period for research candidates, AstraZeneca may elect to designate a limited number of research candidates as development candidates in order to continue preclinical development on such development candidates (and related back-up candidates). From such pool of development candidates designated by AstraZeneca, during a specified option exercise period, AstraZeneca may then exercise one of its options to obtain exclusive rights to clinically develop and commercialize an identified development candidate (and related back-up candidates) in certain fields. If AstraZeneca does not exercise one of its options to acquire exclusive rights to clinically develop and commercialize a particular development candidate during the defined option exercise period for such development candidate, AstraZeneca's rights to exercise an option and other rights granted under the 2018 A&R Agreements with respect to such development candidate (and related back-up candidates) will terminate, all rights to exploit such development candidate (and related back-up candidates) will be returned to us and all data and results generated by AstraZeneca with respect to such development candidate (and related back-up candidates) will be either assigned or licensed to us. Upon the earlier of termination of the 2018 A&R Agreements for any reason and a specified anniversary of the effective date of the 2013 AZ Agreements, all unexercised options, and the right to exercise any and all options if not previously exercised by AstraZeneca, will automatically terminate.

On a target-by-target basis, we and AstraZeneca have agreed to certain defined exclusivity obligations under the 2018 A&R Agreements with respect to the research, development and commercialization of mRNA medicines for such target in certain fields. In addition, we and AstraZeneca have agreed to certain defined exclusivity obligations with respect to the research, development and commercialization of mRNA medicines coding for the same polypeptide as any development candidate being developed under the 2018 A&R Agreements.

Unless earlier terminated, the 2018 A&R Agreements will continue until the expiration of AstraZeneca's earn-out and contingent option exercise payment obligations for optioned product candidates. Either party may terminate the 2018 A&R Agreements upon the other party's material breach, either in its entirety or in certain circumstances, with respect to relevant candidates, subject to a defined materiality threshold and specified notice and cure provisions. If AstraZeneca has the right to terminate the 2018 A&R Agreements for our material breach, then AstraZeneca may elect, in lieu of terminating the 2018 A&R Agreements, in their entirety or with respect to such candidates, to have the 2018 A&R Agreements remain in effect, subject to reductions in certain payments we are eligible to receive and certain adjustments to AstraZeneca's obligations under the 2018 A&R Agreements. AstraZeneca may terminate the 2018 A&R Agreements in full, without cause, upon 90 days' prior notice to us.

Accounting Treatment

For periods prior to January 1, 2019, we applied the provisions of ASC 605 in accounting for these arrangements, except for the 2017 AZ Agreement which was accounted for under ASC 808. In August 2016, AstraZeneca exercised a product option available pursuant to the 2013 AZ Agreements to obtain exclusive rights to clinically develop and commercialize the VEGF-A product (AZD8601). This option exercise is referred to as the 2016 VEGF Exercise. Consistent with our conclusions under ASC 605 and pursuant to ASC 606, we determined that the 2016 VEGF Exercise and the 2017 AZ Agreement should be accounted for as separate transactions as the agreements are not interrelated or interdependent. Conversely, the 2013 Agreements, as amended by the 2018 A&R Agreements, and the 2016 AZ Agreement, were combined for accounting purposes and treated as a single agreement, as these agreements were negotiated in contemplation of each other. As of the date of our initial application of ASC 606, we applied the practical expedient to include the aggregate effect of all modifications to the arrangement that occurred before January 1, 2019 with respect to (i) identification of the satisfied and unsatisfied performance obligations, (ii) determination of the transaction price and (iii) allocation of the transaction price to the satisfied and unsatisfied performance obligations. Therefore, we aggregated effects of all the modifications prior to January 1, 2019 to the 2013 Agreements, including the effects of the 2018 A&R Agreements, and the 2016 AZ Agreement were combined into one transaction for accounting purposes. We will refer to this combined transaction as the Combined 2018 AZ Agreements. We determined that all aspects of Combined 2018 AZ Agreements and the 2016 VEGF Exercise represent a transaction with a customer and therefore is accounted for in accordance with ASC 606 as of the date of the initial application.

Combined 2018 AZ Agreements

We identified the following performance obligations in the Combined 2018 AZ Agreements: (i) a combined performance obligation that includes a research license, research and development pool services, and manufacturing obligations related to the 2013 AZ Agreements, as amended by the 2018 A&R Agreements, collectively referred to as the Combined 2018 AZ Agreement Performance Obligation, (ii) preclinical development services for IL12, (iii) preclinical development services for an oncology development target, (iv) a combined performance obligation for a development and commercialization license and manufacturing obligations for IL12, and

(v) a material right to receive development and commercialization rights and manufacturing services for an oncology development target.

We concluded that the research license is not distinct from the research and development pool services or the manufacturing obligations related to the 2018 A&R Agreements, as AstraZeneca cannot fully exploit the value of the research license without receipt of such services and supply. Our services and supply involve specialized expertise, particularly as it relates to mRNA technology that is not available in the marketplace. Any supply requested by AstraZeneca in excess of the minimum quantities specified in the agreement are considered customer options and treated as separate contracts for accounting purposes. Further, we concluded that AstraZeneca cannot exploit the value of the development and commercialization license for IL12 without receipt of supply as the development and commercialization license does not convey to AstraZeneca the right to manufacture and therefore combined the development and commercialization license and the manufacturing obligations for IL12 into one performance obligation.

As of January 1, 2019, the date of initial adoption of ASC 606, the total transaction price was determined to be \$400.0 million comprised of the \$240.0 million in upfront payments pertaining to the 2013 AZ Agreements and \$160.0 million of variable consideration comprised of \$40.0 million of estimated reimbursement for IL12 manufacturing obligations and \$120.0 million of milestone payments (\$60.0 million toxicity milestone and \$60.0 million competition milestone), received prior to the adoption date of ASC 606. We utilize the most likely amount method to determine the amount of reimbursement for IL12 manufacturing obligations to be received. We determined that any sales-based royalties related to IL12 will be recognized when the related sales occur as they were determined to relate predominately to the license granted and therefore have been excluded from the transaction price. In addition, we are eligible to receive future milestones and royalties on future commercial sales for optioned product candidates under the 2018 A&R Agreements and future royalties under the 2016 Agreement; however, these amounts are not considered variable consideration under the Combined 2018 Agreements as we are only eligible to receive such amounts if AstraZeneca exercises its options (including certain options that are deemed to be material rights). We have concluded that the exercise of an optioned product candidate represents a separate transaction under ASC 606. We will re-evaluate the transaction price at the end of each reporting period. There was a \$1.8 million increase to the transaction price resulting from a \$1.0 million sublicense reimbursement received in the third quarter of 2019 and a change in estimate of variable consideration of \$0.8 million during the nine months ended September 30, 2019.

The transaction price was allocated to the performance obligations based on the relative estimated standalone selling prices of each performance obligation. We developed the estimated standalone selling price for the licenses included in the Combined 2018 AZ Agreement Performance Obligation and the combined performance obligation for a development and commercialization license and manufacturing obligations for IL12 primarily based on the probability-weighted present value of expected future cash flows associated with each license related to each specific program. In developing such estimate, we also considered applicable market conditions and relevant entity-specific factors, including those factors contemplated in negotiating the agreement, probability of success and the time needed to commercialize a product candidate pursuant to the associated license. We developed the estimated standalone selling price for the services and/or manufacturing and supply included in each of the performance obligation, as applicable, primarily based on the nature of the services to be performed and/or goods to be manufactured and estimates of the associated costs, adjusted for a reasonable profit margin that would be expected to be realized under similar contracts. The estimated standalone selling price of the material right to receive development and commercialization rights and manufacturing services for an oncology development target was developed by estimating the amount of discount that AstraZeneca would receive when exercising the option and adjusting such amount by the likelihood that the option will be exercised.

As of September 30, 2019, the transaction price allocated to each performance obligation is as follows: (i) \$293.2 million to the Combined 2018 AZ Agreement Performance Obligation, (ii) \$8.1 million to the preclinical development services for IL12 performance obligation, (iii) \$8.1 million to the preclinical development services for an oncology development target performance obligation, (iv) \$90.7 million to the combined performance obligation for a development and commercialization license and manufacturing obligations for IL12, and (v) \$1.6 million to the material right to receive development and commercialization rights and manufacturing services for an oncology development target. As part of the allocation of the transaction price to each of the performance obligations, we concluded that the \$60.0 million toxicity milestone and the estimated reimbursement for IL12 manufacturing costs can be allocated entirely to specific performance obligations because the variable payment relates specifically to our effort to satisfy the performance obligation and such allocation is consistent with the allocation objectives of ASC 606.

We measure proportional performance over time using an input method based on cost incurred relative to the total estimated costs for the Combined 2018 AZ Agreement Performance Obligation and the preclinical development services for IL12 and the other oncology target performance obligations. We recognize revenue related to the amounts allocated to the combined performance obligation for a

development and commercialization license and manufacturing obligations for IL12 based on the point in time upon which control of supply is transferred to AstraZeneca for each delivery of the associated supply.

We recognize revenue for the Combined 2018 AZ Agreement Performance Obligation, on a quarterly basis, by determining the proportion of effort incurred as a percentage of total effort we expect to expend. This ratio is applied to the transaction price allocated to this combined performance obligation. We also estimate the development plan, including expected demand from AstraZeneca, and the associated costs for this combined performance obligation, as we will satisfy this combined performance obligation as the manufacturing services are performed. Management has applied significant judgment in the process of developing our budget estimates. Any changes to these estimates will be recognized in the period in which they change as a cumulative catch up.

For the three months ended September 30, 2019 and 2018, we recognized collaboration revenue of \$3.5 million and \$19.8 million, respectively, from the Combined 2018 AZ Agreements. For the nine months ended September 30, 2019 and 2018, we recognized collaboration revenue of \$4.3 million and \$33.2 million, respectively, from the Combined 2018 AZ Agreements. The revenue recognized for the three and nine months ended September 30, 2019 includes the amortization of deferred revenue due to the satisfaction of our performance obligation during the periods. As of September 30, 2019, the aggregate amount of the transaction price allocated to the remaining performance obligations that are unsatisfied is \$110.4 million. \$100.7 million is expected to be recognized as revenue through December 31, 2027 and \$9.7 million is expected to be recognized as revenue at the earlier of expiration or modification of the Combined 2018 AZ Agreement. We had deferred revenue of \$73.7 million and \$115.6 million as of September 30, 2019 and December 31, 2018, respectively, from the Combined 2018 AZ Agreements, which is classified as current or non-current in the condensed consolidated balance sheets based on the period the services are expected to be performed or control of the supply is expected to be transferred.

2016 VEGF Exercise

We concluded that the 2016 VEGF Exercise should be treated as a separate transaction for accounting purposes. We identified one performance obligation in this arrangement which is comprised of the exclusive license to develop and commercialize VEGF and the manufacturing of clinical supply. We concluded that the VEGF license is not distinct from the manufacturing obligations because AstraZeneca cannot fully exploit the value of the license without receipt of such supply. This is due to limitations inherent in the licenses conveyed wherein AstraZeneca does not have the contractual right to manufacture during the term of the agreement.

As of January 1, 2019, the date of initial adoption of ASC 606, the total transaction price was determined to be \$55.1 million comprised of the \$40.0 million in fixed payments pertaining to a \$10.0 million option exercise fee and a \$30.0 million milestone achieved prior to the adoption of ASC 606 and \$15.1 million of variable consideration related to the estimated reimbursement for clinical supply. We are eligible to receive future milestones and royalties on future commercial sales under this arrangement. We utilize the most likely amount method to estimate any development and regulatory milestone payments to be received and the amount of estimated reimbursement for clinical supply. As of January 1, 2019, there were no milestones that had not been achieved included in the transaction price. We considered the stage of development and the risks associated with the remaining development required to achieve each milestone, as well as whether the achievement of the milestone is outside of our or AstraZeneca's control. The outstanding milestone payments were fully constrained, as a result of the uncertainty whether any of the milestones would be achieved. We determined that any commercial milestones and sales-based royalties will be recognized when the related sales occur as they were determined to relate predominantly to the license granted and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur. When a milestone payment is included in the transaction price in the future, it will be recognized as revenue based on the relative completion of the underlying performance obligation. There was a \$2.5 million increase to the transaction price resulting from a \$2.0 million sublicense reimbursement received in the third quarter of 2019, and a change in estimate of variable consideration of \$0.5 million during the nine months ended September 30, 2019.

We recognize revenue related to the amount of the transaction price allocated to the VEGF Exercise performance obligation based on the point in time upon which control of supply is transferred to AstraZeneca for each delivery of the associated supply.

Our collaboration revenue from the 2016 VEGF Exercise for both the three and nine months ended September 30, 2019 was immaterial. We did not recognize any collaboration revenue from the 2016 VEGF Exercise for the three or nine months ended September 30, 2018. As of September 30, 2019, the aggregate amount of the transaction price allocated to the remaining performance obligation that is unsatisfied is \$53.4 million, which is expected to be recognized as revenue through December 31, 2023. We had deferred revenue of \$41.2 million as of September 30, 2019 and December 31, 2018, from the 2016 VEGF Exercise, which is classified as current or non-current in the condensed consolidated balance sheets based on the period the control of the supply is expected to be transferred.

2017 AZ Agreement

We concluded the 2017 AZ Agreement is under the scope of ASC 808 as we and AstraZeneca are both active participants in the development, manufacturing and commercialization activities and are exposed to significant risks and rewards that are dependent on commercial success of the activities of the arrangement. Additionally, we determined the development, manufacturing and commercialization activities are not deliverables under ASC 606. As a result, the activities conducted pursuant to the development, manufacturing and commercialization activities are accounted for as a component of the related expense in the period incurred. We considered the guidance in ASC 606 by analogy in determining the appropriate treatment for the transactions between us and AstraZeneca and concluded that reimbursement for transactions in which we are considered to be principal because we control a promised good or service before transferring that good or service to the customer, are accounted for as gross revenue.

We did not recognize any revenue from the 2017 AZ Agreement for the three or nine months ended September 30, 2019 and 2018, respectively.

Merck – Strategic Alliances in Infectious Diseases and Cancer Vaccines

2015 Strategic Alliance with Merck – Infectious Disease

In January 2015, we entered into a Master Collaboration and License Agreement with Merck, which was amended in January 2016, June 2016, and May 2019, and which we refer to, as amended, as the 2015 Merck Agreement. Pursuant to the 2015 Merck Agreement, we and Merck have agreed to research, develop, and commercialize potential mRNA medicines for the prevention of infections by RSV. Pursuant to the 2015 Merck Agreement, Merck is primarily responsible for research, development, and commercialization activities and associated costs of such research and commercialization. We are responsible for designing and manufacturing all mRNA constructs for preclinical and Phase 1 and Phase 2 clinical development purposes, and Merck pays us for such manufacture, and we are responsible for certain costs associated with the conduct of a Phase 1 clinical trial for a RSV vaccine product candidate (mRNA-1172). Responsibility for manufacturing mRNA constructs for late stage clinical development and commercialization purposes is to be determined.

The 2015 Merck Agreement includes a three-year period, expected to end on January 12, 2022, during which Merck may continue to preclinically and clinically develop RSV vaccine product candidates that arose during an initial four-year research period which terminated in January 2019. Merck may, prior to the end of this three-year period, elect to exclusively develop and commercialize up to five RSV vaccine product candidates.

We and Merck have agreed to certain defined exclusivity obligations during the term of the 2015 Merck Agreement with respect to potential mRNA medicines against RSV infection. As part of the May 2019 amendment of the 2015 Merck Agreement, these exclusivity obligations do not restrict Moderna from researching, developing, and commercializing a potential mRNA medicine for the prevention of a specific set of respiratory infections, including RSV, for the pediatric population.

Under the terms of the 2015 Merck Agreement, we received a \$50.0 million upfront payment. We are eligible to receive, on a product-by-product basis, up to \$300.0 million in aggregate milestone payments upon the achievement of certain development, regulatory, and commercial milestone events. To date, we have received from Merck a clinical milestone payment of \$5.0 million with respect to the initiation of a Phase 1 clinical trial for a Merck RSV vaccine product candidate. In addition, under the terms of the 2015 Merck Agreement, we are eligible to receive an additional milestone payment unless Merck elects not to continue with further clinical development of mRNA-1172. On a product-by-product basis, we are also entitled to receive royalties on Merck's net sales of products at rates ranging from the mid-single digits to low teens, subject to certain reductions, with an aggregate minimum floor. Additionally, concurrent with entering into the 2015 Merck Agreement in 2015, Merck made a \$50.0 million equity investment in us, and concurrent with amending the 2015 Merck Agreement in January 2016, we received an upfront payment of \$10.0 million from Merck.

Unless earlier terminated, the 2015 Merck Agreement will continue on a product-by-product and country-by-country basis for so long as royalties are payable by Merck on a given product in a given country. Either party may terminate the 2015 Merck Agreement upon the other party's material breach, either in its entirety or with respect to a particular program, product candidate, product or country, subject to specified notice and cure provisions. Merck may terminate the 2015 Merck Agreement in full or with respect to a particular product candidate or product upon certain advance notice to us for any reason, or earlier if Merck determines the alliance or product is no longer commercially practicable. If Merck has the right to terminate the 2015 Merck Agreement, in its entirety or with respect to a program, product candidate or product, for our material breach, then Merck may elect, in lieu of terminating the 2015 Merck Agreement, to have the 2015 Merck Agreement remain in effect, subject to reductions in certain payments we are eligible to receive.

with respect to the terminable rights. Upon a termination of the 2015 Merck Agreement with respect to a program, all licenses and other rights granted to Merck with respect to such program will terminate and the continued development and commercialization of product candidates and products will revert to us. If the 2015 Merck Agreement is terminated with respect to a given product candidate or product, all licenses and other rights granted to Merck with respect to such product candidate or product will terminate and, to the extent we terminated for Merck's breach, Merck will grant us licenses under select Merck technology for our continued development and commercialization of such product candidate or product. As a part of the May 2019 amendment of the 2015 Merck Agreement, we and Merck agreed to conclude the collaboration as it relates to development of potential mRNA medicines for other viruses, including mRNA-1278 for the prevention of VZV infection.

Accounting Treatment

For periods prior to January 1, 2019, we applied the provisions of ASC 605 in accounting for this arrangement. As of the date of our initial application of ASC 606, we applied the practical expedient to include the aggregate effect of all modifications to the arrangement that occurred before January 1, 2019 with respect to (i) identification of the satisfied and unsatisfied performance obligations, (ii) determination of the transaction price and (iii) allocation of the transaction price to the satisfied and unsatisfied performance obligations. Additionally, we determined that all aspects of amended 2015 Merck Agreement represent a transaction with a customer and therefore the amended 2015 Merck Agreement is accounted for in accordance with ASC 606 as of the date of the initial application. As of the date of initial adoption of ASC 606, the four-year research period was substantially complete and we concluded there were no unsatisfied performance obligations pertaining to the amended 2015 Merck Agreement. Additionally, we concluded the following customer options are marketing offers as such options did not provide any discounts or other rights that would be considered a material right in the arrangement: (i) research services during the three-year period following the initial four-year research period during which Merck may continue to preclinically and clinically develop product candidates and (ii) clinical mRNA supply for Phase 1 and Phase 2 and/or non-cGMP mRNA supply beyond the initial four-year research period. Therefore, such options will be accounted for as a separate contract upon the customer's election. After completion of the initial four-year research period, and as part of the May 2019 amendment of the 2015 Merck Agreement, Merck elected to establish a new RSV vaccine product candidate and elected to conduct a Phase 1 clinical trial. We are responsible for certain costs associated with the conduct of the Phase 1 clinical trial.

As of January 1, 2019, the date of initial application of ASC 606, the total transaction price of \$65.0 million comprised the \$60.0 million in aggregate upfront payments, including \$50.0 million related to research and development funding plus a \$10.0 million funding from the 2016 amendment of the 2015 Merck Agreement, and a \$5.0 million payment pertaining to achievement of a development milestone during the year ended December 31, 2017, which had been allocated entirely to the satisfied performance obligation and recognized in full. We utilize the most likely amount method to estimate any development and regulatory milestone payments to be received. As of January 1, 2019, there were no milestones that had not been achieved included in the transaction price. We considered the stage of development and the risks associated with the remaining development required to achieve each milestone, as well as whether the achievement of the milestone is outside of our or Merck's control. The outstanding milestone payments were fully constrained, as a result of the uncertainty whether any of the milestones would be achieved. We determined that any commercial milestones and sales-based royalties will be recognized when the related sales occur as they were determined to relate predominantly to the license granted and therefore have also been excluded from the transaction price. When a milestone payment is included in the transaction price in the future, it will be recognized as revenue based on the relative completion of the underlying performance obligation. We determined that our obligation under the May 2019 amendment to reimburse Merck for certain costs associated with the RSV vaccine Phase 1 clinical trial represents consideration payable to a customer and is accounted for as a reduction of the transaction price. The consideration amount is determined based on the most likely method and recorded as contra-revenue as costs are incurred. The one-time payment upon election by Merck to continue developing RSV is fully constrained as it is contingent upon completion of the RSV Phase 1 clinical trial and upon decisions to be made by Merck to continue development thereafter. We will re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur. For the nine months ended September 30, 2019, there was a \$3.8 million decrease to the transaction price related to reimbursements paid to Merck for RSV vaccine Phase I clinical trial costs.

We had no deferred revenue as of September 30, 2019 or December 31, 2018 from the amended Merck 2015 Agreement as all performance obligations under the amended 2015 Merck Agreement were completed. For the three and nine months ended September 30, 2018, we recognized collaboration revenue of \$3.9 million and \$16.6 million, respectively, from the amended 2015 Merck Agreement.

Additionally, we recognized contra-revenue of \$1.8 million and \$3.1 million for the three and nine months ended September 30, 2019, respectively, related to consideration payable to Merck under the May 2019 Amendment and collaboration revenue earned pursuant to separate agreements with Merck related to the exercise of customer options to purchase clinical mRNA supply to further develop a

product candidate after the initial four-year research period. Clinical mRNA supply is recognized as collaboration revenue at a point in time upon which control of supply is transferred to Merck for each delivery of the associated supply.

2016 Cancer Vaccine Strategic Alliance—Personalized mRNA Cancer Vaccines

In June 2016, we entered into a personalized mRNA cancer vaccines (PCV) Collaboration and License Agreement with Merck Sharp & Dohme Corp., or Merck, which we refer to as the PCV Agreement, to develop and commercialize PCVs for individual patients using our mRNA vaccine and formulation technology. Under the strategic alliance, we identify genetic mutations present in a particular patient's tumor cells, synthesize mRNA for these mutations, encapsulate the mRNA in one of our proprietary LNPs and administer to each patient a unique mRNA cancer vaccine designed to specifically activate the patient's immune system against her or his own cancer cells.

Pursuant to the PCV Agreement, we are responsible for designing and researching PCVs, providing manufacturing capacity and manufacturing PCVs, and conducting Phase 1 and Phase 2 clinical trials for PCVs, alone and in combination with KEYTRUDA (pembrolizumab), Merck's anti-PD-1 therapy, all in accordance with an agreed upon development plan and budget and under the oversight of a committee comprised of equal representatives of each party. The parties have entered into a clinical quality agreement with respect to Moderna's manufacture and supply activities. We received an upfront payment of \$200.0 million from Merck. In November 2017, we and Merck announced the achievement of a key milestone for the first-in-human dosing of a PCV (mRNA-4157) as a part of the alliance. The Phase 1 open-label, dose escalation, multicenter clinical trial in the United States (KEYNOTE-603) is designed to assess the safety, tolerability and immunogenicity of mRNA-4157 alone in subjects with resected solid tumors and in combination with KEYTRUDA, in subjects with unresectable solid tumors.

Until the expiration of a defined period of time following our completion of Phase 1 and Phase 2 clinical trials for PCVs under the PCV Agreement and delivery of an associated data package to Merck, Merck has the right to elect to participate in future development and commercialization of PCVs by making a \$250.0 million participation payment to us. If Merck exercises its election and pays the participation payment, then the parties will equally co-fund subsequent clinical development of PCVs, with Merck primarily responsible for conducting clinical development activities under a jointly agreed development plan and budget. Each party may also conduct additional clinical trials for PCVs that are not included in the jointly agreed development plan and budget, in which case the non-conducting party will reimburse the conducting party for half of the total costs for such trials, plus interest, from its share of future profits resulting from sales of such PCVs, if any. Merck will lead worldwide commercialization of PCVs, subject to Moderna's option to co-promote PCVs in the United States, and the parties will equally share the profits or losses arising from worldwide commercialization. Until a PCV becomes profitable, we may elect to defer payment of our share of the commercialization and related manufacturing costs and instead reimburse Merck for such costs, plus interest, from our share of future profits resulting from sales of such PCV, if any. Subject to customary "back-up" supply rights granted to Merck, we will manufacture (or have manufactured) PCVs for preclinical and clinical purposes. Manufacture of PCVs for commercial purposes will be determined by the parties in accordance with the terms of the PCV Agreement. Under the PCV Agreement, we grant certain licenses to Merck to perform its collaboration activities.

If Merck does not exercise its right to participate in future development and commercialization of PCVs, then Moderna will retain the exclusive right to develop and commercialize PCVs developed during the strategic alliance, subject to Merck's rights to receive a percentage in the high teens to the low 20s, subject to reductions of our net profits on sales of such PCVs. During a limited period following such non-exercise, Merck has the right to perform clinical studies of such PCVs in combination with KEYTRUDA, for which we agree to use reasonable efforts to supply such PCVs. During such limited period, we also have the right to perform clinical studies of PCVs in combination with KEYTRUDA, for which Merck agrees to use reasonable efforts to supply KEYTRUDA. In addition, following its non-exercise, Merck is also entitled to receive a percentage in the high teens to the low 20s, subject to reductions, of our net profits on sales of certain PCVs first developed by us following such non-exercise and reaching a specified development stage within a defined period of time.

We and Merck have agreed to certain defined, limited exclusivity obligations with respect to the development and commercialization of PCVs.

2018 Expansion of the Cancer Vaccine Strategic Alliance—Shared Neoepitope Cancer Vaccines

In April 2018, we and Merck agreed to expand our cancer vaccine strategic alliance to include the development and commercialization of our KRAS vaccine development candidate, mRNA-5671 or V941, and potentially other shared neoantigen mRNA cancer vaccines (SAVs). We preclinically developed mRNA-5671 prior to its inclusion in the cancer vaccine strategic alliance and it is comprised of a

novel mRNA construct designed by us and encapsulated in one of our proprietary LNPs. The PCV Agreement was amended and restated to include the new SAV strategic alliance (PCV/SAV Agreement).

We have granted Merck certain licenses and we and Merck have agreed to certain exclusivity obligations with respect to SAVs and particular SAV programs, which obligations are subject to termination or expiration upon certain triggering events. Under the PCV/SAV Agreement, Merck will be responsible for conducting Phase 1 and Phase 2 clinical trials for mRNA-5671 and for all costs associated with such activities, in accordance with a jointly agreed development plan and budget, and we will be responsible for manufacturing and supplying all mRNA-5671 required to conduct such trials and for all costs and expenses associated with such manufacture and supply. Under the PCV/SAV Agreement, our budgeted commitment for PCV increased to \$243.0 million. Until the expiration of a defined period of time following the completion of Phase 1 and Phase 2 clinical trials for mRNA-5671 under the PCV/SAV Agreement and our delivery of an associated data package to Merck, Merck has the right to elect to participate in future development and commercialization of mRNA-5671 by making a participation payment to us. If Merck exercises its participation rights, then the parties will equally co-fund subsequent clinical development of mRNA-5671, with Merck primarily responsible for conducting clinical development activities under a jointly agreed development plan and budget. If Merck declines to participate in future development and commercialization activities following the initial Phase 1 and Phase 2 clinical trials for mRNA-5671, then we will retain the rights to develop and commercialize mRNA-5671. If Merck elects to participate in future development and commercialization of mRNA-5671, Merck may also conduct additional clinical trials for mRNA-5671 that are not included in the jointly agreed development plan and budget, in which case we will reimburse Merck for half of the total development costs for such clinical trials, plus interest, from our share of future profits resulting from sales of mRNA-5671, if any. If Merck does conduct additional clinical trials for mRNA-5671, we will be responsible for manufacturing and supplying all mRNA-5671 required to conduct such trials. Merck will lead worldwide commercialization of mRNA-5671, subject to our option to co-promote mRNA-5671 in the United States, and the parties will equally share the operating profits or losses arising from worldwide commercialization. Until mRNA-5671 becomes profitable, we may elect to defer payment of our share of the commercialization and related manufacturing costs and instead reimburse Merck for such costs, plus interest, from our share of future profits resulting from sales of mRNA-5671, if any. Subject to “back-up” supply rights granted to Merck, we will manufacture (or have manufactured) mRNA-5671 and other SAVs for preclinical and clinical purposes. After Merck exercises its right to participate in future development and commercialization of mRNA-5671 and other SAVs, we will grant the applicable development and commercialization licenses and the parties are obligated to discuss responsibility for future manufacturing, giving consideration to applicable criteria.

Pursuant to the PCV/SAV Agreement, for a defined period of time, either party may propose that the parties conduct additional programs for the research and development of SAVs directed to different shared neoantigens. If the parties agree to conduct any such programs, then we will be responsible for conducting and funding preclinical discovery and research activities for such SAVs, and otherwise the programs would be conducted on substantially the same terms as mRNA-5671 program. If we or Merck propose a new SAV program and the other party does not agree to conduct such program, then the PCV/SAV Agreement includes provisions allowing the proposing party to proceed with such development, at the proposing party’s expense. If Merck is the proposing party, we will be responsible for manufacturing and supplying material for such program at Merck’s expense. In such case, the non-proposing party will have the right to opt-in to such SAV program any time before the proposing party commits to performing Good Laboratory Practice (GLP)-toxicity studies. Until the expiration of a defined period of time following our completion of Phase 1 and Phase 2 clinical trials for any SAV program mutually agreed by the parties under the PCV/SAV Agreement and our delivery of an associated data package to Merck, Merck has the right to elect to participate in future development and commercialization of such SAV by making a participation payment to us.

Unless earlier terminated, the PCV/SAV Agreement will continue on a program-by-program basis until Merck terminates its participation in such program. Following any such termination, we will retain the exclusive right to develop and commercialize PCVs or SAVs developed as a part of such program, subject to restrictions and certain limited rights retained by Merck.

In connection with the amendment of the PCV Agreement to include the development and commercialization of mRNA-5671 and potentially other SAVs, Merck made a contemporaneous equity investment in our Series H redeemable convertible preferred stock, resulting in gross proceeds of \$125.0 million, of which \$13.0 million is determined to be a premium and recorded to deferred revenue.

Accounting Treatment

We determined that the PCV/SAV Agreement should be accounted for separately from the amended 2015 Merck Agreement, as the agreements were not negotiated in contemplation of one another and the elements within each of the agreements are not closely interrelated or interdependent on each other.

For periods prior to January 1, 2019, we applied the provisions of ASC 605 in accounting for this arrangement. As of the date of our initial application of ASC 606, we applied the practical expedient to include the aggregate effect of all modifications to the arrangement that occurred before January 1, 2019 with respect to: (i) identification of the satisfied and unsatisfied performance obligations, (ii) determination of the transaction price and (iii) allocation of the transaction price to the satisfied and unsatisfied performance obligations. Additionally, we determined that all aspects of the PCV/SAV Agreement represent a transaction with a customer and therefore the PCV/SAV Agreement is accounted for in accordance with ASC 606 as of the date of the initial application. Further, the equity investment in our Series H redeemable convertible preferred stock was considered together with the PCV/SAV Agreement as the transactions were executed contemporaneously in contemplation of one another. Further, the purchase price paid by Merck with respect to the investment in the Series H redeemable convertible preferred stock was not representative of fair value on the date of such purchase. As such, the incremental proceeds received in excess of the fair value of the underlying stock related to the equity investment were included in the transaction price related to the PCV/SAV Agreement and the shares of Series H redeemable convertible preferred stock purchased by Merck were recorded at their respective fair value on the date of issuance.

We identified the following performance obligations in the PCV/SAV Agreement: (i) a research license and research and development services, including manufacturing and supply of PCVs, during the proof of concept (POC) term for the PCV program, referred to as the PCV Performance Obligation, and (ii) research license and manufacturing and supply of mRNA-5671 during the POC term for the KRAS program, referred to as the KRAS Performance Obligation. We concluded that the research license is not distinct from the research and development services, including manufacturing and supply of PCVs, during the POC term for the PCV program, as Merck cannot fully exploit the value of the license without receipt of such services and supply. Our services and supply involve specialized expertise, particularly as it relates to mRNA technology that is not available in the marketplace. Therefore, the research license has been combined with the research and development services, including manufacturing and supply of PCVs, during the POC term for the PCV program, into a single performance obligation. Similarly, we concluded that the research license is not distinct from the manufacturing and supply of mRNA-5671 during the POC term for the KRAS program, as Merck cannot fully exploit the value of the license without receipt of such supply which must be provided by us. This is due to limitations inherent in the licenses conveyed wherein Merck does not have the contractual right to manufacture during the POC term. Therefore, the research license has been combined with the manufacturing and supply of mRNA-5671, during the POC term for the KRAS program, into a single performance obligation. Conversely, we concluded that the PCV Performance Obligation and the KRAS Performance Obligation are distinct from each other because Merck can fully exploit the value of each program for its intended purpose without the promises associated with the other program. Additionally, we concluded the following customer options are marketing offers as such options did not provide any discounts or other rights that would be considered a material right in the arrangement: (i) Merck participation election license related to future joint development and commercialization on a program-by-program basis, (ii) manufacturing and supply in support of certain SAV programs and/or the PCV program upon Merck election to not participate in future development and commercialization of that program and (iii) research and development services associated with certain SAV programs. Therefore, such options will be accounted for as a separate contract upon the customer's election.

As of January 1, 2019, the date of initial application of ASC 606, the total transaction price was determined to be \$213.0 million comprised of the \$200.0 million upfront payment pertaining to the PCV Agreement and the premium associated with the contemporaneous sale of Series H redeemable convertible preferred stock of \$13.0 million. We determined there are no components of variable consideration that should be included in the transaction price as of the date of initial application, as additional consideration to which we could be entitled is subject to Merck's election to exercise a customer option that was deemed to be a marketing offer. We will re-evaluate the transaction price at the end of each reporting period. There were no changes to the transaction price during the nine months ended September 30, 2019.

The transaction price was allocated to the performance obligations based on the relative estimated standalone selling price of each performance obligation. We developed the estimated standalone selling price for the license included in each of the PCV Performance Obligation and the KRAS Performance Obligation primarily based on the probability-weighted present value of expected future cash flows associated with each license related to each specific program. In developing such estimate, we also considered applicable market conditions and relevant entity-specific factors, including those factors contemplated in negotiating the agreement, probability of success and the time needed to commercialize a product candidate pursuant to the associated license. We developed the estimated standalone selling price for the services and/or manufacturing and supply included in each of the PCV Performance Obligation and the KRAS Performance Obligation, as applicable, primarily based on the nature of the services to be performed and/or goods to be manufactured and estimates of the associated cost, adjusted for a reasonable profit margin that would be expected to be realized under similar contracts.

As of September 30, 2019, the transaction price allocated to each performance obligation is as follows: (i) \$206.3 million to the PCV Performance Obligation and (ii) \$6.7 million allocated to the KRAS Performance Obligation. We will recognize revenue related to amounts allocated to the PCV Performance Obligation over time as the underlying services are performed using a proportional

performance model. We measure proportional performance using an input method based on the costs incurred relative to the total estimated costs of research and development efforts. We recognize revenue related to the amounts allocated to the KRAS Performance Obligation based on the point in time upon which control of supply is transferred to Merck for each delivery of the associated supply.

For the three months ended September 30, 2019 and 2018, we recognized collaboration revenue of \$10.9 million and \$10.6 million, respectively, in the condensed consolidated statements of operations, from the Merck PCV/SAV Agreement. For the nine months ended September 30, 2019 and 2018, we recognized collaboration revenue of \$31.6 million and \$30.9 million, respectively, in the condensed consolidated statements of operations, from the Merck PCV/SAV Agreement. The revenue recognized during the three and nine months ended September 30, 2019 includes the amortization of deferred revenue due to the satisfaction of our performance during the periods. As of September 30, 2019, the aggregate amount of the transaction price allocated to the remaining performance obligations that are unsatisfied is \$93.6 million, which is expected to be recognized as revenue through December 31, 2021. We had deferred revenue of \$93.6 million and \$111.3 million, as of September 30, 2019 and December 31, 2018, respectively, from the Merck PCV/SAV Agreement, which is classified as current or non-current in the condensed consolidated balance sheets based on the period the services are expected to be performed or control of the supply is expected to be transferred.

Vertex – 2016 Strategic Alliance in Cystic Fibrosis

In July 2016, we entered into a Strategic Collaboration and License Agreement, with Vertex Pharmaceuticals Incorporated, and Vertex Pharmaceuticals (Europe) Limited, together, Vertex, which we refer to as the Vertex Agreement. The Vertex Agreement, which was amended in July 2019, which we refer to as the 2019 Vertex Amendment, is aimed at the discovery and development of potential mRNA medicines for the treatment of cystic fibrosis (CF) by enabling cells in the lungs of people with CF to produce functional CFTR proteins.

Pursuant to the Vertex Agreement, we lead discovery efforts during an initial research period that currently extends until February 2020, leveraging our Platform technology and mRNA delivery expertise along with Vertex's scientific experience in CF biology and the functional understanding of CFTR. Vertex is responsible for conducting development and commercialization activities for candidates and products that arise from the strategic alliance, including the costs associated with such activities. Subject to customary "back-up" supply rights granted to Vertex, we exclusively manufacture (or have manufactured) mRNA for preclinical, clinical and commercialization purposes. The parties established a joint steering committee to oversee and coordinate activities under the Vertex Agreement. We and Vertex have granted each other certain licenses under the Vertex Agreement.

Under the terms of the Vertex Agreement, we received a \$20.0 million upfront payment from Vertex. In July 2019, Vertex elected to extend the initial three-year research period by six months by making a \$2.0 million payment to us pursuant to the 2019 Vertex Amendment. Vertex has the right to extend the initial research period for an additional 18-month period by making an additional payment to us. Vertex has rights to further extend the research period for two additional one-year periods by making an additional payment to us for each one-year extension. We are eligible to receive up to \$55.0 million in payments for achievement of development milestones, up to \$220.0 million in payments for achievement of regulatory milestones and potentially could receive an additional \$3.0 million milestone payment for achievement of a regulatory milestone for second and each subsequent product under the Vertex Agreement. Vertex will also pay us tiered royalties at rates ranging from the low- to high-teens on worldwide net sales of products arising from the strategic alliance, subject to certain reductions, with an aggregate minimum floor. In connection with the strategic alliance, Vertex also made a \$20.0 million equity investment in our Series F redeemable convertible preferred stock. During the term of the Vertex Agreement, we and Vertex have agreed to certain defined exclusivity obligations under the Vertex Agreement with respect to the development and commercialization of certain mRNA medicines.

Unless earlier terminated, the Vertex Agreement will continue until the expiration of all royalty terms. Vertex may terminate the Vertex Agreement for convenience upon 90 days' prior written notice, except if termination relates to a product in a country where Vertex has received marketing approval, which, in such case, Vertex must provide 180 days' prior written notice. Either party may terminate the Vertex Agreement upon the other party's material breach, subject to specified notice and cure provisions. Each party may also terminate the Vertex Agreement in the event that the other party challenges the validity or enforceability of such party's patent rights, subject to certain exceptions, or if the other party becomes insolvent.

Accounting Treatment

For periods prior to January 1, 2019, we applied the provisions of ASC 605 in accounting for this arrangement. As of the date of the initial application of ASC 606, we determined that all aspects of the arrangement with Vertex represent a transaction with a customer and therefore should be accounted for in accordance with ASC 606. We identified one performance obligation comprised of: (i) a research, development and commercialization license and (ii) research and development services, including manufacturing and

supply of non-cGMP mRNA, during the initial three-year research period. We concluded that the license is not distinct from the research and development services, including manufacturing and supply of non-cGMP mRNA, during the initial three-year research period, as Vertex cannot fully exploit the value of the license without receipt of such services and supply. Our services and supply involve specialized expertise, particularly as it relates to mRNA technology that is not available in the marketplace. Therefore, the license has been combined with the research and development services, including manufacturing and supply of non-cGMP supply, into a single performance obligation. Additionally, we concluded the following customer options are marketing offers as such options did not provide any discounts or other rights that would be considered a material right in the arrangement: (i) Vertex's right to extend the research period for an additional year and (ii) clinical mRNA supply and/or non-cGMP mRNA supply beyond the initial three-year research period. Therefore, such options will be accounted for as a separate contract upon the customer's election.

As of January 1, 2019, the date of initial application of ASC 606, the total transaction price was determined to be \$24.4 million, comprised of the \$20.0 million upfront payment and \$4.4 million in research and development funding related to the research and development services and supply of non-cGMP mRNA. We utilize the most likely amount method to determine the amount of research and development funding to be received. We also utilize the most likely amount method to estimate any development and regulatory milestone payments to be received. As of January 1, 2019, there were no milestones included in the transaction price. We considered the stage of development and the risks associated with the remaining development required to achieve each milestone, as well as whether the achievement of the milestone is outside of our or Vertex's control. The outstanding milestone payments were fully constrained, as a result of the uncertainty whether any of the milestones would be achieved. We determined that any sales-based royalties will be recognized when the related sales occur as they were determined to relate predominantly to the license granted and therefore have also been excluded from the transaction price.

As of June 30, 2019, all performance obligations under the Vertex Agreement were completed. The 2019 Vertex Amendment represents a contract modification and is accounted for as a separate contract. Pursuant to the 2019 Vertex Amendment, we identified one performance obligation comprised of: (i) a research, development and commercialization license and (ii) research and development services, including manufacturing and supply of non-cGMP mRNA, during the extended six-month initial research period. We concluded that the license is not distinct from the research and development services, including manufacturing and supply of non-cGMP mRNA. Additionally, we concluded the following customer options are marketing offers as such options did not provide any discounts or other rights that would be considered a material right in the arrangement: (i) Vertex's rights to extend the extended initial research period and (ii) clinical mRNA supply and/or non-cGMP mRNA supply beyond the extended initial research period. Therefore, such options will be accounted for as a separate contract upon the customer's election. The total transaction price was determined to be \$4.1 million, comprised of the \$2.0 million upfront payment and \$2.1 million in research and development funding related to the research and development services and supply of non-cGMP mRNA. We utilize the most likely amount method to determine the amount of research and development funding to be received. As of September 30, 2019, there were no milestones included in the transaction price. We will re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur.

For each of the Vertex Agreement and the 2019 Vertex Amendment, the total transaction price was allocated entirely to a single performance obligation. We recognize revenue related to amounts allocated to the single performance obligation over time as the underlying services are performed using a proportional performance model. We measure proportional performance using an input method based on the costs incurred relative to the total estimated costs of the research and development efforts.

For the three months ended September 30, 2019 and 2018, we recognized collaboration revenue of \$0.5 million and \$2.5 million, respectively, in the condensed consolidated statements of operations, from Vertex. For the nine months ended September 30, 2019 and 2018, we recognized collaboration revenue of \$4.3 million and \$9.0 million, respectively, in the condensed consolidated statements of operations, from Vertex. The revenue recognized during the three and nine months ended September 30, 2019 includes the amortization of the deferred revenue due to the satisfaction of our performance during the periods. As of September 30, 2019, the aggregate amount of the transaction price allocated to the remaining performance obligations that are unsatisfied is \$3.6 million, which is expected to be recognized as revenue through the first quarter of 2020. We had deferred revenue of \$1.7 million and \$3.3 million as of September 30, 2019 and December 31, 2018, respectively, from the 2019 Vertex Amendment and the Vertex Agreement, classified as current in the condensed consolidated balance sheets based on the term of the research period.

4. Grants

Biomedical Advanced Research and Development Authority (BARDA)

In September 2016, we received an award of up to \$125.8 million under Agreement No. HHSO100201600029C from BARDA, a component of the Office of the Assistant Secretary for Preparedness and Response, or ASPR within the U.S. Department of Health and

Human Services, or HHS, to help fund our Zika vaccine program. Under the terms of the agreement with BARDA, an initial base award of \$8.2 million supported toxicology studies, a Phase 1 clinical trial, and associated manufacturing activities. Contract options were available, for \$117.6 million to support an additional Phase 1 study of an improved Zika vaccine candidate, Phase 2 and Phase 3 clinical studies, as well as large-scale manufacturing for the Zika vaccine.

As of September 30, 2019, three of the four contract options had been exercised resulting in \$117.3 million of available funding with an additional \$8.4 million available if the final contract option is exercised. For the three and nine months ended September 30, 2019, we recognized revenue of \$1.1 million and \$4.5 million, respectively, relating to the BARDA agreement. For the three and nine months ended September 30, 2018, we recognized revenue of \$2.0 million and \$4.6 million, respectively, relating to the BARDA agreement.

The Bill & Melinda Gates Foundation (Gates Foundation)

In January 2016, we entered a global health project framework agreement with the Gates Foundation to advance mRNA-based development projects for various infectious diseases. The Gates Foundation has committed up to \$20.0 million in grant funding to support our initial project related to the evaluation of antibody combinations in a preclinical setting as well as the conduct of a first-in-human Phase 1 clinical trial of a potential mRNA medicine to help prevent human immunodeficiency virus, or HIV, infections. Follow-on projects which could bring total potential funding under the framework agreement up to \$100.0 million (including the HIV antibody project) to support the development of additional mRNA-based projects for various infectious diseases can be proposed and approved until the sixth anniversary of the framework agreement, subject to the terms of the framework agreement, including our obligation to grant to the Gates Foundation certain non-exclusive licenses. In March 2019, the Gates Foundation provided an additional funding commitment up to \$1.1 million to support a follow-on project.

As of September 30, 2019, up to \$21.1 million has been committed for funding with up to an additional \$80.0 million available, if additional follow-on projects are approved. For the three and nine months ended September 30, 2019, we recognized \$1.9 million and \$3.2 million, respectively, relating to the Gates Foundation agreement. For the three and nine months ended September 30, 2018, we recognized revenue of \$0.5 million and \$1.0 million, respectively, relating to the Gates Foundation agreement. We had deferred revenue of \$1.7 million and \$0.8 million as of September 30, 2019 and December 31, 2018, respectively, related to the Gates Foundation agreement.

Defense Advanced Research Projects Agency (DARPA)

In October 2013, DARPA awarded us up to \$24.6 million under Agreement No. W911NF-13-1-0417, which was subsequently adjusted to \$19.7 million, to research and develop potential mRNA medicines as a part of DARPA's Autonomous Diagnostics to Enable Prevention and Therapeutics, or ADEPT, program, which is focused on assisting with the development of technologies to rapidly identify and respond to threats posed by natural and engineered diseases and toxins. The DARPA awards have been deployed primarily in support of our vaccine and antibody programs to protect against chikungunya infection.

As of September 30, 2019 and December 31, 2018, \$19.7 million has been committed by DARPA. For each of the three and nine months ended September 30, 2019, we recognized revenue of \$0.5 million related to the DARPA agreement. We recognized revenue of \$2.5 million and \$4.0 million for the three and nine months ended September 30, 2018, respectively, related to the DARPA agreement.

5. Financial Instruments

Cash and Cash Equivalents and Investments

The following tables summarize our cash and available-for-sale securities by significant investment category at September 30, 2019 and December 31, 2018 (in thousands):

September 30, 2019							
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	\$ 173,711	\$ —	\$ —	\$ 173,711	\$ 173,711	\$ —	\$ —
Available-for-sale:							
Level 2:							
Certificates of deposit	81,350	147	—	81,497	—	81,497	—
U.S. treasury securities	146,825	421	—	147,246	—	124,355	22,891
Debt securities of U.S. government agencies and corporate entities	932,510	3,457	(21)	935,946	—	678,977	256,969
	<u>\$ 1,334,396</u>	<u>\$ 4,025</u>	<u>\$ (21)</u>	<u>\$ 1,338,400</u>	<u>\$ 173,711</u>	<u>\$ 884,829</u>	<u>\$ 279,860</u>
December 31, 2018							
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	\$ 658,365	\$ 20	\$ (21)	\$ 658,364	\$ 658,364	\$ —	\$ —
Available-for-sale:							
Level 2:							
Certificates of deposit	173,102	42	(36)	173,108	—	157,920	15,188
U.S. treasury securities	152,205	18	(48)	152,175	—	152,175	—
Debt securities of U.S. government agencies and corporate entities	712,065	40	(1,335)	710,770	—	552,968	157,802
	<u>\$ 1,695,737</u>	<u>\$ 120</u>	<u>\$ (1,440)</u>	<u>\$ 1,694,417</u>	<u>\$ 658,364</u>	<u>\$ 863,063</u>	<u>\$ 172,990</u>

The amortized cost and estimated fair value of marketable securities by contractual maturity at September 30, 2019 are as follows (in thousands):

September 30, 2019		
	Amortized Cost	Estimated Fair Value
Due in one year or less	\$ 882,514	\$ 884,829
Due after one year through five years	278,171	279,860
Total	<u>\$ 1,160,685</u>	<u>\$ 1,164,689</u>

At September 30, 2019, we held 2 available-for-sale securities, or an estimated fair value of \$9.0 million, out of our total investment portfolio that were in a continuous unrealized loss position for more than 12 months with a gross unrealized loss less than \$0.1 million. At December 31, 2018, we held 25 available-for-sale securities, or an estimated fair value of \$82.8 million, out of our total investment portfolio that were in a continuous unrealized loss position for more than 12 months with a gross unrealized loss of \$0.4 million. We concluded that the net declines in market value of our available-for-sale securities investment portfolio were temporary in nature and did not consider any of our investments to be other-than-temporarily impaired. In accordance with our investment policy,

we place investments in investment grade securities with high credit quality issuers, and generally limit the amount of credit exposure to any one issuer. We evaluate securities for other-than-temporary impairment at the end of each reporting period. Impairment is evaluated considering numerous factors, and their relative significance varies depending on the situation. Factors considered include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the issuer, and our intent and ability to hold the investment to allow for an anticipated recovery in fair value. Furthermore, the aggregate of individual unrealized losses that had been outstanding for 12 months or less was not significant as of September 30, 2019 and December 31, 2018. We neither intend to sell these investments nor conclude that we are more-likely-than-not that we will have to sell them before recovery of their carrying values. We also believe that we will be able to collect both principal and interest amounts due to us at maturity.

6. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets, as of September 30, 2019 and December 31, 2018 consists of the following (in thousands):

	September 30, 2019	December 31, 2018
Prepaid expenses	\$ 9,730	\$ 10,401
Tenant incentives receivables	9,904	10,089
Interest receivable on marketable securities	7,044	7,909
Prepaid expenses and other current assets	<u>\$ 26,678</u>	<u>\$ 28,399</u>

Property and Equipment, Net

Property and equipment, net, as of September 30, 2019 and December 31, 2018 consists of the following (in thousands):

	September 30, 2019	December 31, 2018
Building	\$ 144,039	\$ 140,442
Laboratory equipment	103,854	96,907
Leasehold improvements	15,124	13,741
Furniture, fixtures and other	2,142	2,122
Computer equipment and software	11,918	11,513
Internally developed software	7,020	7,020
Construction in progress	5,992	4,688
	<u>290,089</u>	<u>276,433</u>
Less: Accumulated depreciation	(86,401)	(64,456)
Property and equipment, net	<u>\$ 203,688</u>	<u>\$ 211,977</u>

Depreciation and amortization expense for the three months ended September 30, 2019 and 2018 was \$7.3 million and \$6.5 million, respectively. Depreciation and amortization expense for the nine months ended September 30, 2019 and 2018 was \$22.1 million and \$17.5 million, respectively.

Accrued Liabilities

Accrued liabilities, as of September 30, 2019 and December 31, 2018 consists of the following (in thousands):

	September 30, 2019	December 31, 2018
In-licenses	\$ —	\$ 22,000
Property and equipment	2,275	12,089
Compensation-related	23,963	23,406
External goods and services	33,841	21,578
Accrued liabilities	<u>\$ 60,079</u>	<u>\$ 79,073</u>

7. Commitments and Contingencies

Lease Obligations

We have entered into various long-term non-cancelable operating lease arrangements for our facilities and equipment expiring at various times through 2032. Certain of these arrangements have free rent periods or escalating rent payment provisions, which we recognize rent expense under such arrangements on a straight-line basis over the life of the leases. We have two campuses in Massachusetts. We occupy a multi-building campus in Technology Square in Cambridge, MA with a mix of offices and research laboratory space totaling approximately 200,000 square feet. Our Cambridge facility leases have expiry ranges from 2020 to 2029.

In August 2019, we entered into an amendment to our lease agreements to consolidate our Technology Square space in Cambridge, MA. We will acquire approximately 50,000 square feet of additional space at 200 Technology Square in January 2020, and will exit our current leased space of approximately 60,000 square feet at 500 Technology Square by May 2020 in two phases. In addition, our current 200 Technology Square lease has been extended for two years to 2029. The amendment provides an additional aggregated tenant improvement allowance of \$3.5 million for the design and construction of improvements at 200 Technology Square.

We have an approximately 200,000 square foot manufacturing facility in Norwood, MA. This facility is leased through 2032 with options for two extension periods of ten years.

In addition, in February 2019, we entered into a new lease agreement for office and laboratory space of an additional approximately 200,000 square feet, located in Norwood, MA. The lease commenced in the second quarter of 2019 and expires in early 2031. We have the option to extend the lease for up to four additional five-year terms. Contemporaneously, we entered into an agreement to sublease approximately 64 percent of the leased space to a third party. We have no rent obligations to the landlord for the space occupied by the third party. All sublease payments from the third party are paid directly to the landlord. The sublease can expire between May 2020 and February 2021 at the third party's option.

Total rent expense for the three months ended September 30, 2019 and 2018 was \$5.7 million and \$4.7 million, respectively. Total rent expense for the nine months ended September 30, 2019 and 2018 was \$15.9 million and \$14.7 million, respectively. Future minimum lease payments under non-cancelable operating lease agreements at September 30, 2019, are as follows (in thousands):

Fiscal Year	Minimum Lease Payments
2019 (remainder of the year)	\$ 5,440
2020	19,972
2021	19,886
2022	20,347
2023	20,583
Thereafter	161,218
Total	<u>\$ 247,446</u>

Strategic Collaborations

Under our strategic collaboration agreements, we are committed to perform certain research, development, and manufacturing activities. As part of our PCV Agreement and PCV/SAV Agreement with Merck, we are committed to perform certain research, development and manufacturing activities related to PCV products through an initial Phase 2 clinical trial up to a budgeted amount of \$243.0 million for both periods as of September 30, 2019 and December 31, 2018 (see Note 3).

Purchase Commitments and Purchase Orders

We have agreements with third parties for various services, including manufacturing and services related clinical operations and support, for which we are not contractually able to terminate for convenience and avoid any and all future obligations to these vendors. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly, to reimburse them for their unrecoverable outlays incurred prior to cancellation. At September 30, 2019 and December 31, 2018, we had cancelable open purchase orders of \$95.4 million and \$64.2 million, respectively, in total under such agreements for our significant clinical operations and support. These amounts represent only our estimate of those items for which we had a contractual commitment to pay at September 30, 2019 and December 31, 2018, assuming we would not cancel these agreements. The actual amounts we pay in the future to the vendors under such agreements may differ from the purchase order amounts.

Legal Proceedings

We are not currently a party to any material legal proceedings.

8. Shareholders' Equity

On February 28, 2018 and May 7, 2018, the Board of Directors approved an amendment to our Certificate of Incorporation resulting in a total of 775,000,000 shares of common stock and a total of 509,352,795 shares of redeemable convertible preferred stock being authorized, respectively. Upon completion of our IPO, our authorized capital stock consists of 1,600,000,000 shares of common stock, par value \$0.0001 per share, and 162,000,000 shares of preferred stock, par value \$0.0001 per share, all of which shares of preferred stock are undesignated.

On December 11, 2018, we completed our IPO, whereby we sold 26,275,993 shares of common stock at a price of \$23.00 per share. The aggregate net proceeds received by us from the IPO were \$563.0 million, net of underwriting discounts and commissions of \$33.2 million and offering expenses of \$8.1 million payable by us. Upon the closing of the IPO, all outstanding shares of our redeemable convertible preferred stock were converted into 236,012,913 shares of the common stock.

9. Stock-Based Compensation

Equity Plans

In connection with the IPO, we adopted our 2018 Stock Option and Incentive Plan (the 2018 Equity Plan) in November 2018. The 2018 Equity Plan became effective on the date immediately prior to the effective date of the IPO and replaced our 2016 Stock Option and Grant Plan (the 2016 Equity Plan). On January 1, 2019, the number of shares of common stock available for issuance under the 2018 Equity Plan increased by 13.2 million shares as a result of the automatic increase provision of the 2018 Equity Plan. As of September 30, 2019, we had a total of 68.7 million shares reserved for future issuance under our Equity Plans, of which 18.1 million shares were available for future grants.

Options

We have granted options generally through the 2018 Equity Plan and 2016 Equity Plan. The following table summarizes our option activity as of September 30, 2019:

	Number of Options	Weighted- Average Exercise Price per Share	Weighted- Average Grant Date Fair Value per Share	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value ⁽¹⁾ (in thousands)
Outstanding at December 31, 2018	50,821,132	\$ 12.16	\$ 6.59	7.1 years	\$ 220,434
Granted	6,543,166	20.01	11.71		
Exercised	(3,554,720)	5.61	3.89		
Canceled/forfeited	(4,846,923)	14.94	8.65		
Outstanding at September 30, 2019	48,962,655	13.43	7.18	7.2 years	201,014
Exercisable at September 30, 2019	24,449,929	9.64	4.58	5.6 years	167,915
Expected to vest at September 30, 2019	24,512,726	17.22	9.78	8.7 years	33,099

⁽¹⁾Aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of common stock for those options in the money as of September 30, 2019.

For the nine months ended September 30, 2019, 3.6 million stock options were exercised. The total intrinsic value of options exercised was \$39.1 million for the nine months ended September 30, 2019. The aggregate intrinsic value represents the difference between the exercise price and the selling price received by option holders upon the exercise of stock options during the period. The total consideration recorded as a result of stock option exercises was approximately \$19.9 million for the nine months ended September 30, 2019.

Restricted Common Stock

We have granted restricted stock awards generally through the 2016 Equity Plan. The following table summarizes our restricted stock activity for the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Fair Value per Share
Outstanding, non-vested at December 31, 2018	198,597	\$ 12.15
Issued	—	—
Vested	(141,153)	12.15
Canceled, forfeited and adjustments, net	(35,880)	12.15
Outstanding, non-vested at September 30, 2019	21,564	12.15

Restricted Common Stock Units

We have granted restricted stock unit awards generally through the 2018 Equity Plan and 2016 Equity Plan. The following table summarizes our restricted stock unit activity during the nine months ended September 30, 2019:

	Units	Weighted-Average Fair Value per Unit
Outstanding, non-vested at December 31, 2018	458,715	\$ 11.93
Issued	1,247,620	19.19
Vested ⁽¹⁾	43,002	11.93
Canceled/forfeited	(47,148)	21.01
Pending settlement ⁽¹⁾	(43,002)	11.93
Outstanding, non-vested at September 30, 2019	1,659,187	17.13

⁽¹⁾ The vested restricted stock units will be settled for common stock on the date which is 360 days after the consummation of the IPO.

2018 Employee Stock Purchase Plan

In November 2018, we adopted our 2018 Employee Stock Purchase Plan (ESPP), which became effective on December 5, 2018. The ESPP initially reserves and authorizes the issuance of up to a total of 810,000 shares of common stock to participating employees. Our ESPP has a six-month offering period, with a new period commencing on the first business day on or after June 1 and December 1 of each year. The purchase price at which shares are sold under the ESPP will be equal to 85% of the lower of the fair market value of the shares on the first business day of the offering period or the last business day of the purchase period. Employees are generally eligible to participate through payroll deductions of between 1% to 50% of their compensation and may not purchase more than 3,000 shares of common stock during each purchase period or \$25,000 worth of shares of common stock in any calendar year. We began our first ESPP offering on June 1, 2019. There were no shares sold under the ESPP during the nine months ended September 30, 2019.

Valuation and Stock-Based Compensation Expense

Stock-based compensation for options granted under our Equity Plans and share purchases under our ESPP is determined using the Black-Scholes option pricing model. The weighted-average assumptions used to estimate the fair value of options granted and ESPP for the nine months ended September 30, 2019 and 2018 are as follows:

	Weighted Average Nine Months Ended September 30,	
	2019	2018
Options:		
Risk-free interest rate	2.39%	2.71%
Expected term	6.07 years	6.06 years
Expected volatility	62%	64%
Expected dividends	—%	—%
Weighted average fair value per share	\$ 11.71	\$ 8.68
ESPP:		
Risk-free interest rate	2.31%	
Expected term	0.50 years	
Expected volatility	50%	
Expected dividends	—%	
Weighted average fair value per share	19.85	

The following table presents the components and classification of stock-based compensation expense for the three and nine months ended September 30, 2019 and 2018 as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30, 2019	
	2019	2018	2019	2018
Options	\$ 18,994	\$ 13,917	\$ 56,475	\$ 37,228
Restricted common stock and units	1,291	803	3,628	3,696
ESPP	519	—	693	—
Total	\$ 20,804	\$ 14,720	\$ 60,796	\$ 40,924
Research and development	\$ 12,616	\$ 8,714	\$ 36,268	\$ 24,498
General and administrative	8,188	6,006	24,528	16,426
Total	\$ 20,804	\$ 14,720	\$ 60,796	\$ 40,924

As of September 30, 2019, there was \$217.1 million of total unrecognized compensation cost related to unvested stock-based compensation with respect to options and restricted stock granted. That cost is expected to be recognized over a weighted-average period of 3.21 years at September 30, 2019.

10. Income Taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities. These differences are measured using the enacted statutory tax rates that are expected to be in effect for the years in which differences are expected to reverse. Valuation allowances are provided when the expected realization of deferred tax assets does not meet a “more likely than not” criterion. Realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. We continued to maintain a full valuation allowance against all our deferred tax assets based on management’s evaluation of all available evidence.

There were no significant income tax provisions or benefits for the three or nine months ended September 30, 2019 and 2018.

Upon adoption of ASC 606 (see Note 2), we recorded a cumulative-effect adjustment of \$28.0 million to the opening balance of accumulated deficit as of January 1, 2019 with a decrease in deferred revenue of \$30.7 million and a decrease in accounts receivable of \$2.7 million. As a result of the cumulative decrease in deferred revenue, our corresponding deferred tax asset decreased by \$8.4 million, which was offset by a corresponding decrease to our valuation allowance.

11. Net Loss per Share

Net Loss per Share Attributable to Common Stockholders

Basic and diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2019 and 2018 are calculated as follows (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss	\$ (123,194)	\$ (80,331)	\$ (390,905)	\$ (243,308)
Premium paid on repurchase of redeemable convertible preferred stock	—	(4,127)	—	(4,127)
Cumulative dividends on redeemable convertible preferred stock	—	(3,361)	—	(10,323)
Net loss attributable to common stockholders	<u>\$ (123,194)</u>	<u>\$ (87,819)</u>	<u>\$ (390,905)</u>	<u>\$ (257,758)</u>
Denominator:				
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	330,769,341	66,283,040	329,592,322	65,887,511
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.37)</u>	<u>\$ (1.32)</u>	<u>\$ (1.19)</u>	<u>\$ (3.91)</u>

The following common stock equivalents, presented based on amounts outstanding as of September 30, 2019 and 2018 were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because their inclusion would have been anti-dilutive:

	September 30,	
	2019	2018
Redeemable convertible preferred stock	—	236,012,913
Stock options	48,962,655	44,075,419
Restricted common stock	21,564	306,281
Restricted common stock units	1,659,187	458,715
	<u>50,643,406</u>	<u>280,853,328</u>

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited financial information and related notes included in this Form 10-Q and our consolidated financial statements and related notes and other financial information in our Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the SEC on March 13, 2019 and amended by Amendment No. 1 to our Annual Report on Form 10-K/A, which was filed with the SEC on April 25, 2019 (as amended, the "2018 Form 10-K"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part II, Item 1A - Risk Factors in this Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of potentially transformative medicines to improve the lives of patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane, or secreted proteins that have a therapeutic or preventive benefit with the potential to address a broad spectrum of diseases. Our platform builds on continuous advances in basic and applied mRNA science, delivery technology, and manufacturing, providing us the capability to pursue in parallel a robust pipeline of new development candidates. We are developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, and cardiovascular diseases, independently and with our strategic collaborators. As we unlock the inherent advantages of mRNA, we aim to address as many diseases and impact as many patients as our technology, talent, and capital permit.

We have a diverse development pipeline, and the broad potential applications of mRNA medicines have led us to raise significant capital and adopt a long-term approach to capital allocation that balances near-term risks and long-term value creation. As of September 30, 2019, we had cash, cash equivalents, and investments of approximately \$1.34 billion. We use this capital to fund operations and investing activities for technology creation, drug discovery and clinical development programs, infrastructure and capabilities to enable our research engine and early development engine (which includes our manufacturing facility in Norwood), our digital infrastructure, creation of our portfolio of intellectual property, and administrative support.

Since our inception, we have incurred significant operating losses. Our net loss was \$384.7 million and \$255.9 million for the years ended December 31, 2018 and 2017, respectively. Our net loss was \$123.2 million and \$390.9 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2019, our accumulated deficit was \$1.37 billion.

For the foreseeable future, we expect to continue to incur significant expenses and operating losses in connection with our ongoing activities, including as we:

- continue our platform research and drug discovery and development efforts;
- conduct clinical studies for our investigational medicines;
- manufacture clinical study materials and develop large-scale manufacturing capabilities;
- seek regulatory approval for our investigational medicines;
- maintain, expand, and protect our intellectual property;
- hire additional personnel to support our program development effort to obtain regulatory approval and secure additional facilities for operations; and
- continue to operate as a public company.

We do not expect to generate revenue from the sale of potential mRNA medicines unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our investigational medicines. If we seek to obtain regulatory approval for and commercialize any of our investigational medicines, we expect to incur significant commercialization expenses.

As a result, we will need substantial additional funding to support our continued operations and pursue our growth strategy. Until we can generate significant revenue from sales of our medicines, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings, government funding arrangements, strategic alliances and marketing, distribution, and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our programs.

Because of the numerous risks and uncertainties associated with pharmaceutical development, we are unable to predict the timing or amount of expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our medicines, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Our Pipeline

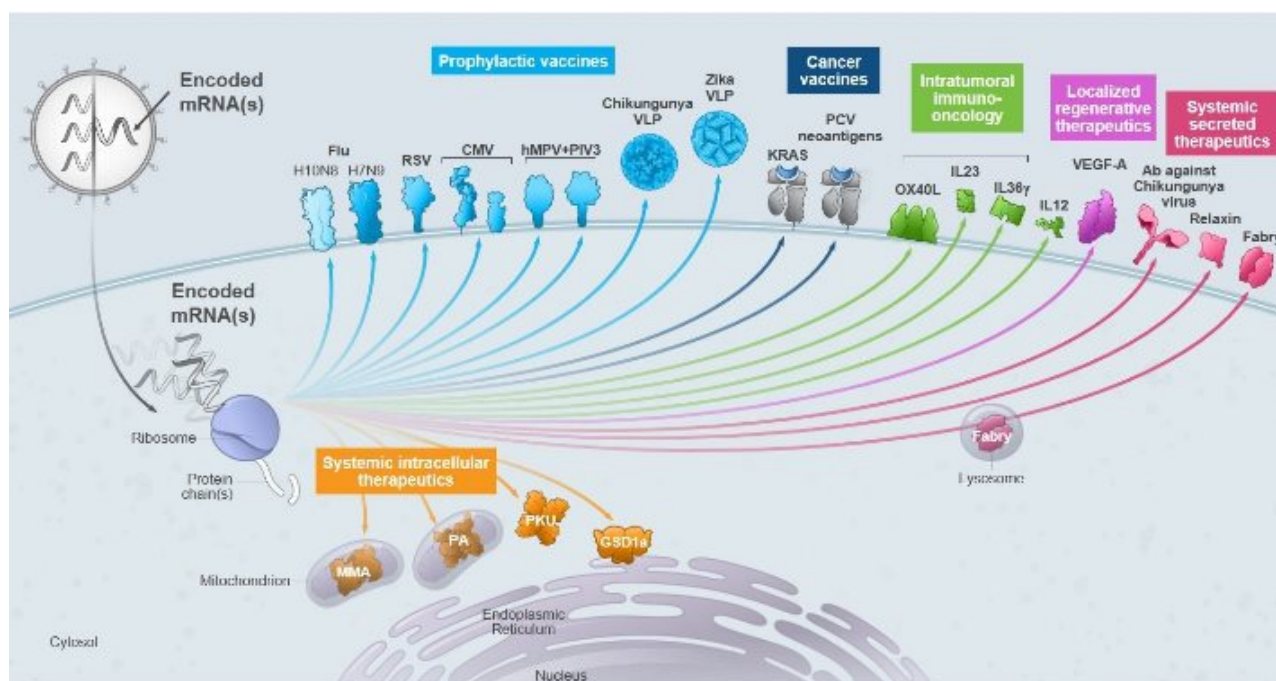
This section describes the pipeline that has emerged thus far from the combination of our strategy, our platform, our infrastructure, and the resources we have amassed.

We have a diverse development pipeline of 21 development candidates across our 20 programs, of which 13 development candidates are in clinical studies on three different continents. Over 1,400 subjects have been enrolled in our clinical trials since December 2015. Our diverse pipeline comprises programs across six modalities and a broad range of therapeutic areas. A modality is a group of potential mRNA medicines with shared product features, and the associated combination of mRNA technologies, delivery technologies, and manufacturing processes. Aspects of our pipeline have been supported through strategic alliances, including with AstraZeneca, Merck, and Vertex, and government-sponsored organizations and private foundations focused on global health initiatives, including BARDA, DARPA, and the Bill & Melinda Gates Foundation.

Our pipeline is shown below in two formats, a traditional format that shows the current stages of development of our pipeline programs, and a cell map illustrating the diversity of biology addressed by our mRNA pipeline programs. We believe the 20 programs in our pipeline represent only an initial wave of potential development candidates, and that our platform over time may yield both multiple new programs within our existing modalities and the potential for multiple programs in new modalities.

Modality	ID #	Program Indication	Preclinical development	Phase 1	Phase 2	Phase 3 and commercial	Moderna rights
 Prophylactic vaccines	mRNA-1172	Respiratory syncytial virus (RSV) vaccine					Merck to pay milestones and royalties
	mRNA-1777	Respiratory syncytial virus (RSV) vaccine					
	mRNA-1647	Cytomegalovirus (CMV) vaccine					Worldwide
	mRNA-1653	Human metapneumovirus and parainfluenza virus 3 (hMPV+PIV3) vaccine	Phase 1b (pediatric)	Phase 1 (adult)			Worldwide
	mRNA-1893	Zika vaccine					Worldwide BARDA funded
	mRNA-1440	Influenza H10N8 vaccine					Worldwide Advancing subject to outside funding
	mRNA-1851	Influenza H7N9 vaccine					Worldwide Advancing subject to outside funding
	mRNA-1388	Chikungunya vaccine					Worldwide Advancing subject to outside funding
 Cancer vaccines	mRNA-4157	Personalized cancer vaccine (PCV)					50-50 global profit sharing with Merck
	mRNA-5671	KRAS vaccine					50-50 global profit sharing with Merck
 Intratumoral immuno-oncology	mRNA-2416	OX40L Solid tumors/lymphoma Advanced ovarian carcinoma (Ph 2 cohort)	Solid tumors/lymphoma	Ovarian			Worldwide
	mRNA-2752	OX40L+IL23+IL36γ (Triplet)					Worldwide
	MEDI1191	IL12 Solid tumors					50-50 U.S. profit sharing, AZ to pay royalties on ex-U.S. sales
 Localized regenerative therapeutics	AZD8601	VE-GF-A Myocardial ischemia					AZ to pay milestones and royalties
 Systemic secreted therapeutics	mRNA-1944	Antibody against Chikungunya virus					Worldwide DARPA funded
	AZD7970	Relaxin Heart failure					50-50 U.S. profit sharing, AZ to pay royalties on ex-U.S. sales
	mRNA-3630	α-GAL Fabry disease					Worldwide
 Systemic intracellular therapeutics	mRNA-3704	MUT Methylmalonic Acidemia (MMA)					Worldwide
	mRNA-3927	PCCA+PCCB Propionic Acidemia (PA)					Worldwide
	mRNA-3283	PAH Phenylketonuria (PKU)					Worldwide
	mRNA-3745	CGI base Glycogen Storage Disease Type 1a (GSD1a)					Worldwide

Abbreviations: AZ, AstraZeneca; α -GAL, alpha galactosidase; G6Pase, glucose 6-phosphatase; IL12, interleukin 12; IL23, interleukin 23; IL36 γ , interleukin 36 gamma; MUT, methylmalonyl-CoA mutase; PAH, phenylalanine hydroxylase; PCCA+PCCB, propionyl-CoA carboxylase subunit A/B; VEGF-A, vascular endothelial growth factor A.



We have developed six modalities. We have a development pipeline of 21 development candidates across our 20 programs, of which 13 development candidates are currently in clinical trials, summarized by modality as follows:

- **Prophylactic vaccines** included eight development candidates across seven programs: RSV vaccine (mRNA-1777 and mRNA-1172 or V172), CMV vaccine (mRNA-1647), hMPV+PIV3 vaccine (mRNA-1653), H10N8 vaccine (mRNA-1440), H7N9 vaccine (mRNA-1851), Zika vaccine (mRNA-1893), and Chikungunya vaccine (mRNA-1388). All seven programs in this modality either have ongoing or completed Phase 1 clinical trials.
- **Cancer vaccines** included two development candidates: Personalized cancer vaccine ("PCV") (mRNA-4157) and KRAS vaccine (mRNA-5671 or V941). We are collaborating with Merck on both programs. PCV is in a Phase 1 clinical trial and the first patient has been dosed in a Phase 2 clinical trial, and the KRAS vaccine is in a Phase 1 clinical trial.
- **Intratumoral immuno-oncology** included three development candidates: OX40L (mRNA-2416), OX40L+IL23+IL36 γ (Triplet) (mRNA-2752), and IL12 (MEDI1191). OX40L is currently being evaluated in a Phase 1/2 trial that includes a Phase 2 expansion cohort in patients with advanced ovarian carcinoma. Triplet and IL12 are currently in Phase 1 clinical trials.
- **Localized regenerative therapeutics** included one development candidate, VEGF-A (AZD8601). The program is being led by AstraZeneca through clinical development and is in a Phase 2a clinical trial.
- **Systemic secreted therapeutics** included three development candidates: antibody against Chikungunya virus (mRNA-1944), Relaxin (AZD7970), and Fabry disease (mRNA-3630). The antibody against Chikungunya virus development candidate is in collaboration with DARPA and the program is in a Phase 1 clinical trial. The Relaxin program in collaboration with AstraZeneca and the Fabry disease program are both in preclinical development.
- **Systemic intracellular therapeutics** included four development candidates: MMA (mRNA-3704), PA (mRNA-3927), PKU (mRNA-3283), and GSD1a (mRNA-3745). The MMA program has open clinical sites for a Phase 1/2 clinical trial, the U.S. Food and Drug Administration (the "FDA") has completed its review of the IND for mRNA-3927 allowing the PA program to proceed to a Phase 1/2 clinical trial, and the PKU and GSD1a programs are in preclinical development.

The following are recent key updates for our development candidates:

- **CMV vaccine (mRNA-1647):** We announced positive data from the three-month interim analysis of the Phase 1 clinical trial of mRNA-1647, which has completed enrollment and is evaluating the safety and immunogenicity of mRNA-1647 in healthy adult volunteers. The clinical trial population includes those who were naïve to CMV infection (CMV-seronegative) and those who had previously been infected by CMV (CMV-seropositive). Participants were randomized to receive either placebo, or 30, 90, 180 or 300 µg of mRNA-1647 on a dosing schedule of 0, 2 and 6 months. This first planned interim analysis assessed safety and immunogenicity of the first three dose levels (30, 90, and 180 µg) at three months, one month after the second vaccination and before the third vaccination. Neutralizing antibody titers (levels of circulating antibodies that block infection) were assessed in two assays utilizing epithelial cells and fibroblasts, which measure immune response to the pentamer and gB vaccine antigens, respectively. Seropositive baseline titers are associated with lower rates of congenital CMV transmission.

In seronegative participants:

- A dose-related increase in neutralizing antibody titers was observed in both epithelial cell and fibroblast assays.
- In epithelial cells, after the second vaccination, neutralizing antibody titers were three to five times higher than CMV-seropositive baseline titers at the 90 and 180 µg dose levels.
- In fibroblasts, after the second vaccination, neutralizing antibody titers were equivalent to CMV-seropositive baseline titers at the 90 and 180 µg dose levels.
- For the 12 sentinel participants who received mRNA-1647 under an earlier arm of the protocol (Phase A) and who received three doses (at 0, 2 and 6 months), neutralizing antibody titers were further boosted at seven months and were sustained at or above CMV-seropositive baseline levels for at least 12 months.

In seropositive participants:

- A dose-related increase in neutralizing antibody titers was observed in both epithelial cell and fibroblast assays.
- In epithelial cells, the second vaccination boosted neutralizing antibody titers to a level of 10-fold to 19-fold baseline titers in all dose groups.
- In fibroblasts, the second vaccination boosted neutralizing antibody titers to a level of 2-fold to 4-fold baseline titers in all dose groups.

A safety analysis indicated that the vaccine was generally well-tolerated. There were no vaccine-related serious adverse events. The most common solicited local adverse event (“AE”) was injection site pain. The most common solicited systemic AEs were headache, fatigue, myalgia, chills, and fever. In general, solicited systemic AEs occurred more frequently after the second dose compared to the first, and were more common in the seropositive cohorts compared to the seronegative cohorts. The most common Grade 3 solicited AEs in seropositive participants were myalgia (9-33% of a given dose cohort), chills and fatigue (9-27% of a given dose cohort), and fever (0-27% of a given dose cohort). There was a single Grade 4 AE of an isolated lab finding of elevated partial thromboplastin time, which was elevated at baseline (Grade 1) and self-resolved on the next lab test with no associated clinical findings.

A similar overall safety and tolerability profile was observed in an earlier arm of the protocol (Phase A), for which data are available out to 12 months. Additionally, the 300 µg cohort has completed the second vaccination without clinical trial pause; interim analysis of safety and immunogenicity is pending.

- **hMPV+PIV3 vaccine (mRNA-1653):** The first subject in the Phase 1b age de-escalation clinical trial of mRNA-1653 has been dosed.
- **Zika virus vaccine (mRNA-1893):** The first subject has been dosed in the Phase 1 clinical trial of mRNA-1893, which recently received Fast Track designation from the FDA. This development candidate is being developed in collaboration with the U.S. Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services.
- **Personalized cancer vaccine (PCV) (mRNA-4157):** The first patients have been dosed in the randomized Phase 2 clinical trial investigating a 1 mg dose of mRNA-4157 in combination with Merck’s pembrolizumab (KEYTRUDA), compared to pembrolizumab alone, for the adjuvant treatment of high-risk resected melanoma.

- **OX40L (mRNA-2416):** Based on available data, we have decided to focus the development of mRNA-2416 for the treatment of patients with ovarian cancer in combination with durvalumab (IMFINZI), a PD-L1 inhibitor. The safety cohort of the combination arm (mRNA-2416 and durvalumab) of this Phase 1/2 clinical trial continues to enroll and will be followed by a Phase 2 expansion cohort in patients with advanced ovarian carcinoma. We will not move forward with the mRNA-2416 monotherapy ovarian cancer arm of this study.
- **Antibody against Chikungunya virus (mRNA-1944):** We announced positive interim data in the first analysis of safety and activity in a Phase 1 clinical trial evaluating escalating doses of mRNA-1944 administered via intravenous infusion in healthy adults. mRNA-1944 encodes for an antibody (CHKV-24) with activity against chikungunya virus. At all three dose levels, the administration of mRNA-1944 led to detectable levels of CHKV-24 antibody in all participants, ranging from 1 µg/mL to 14 µg/mL. These results mark the first systemic mRNA therapeutic to show production of a secreted protein in humans.

A total of 22 healthy adults have been enrolled in the clinical trial as of September 12, 2019. The initial analysis evaluated the safety and pharmacology of intravenous administration of mRNA-1944 at three dose levels of 0.1 mg/kg (n=6), 0.3 mg/kg (n=6) and 0.6 mg/kg (n=4); six participants received placebo.

Administration of mRNA-1944 resulted in dose-related increases in CHKV-24 antibody levels, with average C_{max} antibody levels of 2.0, 7.9 and 10.2 µg/mL at the low, middle and high doses, respectively. At all doses, all participants exceeded the levels of antibody expected to be protective against chikungunya infection (> 1 µg/mL) following a single dose. All participants also showed circulating neutralizing antibody activity against chikungunya virus replication in an NT50 assay, demonstrating that mRNA-1944 resulted in the production of fully functional protein *in vivo*. All participants in the clinical trial received antihistamine premedication. No participants received corticosteroids either as premedication or treatment.

None of the participants treated with mRNA-1944 at the low or middle doses experienced significant AEs. Three of the four participants at the high dose had infusion-related AEs, with the highest grade by subject being Grade 1 (n=1), Grade 2 (n=1), and Grade 3 (n=1). The Grade 3 AEs were tachycardia and an elevated white blood cell count. The same participant experienced Grade 2 AEs of nausea, emesis, fever, and inverted T waves on a routine EKG (without associated cardiac symptoms and which later resolved). The fourth participant at the high dose had no related AEs. There were no meaningful changes in liver or kidney laboratory results. There have been no serious AEs in the clinical trial. All AEs were transient and resolved without treatment.

This is an interim analysis of an ongoing clinical trial. At this time, we have not enrolled the last two participants at the 0.6 mg/kg dose. We are evaluating further exploration of the safety and pharmacology of mRNA-1944, which may include repeat dosing or dosing in combination with commonly used steroid premedications to prevent infusion-related reactions.

- **Propionic Acidemia (PA) (mRNA-3927):** FDA granted Fast Track designation for mRNA-3927. Study start-up is ongoing for the open-label, multi-center, dose escalation Phase 1/2 clinical trial of multiple ascending doses of mRNA-3927 in pediatric patients with PA in the U.S.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from the sale of potential mRNA medicines. Our revenue has been primarily derived from strategic alliances with Merck, Vertex and AstraZeneca, and from contracts with government-sponsored and private organizations including DARPA, BARDA, and the Bill & Melinda Gates Foundation, to discover, develop, and commercialize potential mRNA medicines. On January 1, 2019, we adopted Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (ASC 606), using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2019. We recorded the cumulative-effect adjustment of \$28.0 million to the opening balance of accumulated deficit as of January 1, 2019 with a corresponding decrease to deferred revenue.

Total revenue for the three months ended September 30, 2019 and 2018 was \$17.0 million and \$41.8 million, respectively. Total revenue for the nine months ended September 30, 2019 and 2018 was \$46.2 million and \$99.6 million, respectively, and is primarily comprised of collaboration revenue from our strategic alliances as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Collaboration revenue:				
Merck	\$ 9,110	\$ 14,475	\$ 28,456	\$ 47,537
AstraZeneca	3,724	19,727	4,726	33,166
Vertex	504	2,460	4,301	8,993
Total collaboration revenue	\$ 13,338	\$ 36,662	\$ 37,483	\$ 89,696

Cash received from strategic alliances was \$15.9 million and \$51.4 million for the nine months ended September 30, 2019 and 2018, respectively. The timing of revenue recognition is not directly correlated to the timing of cash receipts. Total deferred revenue related to our strategic alliances as of September 30, 2019 and December 31, 2018 was \$213.6 million and \$274.4 million, respectively.

For further information on our adoption of ASC 606 and our revenue recognition policies, see Note 2 to our condensed consolidated financial statements. Our ability to generate revenue from sales of mRNA medicines and become profitable depends upon our ability to successfully develop and commercialize mRNA medicines. For the foreseeable future, we do not expect to generate revenue from product sales. To the extent that existing or potential future strategic alliances generate revenue, our revenue may vary due to many uncertainties in the development of our mRNA medicines under these strategic alliances and other factors. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development efforts. We expect our programs to mature and advance to later stage clinical development, and we expect expenses to increase as we seek regulatory approvals for our investigational medicines and begin to commercialize any approved mRNA medicines.

Research and development expenses

The nature of our business and primary focus of our activities generate a significant amount of research and development costs. Research and development expenses represent costs incurred by us for the following:

- cost to develop our platform;
- discovery efforts leading to development candidates;
- preclinical, nonclinical, and clinical development costs for our programs;
- cost to develop our manufacturing technology and infrastructure; and
- digital infrastructure costs.

The costs above comprise the following categories:

- personnel-related expenses, including salaries, benefits, and stock-based compensation expense;
- expenses incurred under agreements with third parties, such as consultants, investigative sites, contract research organizations, or CROs, that conduct our preclinical and clinical studies, and in-licensing arrangements;
- costs of acquiring, developing, and manufacturing materials for preclinical and clinical studies, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs;
- expenses incurred for the procurement of materials, laboratory supplies, and non-capital equipment used in the research and development process; and
- facilities, depreciation, and amortization, and other direct and allocated expenses incurred as a result of research and development activities.

We use our employee and infrastructure resources for the advancement of our platform, and for discovering and developing programs. Due to the number of ongoing programs and our ability to use resources across several projects, indirect or shared operating costs incurred for our research and development programs are not recorded or maintained on a program- or modality-specific basis.

The following table reflects our research and development expenses, including direct program specific expenses summarized by modality and indirect or shared operating costs summarized under other research and development expenses during the three and nine months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Program expenses by modality:				
Prophylactic vaccines	\$ 5,666	\$ 4,499	\$ 38,326	\$ 18,991
Cancer vaccines	10,346	7,878	33,807	24,699
Intratumoral immuno-oncology	4,205	2,534	11,398	13,098
Localized regenerative therapeutics	1	5	17	85
Systemic secreted therapeutics	1,296	2,803	10,413	11,866
Systemic intracellular therapeutics	5,039	10,887	21,611	29,814
Total program-specific expenses by modality ⁽¹⁾	26,553	28,606	115,572	98,553
Other research and development expenses:				
Discovery programs	13,829	8,593	42,379	24,271
Platform research	21,940	25,747	70,693	67,924
Technical development and unallocated manufacturing expenses	29,372	26,467	69,231	59,302
Shared discovery and development expenses	15,405	9,929	44,643	29,105
Stock-based compensation	12,616	9,708	36,268	24,498
Total research and development expenses	\$ 119,715	\$ 109,050	\$ 378,786	\$ 303,653

⁽¹⁾ Include a total of 21 development candidates for both September 30, 2019 and 2018. Program-specific expenses include external costs and allocated manufacturing costs of mRNA supply and consumables, and are reflected as of the beginning of the period in which the program was internally advanced to development or removed if development was ceased.

A “modality” refers to a group of programs with common product features and the associated combination of enabling mRNA technologies, delivery technologies, and manufacturing processes. The program-specific expenses by modality summarized in the table above include expenses we directly attribute to our programs, which consist primarily of external costs, such as fees paid to outside consultants, central laboratories, investigative sites, and CROs in connection with our preclinical studies and clinical trials, and allocated manufacturing costs of mRNA supply and consumables. Costs to acquire and manufacture mRNA supply for preclinical studies and clinical trials are recognized and included in unallocated manufacturing expenses when incurred, and subsequently allocated to program-specific manufacturing costs after completion of the program-specific production. The timing of allocating manufacturing costs to the specific program varies depending on the program development and production schedule. We do not allocate personnel-related costs, including stock-based compensation, costs associated with our general platform research, technical development, and other shared costs on a program-specific basis. These costs were therefore excluded from the summary of program-specific expenses by modality.

Discovery program expenses are costs associated with research activities for our programs in the preclinical discovery stage, and primarily consist of external costs for CROs and lab services, and allocated manufacturing cost of preclinical mRNA supply and consumables.

Platform research expenses are mainly costs to develop technical advances in mRNA science, delivery science, and manufacturing process design. These costs include personnel-related costs, computer equipment, facilities, preclinical mRNA supply and consumables, and other administrative costs to support our platform research. Technology development and unallocated manufacturing expenses are primarily related to non-program-specific manufacturing process development and manufacturing costs.

Shared discovery and development expenses are research and development costs such as personnel-related costs and other costs, which are not otherwise included in development programs, discovery programs, platform research, technical development and unallocated manufacturing expenses, stock-based compensation, and other expenses.

The largest component of our total operating expenses has historically been our investment in research and development activities, including development of our platform, mRNA technologies, and manufacturing technologies. We expense research and development costs as incurred and cannot reasonably estimate the nature, timing, and estimated costs required to complete the development of the development candidates and investigational medicines we are currently developing or may develop in the future. There are numerous risks and uncertainties associated with the research and development of such development candidates and investigational medicines, including, but not limited to:

- scope, progress, and expense of developing ongoing and future development candidates and investigational medicines;
- entry in and completion of related preclinical studies;
- enrollment in and completion of subsequent clinical trials;
- safety and efficacy of investigational medicines resulting from these clinical trials;
- changes in laws or regulations relevant to the investigational medicines in development;
- receipt of the required regulatory approvals; and
- commercialization, including establishing manufacturing and marketing capabilities.

A change in expectations or outcomes of any of the known or unknown risks and uncertainties may materially impact our expected research and development expenditures. Continued research and development is central to the ongoing activities of our business. Investigational medicines in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development costs to continue to increase in the future as our investigational medicines progress through the development phases and as we identify and develop additional programs. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our investigational medicines, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time due to the early stage of development of our investigational medicines. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and administrative expenses

General and administrative expenses consist primarily of personnel-related costs, including stock-based compensation, for executives, finance, legal, human resources, business development and other administrative and operational functions, professional fees, accounting and legal services, information technology and facility-related costs, and expenses associated with obtaining and maintaining intellectual property, or IP. These costs relate to the operation of the business, unrelated to the research and development function, or any individual program.

We anticipate general and administrative expenses will increase if research and development expands. In addition, if we obtain regulatory approval for any of our investigational medicines and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support medicine sales, marketing, and distribution activities.

We have a broad IP portfolio covering our development and commercialization of mRNA vaccine and therapeutic programs, including those related to mRNA design, formulation, and manufacturing platform technologies. We regularly file patent applications to protect innovations arising from our research and development. We also hold trademarks and trademark applications in the United States and foreign jurisdictions. Costs to secure and defend our IP are expensed as incurred and are classified as general and administrative expenses.

General and administrative expenses, including IP-related expenses, totaled \$28.2 million and \$18.5 million for the three months ended September 30, 2019 and 2018, respectively, and were \$84.0 million and \$56.2 million for the nine months ended September 30, 2019 and 2018, respectively. IP-related expenses, including our internal personnel-related costs, were \$3.7 million and \$2.1 million for the three months ended September 30, 2019 and 2018, respectively, and were \$10.9 million and \$8.6 million for the nine months ended September 30, 2019 and 2018, respectively. We did not incur litigation expenses related to our IP during the three or nine months ended September 30, 2019 and 2018.

Interest income

Interest income consists of interest generated from our investments in cash and cash equivalents, money market funds, and high-quality fixed income securities.

Other expense, net

Other expense, net consists of interest expense, gains (losses) from the sale of investments in marketable securities, and other income and expense unrelated to our core operations. Interest expense is primarily derived from our lease financing obligation related to our Norwood manufacturing facility.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, are reflected in the condensed consolidated financial statements prospectively from the date of change in estimates.

On January 1, 2019, we adopted ASC 606, *Revenue from Contracts with Customers*, using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2019. We recognized the cumulative effect of the adoption as an adjustment to the opening balance of accumulated deficit in the current period's condensed consolidated balance sheet. Results for reporting periods beginning after January 1, 2019, are presented under ASC 606. Prior period amounts have not been adjusted and continue to be reported in accordance with our historic accounting under ASC Topic 605, *Revenue Recognition* (ASC 605). ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

Other than our adoption of ASC 606, there have been no material changes in our critical accounting policies and estimates in the preparation of our condensed consolidated financial statements during the three months and nine months ended September 30, 2019 compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, as amended.

Recently issued accounting pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to our condensed consolidated financial statements, such standards will not have a material impact on our financial statements or do not otherwise apply to our operations.

Results of operations

The following tables summarize our condensed consolidated statements of operations for each period presented (in thousands):

	Three Months Ended September 30,		Change 2019 vs. 2018	
	2019	2018	\$	%
Revenue:				
Collaboration revenue	\$ 13,338	\$ 36,662	\$ (23,324)	(64)%
Grant revenue	3,708	5,095	(1,387)	(27)%
Total revenue	17,046	41,757	(24,711)	(59)%
Operating Expenses:				
Research and development	119,715	109,050	10,665	10%
General and administrative	28,188	18,525	9,663	52%
Total operating expenses	147,903	127,575	20,328	16%
Loss from operations	(130,857)	(85,818)	(45,039)	52%
Interest income	9,252	6,519	2,733	42%
Other expense, net	(1,767)	(1,032)	(735)	71%
Loss before income taxes	(123,372)	(80,331)	(43,041)	54%
Benefit from income taxes	(178)	—	(178)	
Net loss	\$ (123,194)	\$ (80,331)	\$ (42,863)	53%

	Nine Months Ended September 30,		Change 2019 vs. 2018	
	2019	2018	\$	%
Revenue:				
Collaboration revenue	\$ 37,483	\$ 89,696	\$ (52,213)	(58)%
Grant revenue	8,671	9,951	(1,280)	(13)%
Total revenue	46,154	99,647	(53,493)	(54)%
Operating Expenses:				
Research and development	378,786	303,653	75,133	25%
General and administrative	83,994	56,229	27,765	49%
Total operating expenses	462,780	359,882	102,898	29%
Loss from operations	(416,626)	(260,235)	(156,391)	60%
Interest income	30,546	18,129	12,417	68%
Other expense, net	(5,351)	(1,044)	(4,307)	413%
Loss before income taxes	(391,431)	(243,150)	(148,281)	61%
(Benefit from) provision for income taxes	(526)	158	(684)	
Net loss	\$ (390,905)	\$ (243,308)	\$ (147,597)	61%

Revenue

Total revenue decreased by \$24.7 million, or 59%, for the three months ended September 30, 2019 compared to the same period in 2018. Total revenue decreased by \$53.5 million, or 54%, for the nine months ended September 30, 2019 compared to the same period in 2018. The decreases were due to a decrease in collaboration revenue across all our strategic alliances, particularly AstraZeneca and Merck, largely driven by our adoption of ASC 606. See Note 2 to our condensed consolidated financial statements for further information on our adoption of ASC 606.

Operating expenses

Research and development expenses

Research and development expenses increased by \$10.7 million, or 10%, for the three months ended September 30, 2019 compared to the same period in 2018. The increase was primarily attributable to an increase in personnel related costs of \$10.8 million, and an increase in stock-based compensation of \$3.9 million, partially offset by a decrease in information technology and facility-related costs of \$2.0 million, a decrease in consulting and outside services of \$1.2 million and a decrease in lab supplies and materials of \$1.1 million. Research and development expenses increased by \$75.1 million, or 25%, for the nine months ended September 30, 2019 compared to the same period in 2018. The increase was primarily attributable to an increase in personnel related costs of \$31.7 million, an increase in clinical trial and manufacturing costs of \$12.4 million, an increase in stock-based compensation of \$11.8 million, an increase in lab supplies and materials of \$10.2 million, an increase in consulting and outside services of \$4.9 million, and an increase in depreciation and amortization of \$3.7 million. For both the three and nine months ended September 30, 2019, the increases in personnel related costs and stock-based compensation were largely driven by an increase in the number of employees supporting our research and development programs.

General and administrative expenses

General and administrative expenses increased by \$9.7 million, or 52%, for the three months ended September 30, 2019 compared to the same period in 2018. The increase was mainly due to an increase in information technology and facility-related costs of \$2.8 million, an increase in stock-based compensation of \$2.2 million, an increase in legal and insurance related costs of \$2.1 million, and an increase in consulting and outside services of \$2.0 million. General and administrative expenses increased by \$27.8 million, or 49%, for the nine months ended September 30, 2019 compared to the same period in 2018. The increase was mainly due to an increase in stock-based compensation of \$8.1 million, an increase in consulting and outside services of \$5.4 million, an increase in legal and insurance related costs of \$5.4 million, an increase in personnel related costs of \$4.6 million, and an increase in information technology and facility-related costs of \$3.6 million. These increases for the three and nine months ended September 30, 2019 compared to the same periods in 2018 were primarily driven by an increase in the number of employees and increased costs related to operating as a publicly traded company.

Interest income

Interest income increased by \$2.7 million, or 42%, for the three months ended September 30, 2019 compared to the same period in 2018. Interest income increased by \$12.4 million, or 68%, for the nine months ended September 30, 2019 compared to the same period in 2018. The increases in interest income from our investments in marketable securities for both the three month and nine month periods were mainly driven by a higher weighted average balance of cash and investments and market performance in 2019.

Other expense, net

The following table summarizes other expense, net for each period presented (in thousands):

	Three Months Ended September 30,		Change 2019 vs. 2018	
	2019	2018	\$	%
Gain on investments	\$ 79	\$ 771	\$ (692)	(90)%
Interest expense	(1,543)	(1,519)	(24)	2%
Other expense, net	(303)	(284)	(19)	7%
Total other expense, net	<u>\$ (1,767)</u>	<u>\$ (1,032)</u>	<u>\$ (735)</u>	

	Nine Months Ended September 30,		Change 2019 vs. 2018	
	2019	2018	\$	%
Gain on investments	\$ 93	\$ 1,362	\$ (1,269)	(93)%
Interest expense	(4,617)	(1,571)	(3,046)	194%
Other expense, net	(827)	(835)	8	(1)%
Total other expense, net	<u>\$ (5,351)</u>	<u>\$ (1,044)</u>	<u>\$ (4,307)</u>	

Other expense, net increased by \$0.7 million and \$4.3 million for the three and nine months ended September 30, 2019, respectively, compared to the same periods in 2018. The increase in other expenses for the three months ended September 30, 2019 was primarily related to a \$0.7 million decrease in gain on investments. The increase for the nine months ended September 30, 2019 was primarily related to interest expense on our Norwood lease financing obligation of \$3.0 million and a decrease in gain on investments of \$1.3 million.

Liquidity and capital resources

We have historically funded our operations primarily from the sale of equity instruments and from proceeds from certain strategic alliance arrangements and grant agreements. As of September 30, 2019, we had cash, cash equivalents and investments of \$1.34 billion. Cash, cash equivalents and investments are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting primarily of government and corporate debt securities, are stated at fair value. As of September 30, 2019, we had current and non-current investments of approximately \$884.8 million and \$279.9 million, respectively.

We began construction of our Norwood manufacturing facility, or Norwood, in the second half of 2016. Our capital expenditures related to Norwood were \$3.9 million and \$75.3 million for the nine months ended September 30, 2019 and 2018, respectively. Cash disbursements related to Norwood were \$14.4 million and \$83.2 million for the nine months ended September 30, 2019 and 2018.

On January 30, 2018 and February 15, 2018, we issued Series G preferred stock for total gross proceeds of \$560.0 million. On May 7, 2018, we issued Series H preferred stock for gross proceeds of \$125.0 million of which \$13.0 million is determined to be a premium and recorded to deferred revenue as part of the Merck PCV/SAV agreement executed contemporaneously with our Series H redeemable convertible preferred stock issuance. Please refer to Note 3 to our condensed consolidated financial statements.

On December 11, 2018, we closed our IPO, whereby we sold 26,275,993 shares of common stock at a price of \$23.00 per share. The shares began trading on the Nasdaq Global Select Market on December 7, 2018. The aggregate net proceeds received by us from the IPO were \$563.0 million, net of underwriting discounts, commissions and offering expenses payable by us.

Cash flow

The following table summarizes the primary sources and uses of cash for each period presented (in thousands):

	Nine Months Ended September 30,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	\$ (363,195)	\$ (239,845)
Investing activities	(145,293)	(379,267)
Financing activities	23,531	650,927
Net (decrease) increase in cash, cash equivalents and restricted cash	\$ (484,957)	\$ 31,815

Operating activities

We derive cash flows from operations primarily from cash collected from certain strategic alliances. Our cash flows from operating activities are significantly influenced by our use of cash for operating expenses and working capital to support the business. We have historically experienced and will continue to expect negative cash flows from operating activities due to our investments in mRNA technologies, digital infrastructure, manufacturing technology, and infrastructure.

Net cash used in operating activities for the nine months ended September 30, 2019 was \$363.2 million and consisted of net loss of \$390.9 million less non-cash adjustments of \$79.5 million, plus a net change in assets and liabilities of \$51.8 million. Non-cash items primarily included stock-based compensation of \$60.8 million, depreciation and amortization of \$22.1 million, and amortization of investment premium and discount of \$3.4 million. The net change in assets and liabilities was primarily due to a decrease in deferred revenue of \$32.8 million, a decrease in accounts payable of \$19.2 million, a decrease in accrued liabilities of \$8.3 million and an increase in prepaid expenses and other assets of \$1.4 million, partially offset by a decrease in accounts receivable of \$4.4 million and an increase in deferred lease obligations of \$3.8 million.

Net cash used in operating activities for the nine months ended September 30, 2018 was \$239.8 million and consisted of net loss of \$243.3 million less non-cash adjustments of \$57.3 million, plus a net change in assets and liabilities of \$53.9 million. Non-cash items primarily included stock-based compensation of \$40.9 million and depreciation and amortization of \$17.5 million. The net change in assets and liabilities was primarily due to a decrease in accrued liabilities of \$17.2 million, an increase in prepaid expense and other

assets of \$5.2 million, a decrease in deferred revenue of \$37.1 million, and an increase in accounts payable of \$0.7 million, partially offset by an increase in deferred lease obligations of \$2.2 million, a decrease in accounts receivable of \$1.9 million and an increase in other liabilities of \$0.9 million.

Investing activities

Our primary investing activities consist of purchases, sales, and maturities of our investments and capital expenditures for manufacturing, laboratory, computer equipment and software.

Net cash used in investing activities for the nine months ended September 30, 2019 was \$145.3 million, which included purchases of marketable securities of \$949.3 million and capital expenditures of \$24.9 million, partially offset by proceeds from maturities of marketable securities of \$747.8 million and proceeds from sales of marketable securities of \$81.0 million.

Net cash used in investing activities for the nine months ended September 30, 2018 was \$379.3 million, which included purchases of marketable securities of \$951.2 million, and capital expenditures of \$92.1 million, partially offset by proceeds from maturities of marketable securities of \$493.5 million and proceeds from sales of marketable securities of \$170.5 million.

Financing activities

We generated cash from financing activities of \$23.5 million for the nine months ended September 30, 2019, primarily from \$19.5 million in net proceeds from the issuance of common stock through our equity plans and \$3.7 million in reimbursement of assets under our Norwood lease financing obligation.

We generated cash from financing activities of \$650.9 million for the nine months ended September 30, 2018, primarily from net proceeds from the issuance of redeemable convertible preferred stock of \$661.1 million.

Operation and funding requirements

Since our inception, we have incurred significant losses and negative cash flows from operations due to our significant research and development expenses. We have an accumulated deficit of \$1.37 billion as of September 30, 2019. We expect to continue to incur significant losses in the foreseeable future and expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development of our development candidates and clinical activities for our investigational medicines. In addition, we expect to incur additional costs associated with operating as a public company.

We are subject to all the risks related to the development and commercialization of novel medicines, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. 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 believe that our cash, cash equivalents, and investments as of September 30, 2019, will be sufficient to enable us to fund our projected operations through at least the next 12 months from the issuance of our financial statements.

Until we can generate a sufficient amount of revenue from our programs, we expect to finance future cash needs through public or private equity or debt offerings and potential future strategic alliances from which we receive upfront fees, milestone payments, and other forms of consideration. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back, or discontinue the development or commercialization of one or more of our investigational medicines, or slow down or cease work on one or more of our programs. If we raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders or increased fixed payment obligations, and any such securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise funds through strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or investigational medicines or grant licenses on terms that may not be favorable to us. Any of these events could significantly harm our business, financial condition, and prospects.

Contractual Obligations

As of September 30, 2019, other than disclosed at Note 7 to our condensed consolidated financial statements, there have been no material changes to our contractual obligations and commitments from those described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the Annual Report on Form 10-K for the year ended December 31, 2018.

Off balance sheet arrangements

As of September 30, 2019, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

JOBS Act and emerging growth company status

In April 2012, the JOBS Act was enacted. As an “emerging growth company,” or EGC under the JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include an exemption from the requirement to provide an auditor’s report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. Additionally, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an EGC we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not EGCs. As of June 30, 2019, we determined that we will become a large accelerated filer under the rules of the SEC and we will no longer be classified as an EGC as of December 31, 2019.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our primary exposure to market risk relates to changes in interest rates. As of September 30, 2019 and December 31, 2018, we had cash, cash equivalents, and investments in marketable securities of \$1.34 billion and \$1.69 billion, respectively. Our investment portfolio is comprised of money market funds and marketable debt securities (including U.S. Treasury securities, debt securities of U.S. government agencies and corporate entities, and commercial paper). Our primary investment objectives are the preservation of capital and the maintenance of liquidity and our investment policy defines allowable investments based on quality of the institutions and financial instruments designed to minimize risk exposure. Our exposure to interest rate sensitivity is affected by changes in the general level of U.S. interest rates. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase.

We generally hold investments in marketable debt securities to maturity to limit our exposure to interest rate risk. Due to the short-term maturities and low risk profiles of our investments, we do not anticipate a significant exposure to interest rate risk. If market interest rates were to increase immediately and uniformly by 100 basis points, or one percentage point, from levels at September 30, 2019, the net fair value of our interest sensitive marketable securities would not experience a material change in fair market value.

We currently do not have significant exposure to foreign currencies as we hold no foreign exchange contracts, option contracts, or other foreign hedging arrangements. Further, our operations and revenue generating activities are denominated in U.S. dollars. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the nine months ended September 30, 2019 and 2018.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and is accumulated and communicated to management, including the principal executive officer (our

Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Form 10-Q. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2019.

Changes in Internal Control over Financial Reporting

During the three months ended September 30, 2019, we implemented certain internal controls in connection with our adoption of ASC 606 on January 1, 2019. There were no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2019, which have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors

In addition to the other information set forth in this Form 10-Q, including under the heading “Special Note Regarding Forward-Looking Statements”, the risks and uncertainties that we believe are most important for you to consider are discussed in “Part I, Item 1A—Risk Factors” of our 2018 Form 10-K, which could adversely affect our business, financial condition, or results of operations. The risks described in our 2018 Form 10-K are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may adversely affect our business, financial condition, or results of operations. There are no material changes to the Risk Factors described in our 2018 Form 10-K.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Public Offering of Common Stock

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) of the Securities Act. We are holding the balance of the net proceeds in cash, cash equivalents, and investments. We invested the funds received in short-term, interest-bearing investment-grade securities and government securities.

Item 6. Exhibits

The Exhibits listed below are filed or incorporated by reference as part of this Form 10-Q.

Exhibit No.**Exhibit Index**

10.1	Fifth Amendment to Lease, by and between ModernaTx, Inc. and ARE-Tech Square, LLC dated as of August 28, 2019
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Link Document

+ The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certification will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) 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.

MODERNA, INC.

Date:
November 6, 2019

By: /s/ Stéphane Bancel

Stéphane Bancel
Chief Executive Officer and Director
(Principal Executive Officer)

Date:
November 6, 2019

By: /s/ Lorence Kim, M.D.

Lorence Kim, M.D.
Chief Financial Officer
(Principal Financial Officer)

FIFTH AMENDMENT TO LEASE

THIS FIFTH AMENDMENT TO LEASE (this "**Fifth Amendment**") is made as of August 28, 2019, by and between **ARE-TECH SQUARE, LLC**, a Delaware limited liability company ("**Landlord**"), and **MODERNATX, INC.**, a Delaware corporation, formerly known as Moderna Therapeutics, Inc. ("**Tenant**").

RECITALS

A. Landlord and Tenant are now parties to that certain Lease Agreement dated as of May 26, 2016, as amended by that certain First Amendment to Lease dated as of August 31, 2016, as further amended by that certain Second Amendment to Lease dated as of December 31, 2016, as further amended by that certain Third Amendment to Lease dated April 24, 2017, and as further amended by that certain Fourth Amendment to Lease dated as of April 13, 2018 (as amended, the "**Lease**"). Pursuant to the Lease, Tenant leases certain premises consisting of approximately 124,760 rentable square feet of space ("**Premises**") in that certain building located at 200 Technology Square, Cambridge, Massachusetts ("**Building**"). The Premises are more particularly described in the Lease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.

B. The Lease is currently scheduled to expire on December 31, 2027.

C. Landlord and Tenant are also parties to that certain Lease Agreement dated as of August 10, 2015, as the same has been amended by that certain letter agreement dated as of April 1, 2016 (as amended, the "**500 Building Lease**"), pursuant to which Tenant leases from Landlord approximately 61,618 rentable square feet ("**500 Premises**") in that certain building located at 500 Technology Square, Cambridge, Massachusetts. Concurrently with the mutual execution and delivery of this Fifth Amendment by Tenant, Landlord and Tenant are entering into an amendment to the 500 Building Lease (the "**500 Lease Amendment**") pursuant to which Tenant is required to surrender (i) a portion of the 500 Premises (the "**Initial 500 Surrender Premises**") on November 30, 2019 (the "**Initial 500 Surrender Date**"), and (ii) the balance of the 500 Premises (the "**Subsequent 500 Surrender Premises**") on April 30, 2020 (the "**Subsequent 500 Surrender Date**").

D. Landlord and Tenant desire, subject to the terms and conditions set forth below, to amend the Lease to (i) extend the Base Term of the Lease through December 31, 2029 (the "**Fifth Amendment Expiration Date**"), and (ii) make available a tenant improvement allowance to Tenant in the amount of \$2,346,000 for the design and construction of improvements by Tenant pursuant to the Work Letter attached hereto as **Exhibit A** ("**Fifth Amendment Work Letter**").

NOW, THEREFORE, in consideration of the foregoing Recitals, which are incorporated herein by this reference, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

- 1. Base Term.** The Base Term of the Lease is hereby extended with respect to the entire Premises through the Fifth Amendment Expiration Date. Tenant's occupancy of the Premises through the Fifth Amendment Expiration Date shall be on an "as-is" basis and, except as otherwise expressly provided in Section 3 below, Landlord shall have no obligation to provide any tenant improvement allowance or make any alterations to the Premises.
- 2. Base Rent.** Tenant shall continue to pay Base Rent as provided in the Lease through December 31, 2027. Thereafter, Base Rent shall continue to increase by the Rent Adjustment Percentage on each January 1st during the Base Term through the Fifth Amendment Expiration Date.



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Notwithstanding anything the contrary contained in the Lease or in this Fifth Amendment, so long as Tenant is not then-currently in default under the Lease or in default under the 500 Lease (beyond any applicable notice and cure periods), then Tenant shall receive a credit against Base Rent due under the Lease in the amount of \$620,000, which shall be applied to the Base Rent first coming due on December 1, 2019, and Base Rent coming due immediately thereafter until such rent credit is exhausted. If Tenant is in default under the Lease or in default under the 500 Lease as of December 1, 2019, and subsequently cures such default, Tenant shall receive such credit to Base Rent following Tenant's cure of such default, and such credit shall be applied to Base Rent commencing on the date that such default has been cured by Tenant.

Notwithstanding anything the contrary contained in the Lease or in this Fifth Amendment, so long as Tenant is not default under the Lease or in default under the 500 Lease (beyond any applicable notice and cure periods), then Tenant shall receive an additional credit against Base Rent due under the Lease in the amount of \$330,000, which shall be applied to the Base Rent first coming due on April 1, 2020, and Base Rent coming due immediately thereafter until such rent credit is exhausted. If Tenant is in default under the Lease or in default under the 500 Lease as of April 1, 2020, and subsequently cures such default, Tenant shall receive such credit to Base Rent following Tenant's cure of such default, and such credit shall be applied to Base Rent commencing on the date that such default has been cured by Tenant.

3. **Tenant Improvements.** Landlord shall make available a tenant improvement allowance to Tenant in the amount of \$2,346,000 for the design and construction of improvements by Tenant pursuant to the Fifth Amendment Work Letter.
4. **Brokers.** Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with the transaction reflected in this Fifth Amendment and that no Broker brought about this transaction, other than Jones Lang LaSalle. Landlord and Tenant each hereby agrees to indemnify and hold the other harmless from and against any claims by any Broker claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this Fifth Amendment.
5. **OFAC.** Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of the Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("**OFAC**") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "**OFAC Rules**"), (b) not listed on, and shall not during the term of the Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List or the Sectoral Sanctions Identifications List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.
6. **Miscellaneous.**
 - a. This Fifth Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Fifth Amendment may be amended only by an agreement in writing, signed by the parties hereto.
 - b. This Fifth Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective successors and assigns.



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c. This Fifth Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Fifth Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Except as amended and/or modified by this Fifth Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Fifth Amendment. In the event of any conflict between the provisions of this Fifth Amendment and the provisions of the Lease, the provisions of this Fifth Amendment shall prevail. Whether or not specifically amended by this Fifth Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Fifth Amendment.

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IN WITNESS WHEREOF, the parties hereto have executed this Fifth Amendment as of the day and year first above written.

TENANT:

MODERNATX, INC.,
a Delaware corporation

By: /s/ Stephane Bancel
Its: Chief Executive Officer

LANDLORD:

ARE-TECH SQUARE, LLC,
a Delaware limited liability company

By: ARE-MA REGION NO. 31, LLC,
a Delaware limited liability company,
its manager

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

By: /s/ Jackie Clem
Name: Senior Vice President
Title: RE Legal Affairs



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Exhibit A

Fifth Amendment Work Letter

THIS FIFTH AMENDMENT WORK LETTER (this "**Fifth Amendment Work Letter**") is incorporated into that certain Lease Agreement dated as of May 26, 2016 (the "**Original Lease**"), as amended by that certain First Amendment to Lease dated as of August 31, 2016, as further amended by that certain Second Amendment to Lease dated as of December 31, 2016, as further amended by that certain Third Amendment to Lease dated April 24, 2017, as further amended by that certain Fourth Amendment to Lease dated as of April 13, 2018, and as further amended by that certain Fifth Amendment to Lease of even date herewith (the "**Fifth Amendment**"), by and between **ARE-TECH SQUARE, LLC**, a Delaware limited liability company ("**Landlord**"), and **MODERNA THERAPEUTICS, INC.**, a Delaware corporation ("**Tenant**"). Any initially capitalized terms used but not defined herein shall have the meanings given them in the Lease.

1. General Requirements.

(a) **Tenant's Authorized Representative.** Tenant designates Juan Andres ("**Tenant's Representative**") as the only person authorized to act for Tenant pursuant to this Fifth Amendment Work Letter. Landlord shall not be obligated to respond to or act upon any request, approval, inquiry or other communication ("**Communication**") from or on behalf of Tenant in connection with this Fifth Amendment Work Letter unless such Communication is in writing from Tenant's Representative. Tenant may change Tenant's Representative at any time upon not less than 5 business days advance written notice to Landlord.

(b) **Landlord's Authorized Representative.** Landlord designates Tim White and Mike Carli (either such individual acting alone, "**Landlord's Representative**") as the only persons authorized to act for Landlord pursuant to this Fifth Amendment Work Letter. Tenant shall not be obligated to respond to or act upon any request, approval, inquiry or other Communication from or on behalf of Landlord in connection with this Fifth Amendment Work Letter unless such Communication is in writing from Landlord's Representative. Landlord may change either Landlord's Representative at any time upon not less than 5 business days advance written notice to Tenant.

(c) **Architects, Consultants and Contractors.** Landlord and Tenant hereby acknowledge and agree that the architect (the "**TI Architect**") for the Tenant Improvements (as defined in Section 2(a) below), the general contractor and any subcontractors for the Tenant Improvements shall be selected by Tenant, subject to Landlord's approval, which approval shall not be unreasonably withheld, conditioned or delayed. Landlord shall be named a third party beneficiary of any contract entered into by Tenant with the TI Architect, any consultant, any contractor or any subcontractor, and of any warranty made by any contractor or any subcontractor. Tenant may retain a third party project manager reasonably acceptable to Landlord to oversee the construction of the Tenant Improvements. The reasonable costs and fees of such project manager may be paid for out of the TI Fund (as defined in Section 5(d) below).

1. Tenant Improvements.

(a) **Tenant Improvements Defined.** As used herein, "**Tenant Improvements**" shall mean all improvements to the Premises desired by Tenant of a fixed and permanent nature. Other than funding the TI Allowance (as defined below) as provided herein, Landlord shall not have any obligation whatsoever with respect to the construct any improvements in the Premises. Landlord and Tenant acknowledge and agree that the Tenant Improvements may be constructed in multiple phases.

(b) **Tenant's Space Plans.** Tenant shall deliver to Landlord schematic drawings and outline specifications (the "**TI Design Drawings**") detailing Tenant's requirements for the Tenant Improvements.

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Not more than 5 business days thereafter, Landlord shall deliver to Tenant the written objections, questions or comments of Landlord and the TI Architect with regard to the TI Design Drawings. Tenant shall cause the TI Design Drawings to be revised to address such written comments and shall resubmit said drawings to Landlord for approval. Such process shall continue until Landlord has approved the TI Design Drawings.

(c) **Working Drawings.** Following the approval of the TI Design Drawings by Landlord, Tenant shall cause the TI Architect to prepare and deliver to Landlord for review and comment construction plans, specifications and drawings for the Tenant Improvements ("**TI Construction Drawings**"), which TI Construction Drawings shall be prepared substantially in accordance with the TI Design Drawings. Tenant shall be solely responsible for ensuring that the TI Construction Drawings reflect Tenant's requirements for the Tenant Improvements. Landlord shall deliver its written comments on the TI Construction Drawings to Tenant not later than 5 business days after Landlord's receipt of the same; provided, however, that Landlord may not disapprove any matter that is consistent with the TI Design Drawings. Tenant and the TI Architect shall consider all such comments in good faith and shall, within 5 business days after receipt, notify Landlord how Tenant proposes to respond to such comments. Any disputes in connection with such comments shall be resolved in accordance with Section 2(d) hereof. Provided that the design reflected in the TI Construction Drawings is consistent with the TI Design Drawings, Landlord shall approve the TI Construction Drawings submitted by Tenant. Once approved by Landlord, subject to the provisions of Section 4 below, Tenant shall not materially modify the TI Construction Drawings except as may be reasonably required in connection with the issuance of the TI Permit (as defined in Section 3(a) below).

(d) **Approval and Completion.** If any dispute regarding the design of the Tenant Improvements is not settled within 10 business days after notice of such dispute is delivered by one party to the other, Tenant may make the final decision regarding the design of the Tenant Improvements, provided (i) Tenant acts reasonably, (ii) that all costs and expenses resulting from any such decision by Tenant shall be payable out of the TI Fund, and (iii) Tenant's decision will not affect the base Building, structural components of the Building or any Building systems (in which case Landlord shall make the final decision). Any changes to the TI Construction Drawings following Landlord's and Tenant's approval of same requested by Tenant shall be processed as provided in Section 4 hereof.

2. **Performance of the Tenant Improvements.**

(a) **Commencement and Permitting of the Tenant Improvements.** Tenant shall commence construction of the Tenant Improvements upon obtaining and delivering to Landlord a building permit (the "**TI Permit**") authorizing the construction of the Tenant Improvements consistent with the TI Construction Drawings approved by Landlord. The cost of obtaining the TI Permit shall be payable from the TI Fund. Landlord shall assist Tenant in obtaining the TI Permit. Prior to the commencement of the Tenant Improvements, Tenant shall deliver to Landlord a copy of any contract with Tenant's contractors (including the TI Architect), and certificates of insurance from any contractor performing any part of the Tenant Improvement evidencing industry standard commercial general liability, automotive liability, "builder's risk", and workers' compensation insurance. Tenant shall cause the general contractor to provide a certificate of insurance naming Landlord, Alexandria Real Estate Equities, Inc., and Landlord's lender (if any) as additional insureds for the general contractor's liability coverages required above.

(b) **Selection of Materials, Etc.** Where more than one type of material or structure is indicated on the TI Construction Drawings approved by Tenant and Landlord, the option will be within Tenant's reasonable discretion if the matter concerns the Tenant Improvements, and within Landlord's sole and absolute subjective discretion if the matter concerns the structural components of the Building or any Building system.

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(c) **Tenant Liability.** Tenant shall be responsible for correcting any deficiencies or defects in the Tenant Improvements.

(d) **Substantial Completion.** Tenant shall substantially complete or cause to be substantially completed the Tenant Improvements in a good and workmanlike manner, in accordance with the TI Permit subject, in each case, to Minor Variations and normal "punch list" items of a non-material nature which do not interfere with the use of the Premises, respectively ("**Substantial Completion**" or "**Substantially Complete**"). Upon Substantial Completion of the Tenant Improvements in each phase of Tenant Improvements, Tenant shall require the TI Architect and the general contractor to execute and deliver, for the benefit of Tenant and Landlord, a Certificate of Substantial Completion in the form of the American Institute of Architects ("**AIA**") document G704. For purposes of this Fifth Amendment Work Letter, "**Minor Variations**" shall mean any modifications reasonably required: (i) to comply with all applicable Legal Requirements and/or to obtain or to comply with any required permit (including the TI Permit); (ii) to comport with good design, engineering, and construction practices which are not material; or (iii) to make reasonable adjustments for field deviations or conditions encountered during the construction of the Tenant Improvements.

3. **Changes.** Any changes requested by Tenant to the Tenant Improvements after the delivery and approval by Landlord of the TI Design Drawings, shall be requested and instituted in accordance with the provisions of this Section 4 and shall be subject to the written approval of Landlord, which approval shall not be unreasonably withheld, conditioned or delayed.

(a) **Tenant's Right to Request Changes.** If Tenant shall request changes ("**Changes**"), Tenant shall request such Changes by notifying Landlord in writing in substantially the same form as the AIA standard change order form (a "**Change Request**"), which Change Request shall detail the nature and extent of any such Change. Such Change Request must be signed by Tenant's Representative. Landlord shall review and approve or disapprove such Change Request within 5 business days thereafter, provided that Landlord's approval shall not be unreasonably withheld, conditioned or delayed.

(b) **Implementation of Changes.** If Landlord approves such Change and Tenant deposits with Landlord any Excess TI Costs (as defined in Section 5(d) below) required in connection with such Change, Tenant may cause the approved Change to be instituted. If any TI Permit modification or change is required as a result of such Change, Tenant shall promptly provide Landlord with a copy of such TI Permit modification or change.

4. **Costs.**

(a) **Budget For Tenant Improvements.** Before the commencement of construction of the Tenant Improvements, Tenant shall obtain a detailed breakdown, by trade, of the costs incurred or that will be incurred, in connection with the design and construction of the Tenant Improvements (the "**Budget**"), and deliver a copy of the Budget to Landlord. The Budget shall be based upon the TI Construction Drawings approved by Landlord.

(b) **TI Allowance.** Landlord shall provide to Tenant a "**TI Allowance**" in the maximum amount \$2,346,000, which is included in the Base Rent set forth in the Lease.

The TI Allowance shall be disbursed in accordance with this Fifth Amendment Work Letter. Except as provided in the immediately following paragraph, Tenant shall have no right to the use or benefit (including any reduction to Base Rent) of any portion of the TI Allowance not required for the construction of (i) the Tenant Improvements described in the TI Construction Drawings approved pursuant to Section 2(d) or (ii) any Changes pursuant to Section 4. Tenant shall have no right to any portion of the TI Allowance that is not disbursed before January 1, 2021.

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Notwithstanding anything to the contrary contained herein, Tenant may use all or any portion of the TI Allowance to construct Tenant Improvements, subject to all of the terms and conditions of this Fifth Amendment Work Letter, in that certain Premises leased by Tenant from Landlord pursuant to that certain Lease Agreement dated as of July 21, 2008, as amended by that certain First Amendment to Lease dated as of April 13, 2015, as further amended by that certain Second Amendment to Lease dated as of January 24, 2017, and as further amended by that certain Consent to Assignment and Third Amendment to Lease dated of even date herewith.

(c) **Costs Includable in TI Fund.** The TI Fund shall be used solely for the payment of design (including A&E drawings), permits and construction costs in connection with the construction of the Tenant Improvements, including, without limitation, the cost of electrical power and other utilities used in connection with the construction of the Tenant Improvements, the cost of preparing the TI Design Drawings and the TI Construction Drawings, all costs set forth in the Budget, including and the cost of Changes (collectively, "**TI Costs**"). Notwithstanding anything to the contrary contained herein, except as provided below, the TI Fund shall not be used to purchase any furniture, personal property or other non-Building system materials or equipment, including, but not be limited to, non-ducted biological safety cabinets and other scientific equipment not incorporated into the Tenant Improvements; provided, however, that the TI Fund may be used for Tenant's voice and data cabling, special electrical power distribution, telephone and security systems.

(d) **Excess TI Costs.** Landlord shall have no obligation to bear any portion of the cost of any of the Tenant Improvements except to the extent of the TI Allowance. If at any time and from time-to-time, the remaining TI Costs under the Budget exceed the remaining unexpended TI Allowance ("**Excess TI Costs**"), monthly disbursements of the TI Allowance shall be made in the proportion that the remaining TI Allowance bears to the outstanding TI Costs under the Budget, and Tenant shall fund the balance of each such monthly draw. For purposes of any litigation instituted with regard to such amounts, those amounts required to be paid by Tenant will be deemed Rent under the Lease. The TI Allowance and Excess TI Costs is herein referred to as the "**TI Fund**." Notwithstanding anything to the contrary set forth in this Section 5(d), Tenant shall be fully and solely liable for TI Costs and the cost of Minor Variations in excess of the TI Allowance.

(e) **Payment for TI Costs.** During the course of design and construction of the Tenant Improvements, Landlord shall reimburse Tenant for TI Costs once a month against a draw request in Landlord's standard form, containing evidence of payment of such TI Costs by Tenant and such certifications, lien waivers (including a conditional lien release for each progress payment and unconditional lien releases for the prior month's progress payments), inspection reports and other matters as Landlord customarily obtains, to the extent of Landlord's approval thereof for payment, no later than 30 days following receipt of such draw request. Upon completion of the Tenant Improvements (and prior to any final disbursement of the TI Fund), Tenant shall deliver to Landlord: (i) sworn statements setting forth the names of all contractors and first tier subcontractors who did the work and final, unconditional lien waivers from all such contractors and first tier subcontractors; (ii) as-built plans (one copy in print format and two copies in electronic CAD format) for such Tenant Improvements; (iii) a certification of substantial completion in Form AIA G704, (iv) a certificate of occupancy for the Premises; and (v) copies of all operation and maintenance manuals and warranties affecting the Premises.

5. **Miscellaneous.**

(a) **Consents.** Whenever consent or approval of either party is required under this Fifth Amendment Work Letter, that party shall not unreasonably withhold, condition or delay such consent or approval, except as may be expressly set forth herein to the contrary.

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(b) **Modification.** No modification, waiver or amendment of this Fifth Amendment Work Letter or of any of its conditions or provisions shall be binding upon Landlord or Tenant unless in writing signed by Landlord and Tenant.

(c) **Default.** Notwithstanding anything set forth herein or in the Lease to the contrary, Landlord shall not have any obligation to fund any portion of the TI Fund during any period Tenant is in Default under the Lease.

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**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**

CERTIFICATIONS

I, Stéphane Bancel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Moderna, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2019

By: /s/ Stéphane Bancel

Stéphane Bancel
Chief Executive Officer
(Principal Executive Officer)

**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**

CERTIFICATIONS

I, Lorence Kim, M.D. certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Moderna, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2019

By: /s/ Lorence Kim

Lorence Kim M.D.

Chief Financial Officer

(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of Moderna, Inc. (the “Company”) for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), we, Stéphane Bancel, Chief Executive Officer of the Company, and Lorence Kim, M.D., Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to our knowledge:

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

Date: November 6, 2019

By: /s/ Stéphane Bancel

Stéphane Bancel
Chief Executive Officer
(Principal Executive Officer)

Date: November 6, 2019

By: /s/ Lorence Kim

Lorence Kim, M.D.
Chief Financial Officer
(Principal Financial Officer)