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: 001-39083

Vir Biotechnology, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-2730369**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
499 Illinois Street, Suite 500, San Francisco, California	**94158**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 906-4324

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	VIR	Nasdaq Global Select Market

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

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

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

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

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

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

As of November 15, 2019, the registrant had 109,678,822 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future financial condition, future operations, research and development, planned clinical trials and preclinical studies, technology platforms, the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, the potential benefits of collaborations, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions described in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report. Other sections of this report may include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled "Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

VIR BIOTECHNOLOGY, INC.

Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	September 30, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 93,698	$ 47,598
Short-term investments	226,512	50,845
Restricted cash and cash equivalents, current	8,822	10,761
Prepaid expenses and other current assets	8,688	8,579
Total current assets	337,720	117,783
Intangible assets, net	35,999	36,917
Goodwill	16,937	16,937
Property and equipment, net	15,448	12,290
Restricted cash and cash equivalents, noncurrent	2,850	1,003
Other assets	13,688	6,666
TOTAL ASSETS	$ 422,642	$ 191,596
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable	$ 5,815	$ 6,473
Accrued liabilities	22,953	14,534
Deferred revenue, current portion	8,822	8,761
Advanced proceeds from preferred stock financing	—	10,140
Contingent consideration, current portion	6,726	—
Total current liabilities	44,316	39,908
Deferred revenue, noncurrent	8,408	6,561
Convertible preferred stock warrant liability	4,425	1,024
Contingent consideration, noncurrent	3,343	9,250
Deferred tax liability	3,305	3,305
Other long-term liabilities	3,030	1,588
TOTAL LIABILITIES	66,827	61,636
Commitments and contingencies (Note 7)		
Convertible preferred stock, $0.0001 par value; 421,450,000 shares authorized; 88,112,733 and 69,910,520 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively; aggregate liquidation preference of $675,567 and $333,058 as of September 30, 2019 and December 31, 2018, respectively	636,612	309,137
STOCKHOLDERS' DEFICIT:		
Common stock, $0.0001 par value; 558,350,000 shares authorized as of September 30, 2019 and December 31, 2018; 11,728,232 and 8,858,799 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	1	1
Additional paid-in capital	23,869	14,672
Accumulated other comprehensive income (loss)	81	(14)
Accumulated deficit	(304,748)	(193,836)
TOTAL STOCKHOLDERS' DEFICIT	(280,797)	(179,177)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT	$ 422,642	$ 191,596

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

VIR BIOTECHNOLOGY, INC.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Grant revenue	$ 1,166	$ 2,771	$ 6,771	$ 6,680
Contract revenue	237	114	340	862
Total revenue	1,403	2,885	7,111	7,542
Operating expenses:				
Research and development	39,863	29,837	95,541	78,256
General and administrative	9,220	7,394	25,790	21,182
Total operating expenses	49,083	37,231	121,331	99,438
Loss from operations	(47,680)	(34,346)	(114,220)	(91,896)
Other income (expense):				
Interest income	2,012	712	6,564	1,919
Other income (expense), net	(2,659)	178	(3,251)	(14)
Total other income (expense), net	(647)	890	3,313	1,905
Loss before benefit from (provision for) income taxes	(48,327)	(33,456)	(110,907)	(89,991)
Benefit from (provision for) income taxes	13	—	(5)	500
Net loss	$ (48,314)	$ (33,456)	$ (110,912)	$ (89,491)
Net loss per share, basic and diluted	$ (4.60)	$ (4.16)	$ (11.53)	$ (12.20)
Weighted-average shares outstanding, basic and diluted	10,500,848	8,043,283	9,615,379	7,333,986

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

VIR BIOTECHNOLOGY, INC.
Condensed Consolidated Statements of Comprehensive Loss
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Net loss	$ (48,314)	$ (33,456)	$ (110,912)	$ (89,491)
Other comprehensive income (loss):				
Unrealized gains (losses) on investments, net of tax	(159)	(25)	95	(41)
Other comprehensive income (loss)	(159)	(25)	95	(41)
Comprehensive loss	$ (48,473)	$ (33,481)	$ (110,817)	$ (89,532)

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

VIR BIOTECHNOLOGY, INC.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)
(unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Share	Amount	Share	Amount				
Balance at June 30, 2019	88,112,733	$ 636,612	9,722,838	$ 1	$ 19,226	$ 240	$ (256,434)	$ (236,967)
Issuance of common stock in connection with a license agreement	—	—	38,888	—	617	—	—	617
Repayment of promissory notes, net of unvested common stock	—	—	1,390,925	—	1,355	—	—	1,355
Vesting of restricted common stock	—	—	337,075	—	119	—	—	119
Exercise of stock options	—	—	238,506	—	364	—	—	364
Stock-based compensation	—	—	—	—	2,188	—	—	2,188
Other comprehensive loss	—	—	—	—	—	(159)	—	(159)
Net loss	—	—	—	—	—	—	(48,314)	(48,314)
Balance at September 30, 2019	88,112,733	$ 636,612	11,728,232	$ 1	$ 23,869	$ 81	$ (304,748)	$ (280,797)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Share	Amount	Share	Amount				
Balance at June 30, 2018	69,466,076	$ 307,186	7,515,382	$ 1	$ 11,701	$ (16)	$ (133,987)	$ (122,301)
Issuance of Series A-1 convertible preferred stock, net of issuance cost of $50	444,444	1,951	—	—	—	—	—	—
Vesting of restricted common stock	—	—	615,261	—	—	—	—	—
Exercise of stock options	—	—	209,621	—	311	—	—	311
Stock-based compensation	—	—	—	—	1,449	—	—	1,449
Other comprehensive loss	—	—	—	—	—	(25)	—	(25)
Net loss	—	—	—	—	—	—	(33,456)	(33,456)
Balance at September 30, 2018	69,910,520	$ 309,137	8,340,264	$ 1	$ 13,461	$ (41)	$ (167,443)	$ (154,022)

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

VIR BIOTECHNOLOGY, INC.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)
(unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Share	Amount	Share	Amount				
Balance at December 31, 2018	69,910,520	$ 309,137	8,858,799	$ 1	$ 14,672	$ (14)	$ (193,836)	$ (179,177)
Issuance of Series B convertible preferred stock, net of issuance cost of $165	18,202,213	327,475	—	—	—	—	—	—
Issuance of common stock in connection with a license agreement	—	—	38,888	—	617	—	—	617
Repayment of promissory notes, net of unvested shares	—	—	1,390,925	—	1,355	—	—	1,355
Vesting of restricted common stock	—	—	733,041		119	—	—	119
Exercise of stock options	—	—	706,579	—	1,066	—	—	1,066
Stock-based compensation	—	—	—	—	6,040	—	—	6,040
Other comprehensive income	—	—	—	—	—	95	—	95
Net loss	—	—	—	—	—	—	(110,912)	(110,912)
Balance at September 30, 2019	88,112,733	$ 636,612	11,728,232	$ 1	23,869	81	(304,748)	$ (280,797)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Share	Amount	Share	Amount				
Balance at December 31, 2017	65,944,430	$ 292,525	6,210,325	$ 1	$ 9,035	$ —	$ (77,952)	$ (68,916)
Issuance of Series A-1 convertible preferred stock, net of issuance cost of $182	3,222,220	14,269	—	—	—	—	—	—
Issuance of Series A-2 convertible preferred shares as consideration in asset acquisition	743,870	2,343	—	—	—	—	—	—
Vesting of restricted common stock	—	—	1,910,597	—	—	—	—	—
Exercise of stock options	—	—	219,342	—	325	—	—	325
Stock-based compensation	—	—	—	—	4,101	—	—	4,101
Other comprehensive loss	—	—	—	—	—	(41)	—	(41)
Net loss	—	—	—	—	—	—	(89,491)	(89,491)
Balance at September 30, 2018	69,910,520	$ 309,137	8,340,264	$ 1	$ 13,461	$ (41)	$ (167,443)	$ (154,022)

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

VIR BIOTECHNOLOGY, INC.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (110,912)	$ (89,491)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of property and equipment	—	198
Depreciation and amortization	2,435	1,025
Amortization of intangible assets	918	833
Amortization of premiums (accretion of discounts) on investments, net	(571)	(323)
Change in fair value of contingent consideration	819	1,850
Change in estimated fair value of convertible preferred stock warrant liability	3,401	(70)
Preferred stock issued in connection with asset acquisition	—	1,750
Common stock issued in connection with license agreement	617	—
Change in deferred income taxes	—	(500)
Stock-based compensation	6,040	4,101
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(109)	(3,348)
Other assets	(1,399)	(157)
Accounts payable	428	2,705
Accrued liabilities and other long-term liabilities	5,678	6,066
Deferred revenue	1,908	10,773
Net cash used in operating activities	(90,747)	(64,588)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(7,388)	(5,391)
Purchases of short-term investments	(495,934)	(105,240)
Maturities of short-term investments	320,933	35,810
Proceeds from sale of property and equipment	—	25
Asset acquisitions	—	(1,743)
Net cash used in investing activities	(182,389)	(76,539)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of offering costs related to initial public offering	(3,686)	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	317,335	14,215
Proceeds received from financing obligation	1,202	—
Payment of principal on financing lease obligations	(38)	—
Proceeds from repayment of promissory notes	3,265	—
Proceeds from exercise of stock options	1,066	325
Net cash provided by financing activities	319,144	14,540
Net increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents	46,008	(126,587)
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	59,362	188,921
Cash, cash equivalents and restricted cash and cash equivalents at end of period	$ 105,370	$ 62,334
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment purchases included in accounts payable and accrued liabilities	$ 200	$ 377
Issuance costs for convertible preferred stock included in accounts payable and accrued liabilities	$ —	$ 54
Issuance of preferred stock in connection with asset acquisition	$ —	$ 593
Deferred issuance costs incurred and not paid	$ 1,938	$ —
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH AND CASH EQUIVALENTS TO THE CONDENSED CONSOLIDATED BALANCE SHEETS:		
Cash and cash equivalents	$ 93,698	$ 47,670
Restricted cash and cash equivalents, current	8,822	13,661
Restricted cash and cash equivalents, noncurrent	2,850	1,003
Total cash, cash equivalents and restricted cash and cash equivalents	$ 105,370	$ 62,334

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

1. Organization

Vir Biotechnology, Inc. ("Vir" or the "Company") is a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. The Company's approach begins with identifying the limitations of the immune system in combating a particular pathogen, the vulnerabilities of that pathogen and the reasons why previous approaches have failed. The Company then brings to bear powerful technologies that the Company believes, individually or in combination, will lead to effective therapies.

Reverse Stock Split

On September 16, 2019, the Company's board of directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-4.5 reverse split ("Reverse Split") of shares of the Company's common and convertible preferred stock, which was effected on September 27, 2019. The par value per share and authorized shares of common stock and convertible preferred stock were not adjusted as a result of the Reverse Split. All of the share and per share information included in the accompanying condensed consolidated financial statements has been adjusted to reflect the Reverse Split.

Initial Public Offering

On October 10, 2019, the Company completed its initial public offering ("IPO") of its common stock. In connection with its IPO, the Company issued and sold 7,142,858 shares of its common stock at a price of $20.00 per share. As a result of the IPO, the Company received $127.2 million in net proceeds, after deducting underwriting discounts, commissions and estimated offering expenses. At the closing of the IPO, 88,112,733 shares of outstanding convertible preferred stock were automatically converted into 88,112,733 shares of common stock and a warrant to purchase244,444 shares of convertible preferred stock was converted into a warrant to purchase 244,444 shares of common stock.

The condensed consolidated financial statements as of September 30, 2019, including share and per share amounts, do not give effect to the IPO, the conversion of the convertible preferred stock into common stock, or the conversion of a preferred stock warrant into a warrant to purchase common stock and related reclassification into permanent equity, as the IPO and such conversions and reclassification into permanent equity were completed subsequent to September 30, 2019.

Need for Additional Capital

The Company has incurred net losses since inception and expects such losses to continue over the next several years. At September 30, 2019, the Company had an accumulated deficit of $304.7 million. Management expects to incur additional losses in the future to conduct research and development and recognizes the need to raise additional capital to fully implement its business plan. Prior to completing its IPO in October 2019, the Company financed its operations primarily through the sale and issuance of convertible preferred stock. The Company had $320.2 million of cash, cash equivalents and short-term investments at September 30, 2019. Based on the Company's business plans, management believes that its cash, cash equivalents and short-term investments as of September 30, 2019, together with the proceeds received from the IPO, will be sufficient to meet its obligations for at least the next 12 months from the issuance date of these condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and applicable rules and regulations of the Securities and Exchange Commission (the "SEC") regarding interim financial reporting. The condensed consolidated financial statements include the accounts of Vir and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's financial information. The condensed consolidated results of operations for the nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period.

Certain information and footnote disclosures typically included in the Company's annual consolidated financial statements have been condensed or omitted. As such, these interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2018 included in the prospectus dated October 10, 2019 that forms a part ofthe Company's Registration Statement on Form S-1 (File No. 333-233604), as filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act"), on October 11, 2019 (the "Prospectus").

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenue and expense during the reporting periods. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates. The most significant estimates in the Company's condensed consolidated financial statements relate to business combinations, accrued expenses, defined benefit pension plans, the valuation of convertible preferred stock and common stock, the valuation of stock options and the valuation allowance for deferred tax assets.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. Cash and cash equivalents are deposited in checking and sweep accounts at a financial institution. Such deposits may, at times, exceed federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company's investment policy limits investments to certain types of securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and short-term investments and issuers of the short-term investments to the extent recorded on the condensed consolidated balance sheets. As of September 30, 2019, the Company has no off-balance sheet concentrations of credit risk.

Investments

Investments include available-for-sale securities and are carried at estimated fair value. The Company's valuations of marketable securities are generally derived from independent pricing services based on quoted prices in active markets for similar securities at period end. Generally, investments with original maturities beyond three months at the date of purchase and which mature at, or less than 12 months from, the consolidated balance sheet date are considered short-term investments. Unrealized gains and losses deemed temporary in nature are reported as a component of accumulated comprehensive income (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income, on the condensed consolidated statements of operations.

The Company's Swiss subsidiary holds short-term structured deposits which include a feature that provides for the instrument to be settled in U.S. dollars or Swiss Francs (CHF) depending on the strike level set at the onset of the instrument compared to the U.S. dollars to CHF exchange rate at the settlement date. The Company has elected to account for these instruments using the fair value option with gains and losses recognized in earnings.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting and filing fees relating to an initial public offering, are capitalized. The Company has incurred $6 million in deferred offering costs relating to its IPO as of September 30, 2019. The deferred offering costs were offset against offering proceeds upon the completion of the IPO in October 2019. There were no deferred offering costs capitalized as of December 31, 2018.

Convertible Preferred Stock Warrant Liability

A freestanding warrant to purchase shares of Series A-1 convertible preferred stock at a future date was determined to be a freestanding instrument that was accounted for as a liability. At initial recognition, the Company recorded the convertible preferred stock warrant liability on the consolidated balance sheet at its estimated fair value. The warrant liability was subject to remeasurement at each reporting period, with changes in estimated fair value recognized as a component of other income (expense), net until the exercise of the convertible preferred stock warrant or conversion of such warrant into a warrant to purchase shares of common stock. Upon the completion of the IPO in October 2019, the warrant automatically converted into a warrant to purchase shares of common stock.

Recent Accounting Pronouncements Not Yet Adopted

In January 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-01, Financial Instrument—Overall (Subtopic 825-10) ("ASU 2016-01"), which requires entities to measure equity instruments at fair value and recognize any changes in fair value within the statement of operations. ASU 2016-01 is effective for the Company for the annual period beginning January 1, 2019, and the interim period beginning January 1, 2020. The Company is currently evaluating the impact of adopting ASU 2016-01 on the consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases ("Topic 842"). Topic 842 requires lessees to recognize all leases, including operating leases, on the balance sheet as a right-of-use asset and lease liability, unless the lease is a short-term lease. In July 2018, the FASB issued supplemental adoption guidance and clarification to Topic 842 within ASU 2018-10 Codification Improvements to Topic 842, Leases and ASU 2018-11, Targeted Improvements—Leases (Topic 842). This update provides an alternative transition method that allows entities to elect to apply the standard retrospectively as of the beginning of the latest period presented versus retrospectively as of the beginning of the earliest period presented. Topic 842 is effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted. The Company currently plans to adopt the standard on January 1, 2020 and is currently evaluating the impact of adopting Topic 842 on its consolidated financial statements and disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost, which includes the Company's financial instruments. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. In April 2019, the FASB issued ASU No. 2019-04, Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments ("ASU 2019-04"). ASU 2019-04 modified the accounting for available-for-sale debt securities, which must be individually assessed for credit losses when fair value is less than the amortized cost basis. In October 2019, the FASB affirmed a proposed ASU deferring the effective date of ASU 2016-13 for all entities except public companies that are not smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. This proposed ASU has not been finalized as of the date of this report. When finalized, the Company currently plans to adopt ASU 2016-13 effective January 1, 2023. The Company has not yet evaluated the impact of adopting this standard on the consolidated financial statements and disclosures.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles—Goodwill and Other: Simplifying the Test for Goodwill Impairment ("ASU 2017-04"), which simplifies the current requirements for testing goodwill for impairment by eliminating the second step of the two-step impairment test to measure the amount of an impairment loss. ASU 2017-04 is effective for the Company's interim and annual reporting periods beginning after December 31, 2021. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2017-04 will have on its consolidated financial statements and related disclosures. The Company currently plans to adopt ASU 2017-04 on January 1, 2020 and does not expect the adoption of ASU 2017-04 to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-14, Compensation—Retirement Benefits—Defined Benefit Plans—General (Subtopic 715-20): Disclosure Framework—Changes to the Disclosure Requirements for Defined Benefit Plans ("ASU 2018-14"). ASU 2018-14 added, removed and clarified disclosure requirements related to defined benefit pension and other postretirement plans. ASU 2018-14 is effective for the Company for fiscal years ending after December 15, 2021. Early adoption is permitted for all entities. The Company currently plans to adopt ASU 2018-14 in fiscal 2022 and is still evaluating the effect that ASU 2018-14 may have on its notes to consolidated financial statements.

3. Fair Value Measurements

The Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.
- Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amounts of the Company's financial instruments, including accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

Level 3 liabilities consist of contingent consideration and convertible preferred stock warrant liability. The estimated fair value of the contingent consideration was determined by calculating the probability-weighted milestone payments based on the assessment of the likelihood and estimated timing that certain milestones would be achieved. The fair value of the contingent consideration was estimated using discount rates between 14.6% to 17.7% as of September 30, 2019 and 16.8% to 20.3% as of December 31, 2018. The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. The increase in the estimated fair value of contingent consideration is primarily due to the decrease in the derived discount rate. See Note 4—Acquisitions.

The convertible preferred stock warrant liability is valued using the Black-Scholes option pricing model. The assumptions used to calculate the convertible preferred stock warrant liability are as follows:

	September 30, 2019	December 31, 2018
Exercise price	$ 4.50	$ 4.50
Expected term	7.0	7.7
Expected stock price volatility	88.8%	83.5%
Risk-free interest rate	1.6%	2.6%
Expected dividend yield	—	—

The following tables summarize the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy:

		September 30, 2019			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
		(in thousands)			
Assets:					
Money market funds[1]	Level 1	$ 97,892	$ —	$ —	$ 97,892
U.S. government treasuries	Level 2	226,354	158	—	226,512
Bank time deposits	Level 2	4,000	—	—	4,000
Total financial assets		$ 328,246	$ 158	$ —	$ 328,404
Liabilities:					
Convertible preferred stock warrant liability	Level 3	$ 4,425	$ —	$ —	$ 4,425
Contingent consideration	Level 3	10,069	—	—	10,069
Total financial liabilities		$ 14,494	$ —	$ —	$ 14,494

(1) Includes $11.7 million of restricted cash equivalents.

	Valuation Hierarchy	December 31, 2018			
		Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
		(in thousands)			
Assets:					
Money market funds(1)	Level 1	$ 43,600	$ —	$ —	$ 43,600
Structured deposits	Level 2	1,000	—	—	1,000
U.S. government treasuries	Level 2	49,859	—	(14)	49,845
Total financial assets		$ 94,459	$ —	$ (14)	$ 94,445
Liabilities:					
Convertible preferred stock warrant liability	Level 3	$ 1,024	$ —	$ —	$ 1,024
Contingent consideration	Level 3	9,250	—	—	9,250
Total financial liabilities		$ 10,274	$ —	$ —	$ 10,274

(1) Includes $11.8 million of restricted cash equivalents.

As of September 30, 2019, all of the Company's short-term investments were in an unrealized gain position. Total unrealized gains of $8.2 million were recorded in accumulated other comprehensive income (loss) at September 30, 2019. No securities have contractual maturities of longer than one year. There were no transfers between Levels 1, 2, or 3 for any of the periods presented.

The following table sets forth the changes in the estimated fair value of the Company's Level 3 financial liabilities (in thousands):

	Contingent Consideration	Warrant Liability	Total
Balance at December 31, 2018	$ 9,250	$ 1,024	$ 10,274
Changes in fair value	819	3,401	4,220
Balance at September 30, 2019	$ 10,069	$ 4,425	$ 14,494

4. Acquisitions

Acquisition of TomegaVax

In September 2016, the Company entered into an agreement and plan of merger ("TomegaVax Merger Agreement") to acquire all of the equity interests of TomegaVax, Inc. ("TomegaVax"). The primary asset purchased in the acquisition was an in-process cytomegalovirus ("CMV") vector-based vaccine platform for use in hepatitis B virus ("HBV"), human immunodeficiency virus ("HIV"), and tuberculosis ("TB"). The acquisition was accounted for as an asset purchase and the Company recorded the entire purchase price of $5.2 million in research and development expenses in 2016.

In connection with the entry into the TomegaVax Merger Agreement, the Company also entered into a letter agreement with TomegaVax (the "TomegaVax Letter Agreement"), which provides for certain payments to TomegaVax's former stockholders prior to September 2024, in each case so long as the Company is continuing to pursue the development of the TomegaVax technology. Under the terms of the TomegaVax Letter Agreement, the Company will be required to pay to the former stockholders of TomegaVax milestone payments of up to an aggregate of $30.0 million if the per share price of the Company's publicly traded common stock, or implied price per share of the Company's Series A-1 convertible preferred stock (or common stock upon conversion) upon a certain asset sale, merger or stock sale, is at least $45 (as adjusted in the case of any stock dividend, stock split or other similar recapitalization), with the amount of such payments determined by the share price and the stage of the Company's clinical development at the time of the relevant event triggering the payment. The share price of the Company's publicly traded common stock will be determined using the average of the daily volume-weighted average trading price of the Company's common stock for each trading day during a consecutive 90-day period. The foregoing payments are payable (i) during any date after the completion of an initial public offering by the Company or any successor or affiliate controlling the TomegaVax technology, provided that no payment will be due before the first anniversary of the initial public offering, (ii) upon the sale of all assets related to the TomegaVax technology or (iii) upon a merger or stock sale of the Company or any successor or affiliate controlling the TomegaVax technology, in each case subject to certain conditions with respect to the timing of the payments. The payments under the TomegaVax Letter Agreement can be made in cash or shares of the Company's common stock, at the discretion of the Company's board of directors. None of the milestones have been achieved as of September 30, 2019, therefore no amounts were recognized relating to the contingent consideration during the nine months ended September 30, 2019.

Acquisition of Humabs

In August 2017, the Company acquired all of the outstanding equity of Humabs Biomed SA ("Humabs"), a private Swiss company which discovers and develops monoclonal antibodies derived from individuals whose immune systems have successfully responded to major diseases. The Company acquired all of Humabs' rights, title and interest in and to substantially all of the assets of Humabs except for rights under certain license agreements with third-parties. The Company is obligated to pass-through to the former Humabs shareholders any amounts received by Humabs under such license agreements, net of any program expenses. The transaction was accounted for as an acquisition of a business. The estimated fair value of total consideration was $42.3 million at the acquisition date. The consideration paid consisted of $30.0 million in cash and 1,666,656 shares of common stock, valued at $2.5 million as of the date of the transaction, to former Humabs shareholders. The Company also agreed to pay additional amounts in cash upon the achievement of specified milestone events: (i) up to $135.0 million upon the achievement of clinical, regulatory and commercial milestones for an HBV product; and (ii) up to $105.0 million upon the achievement of clinical, regulatory and commercial milestones for another product. The estimated fair value of this contingent consideration was $6.3 million as of the date of acquisition. Payments will vary based on milestones that are reached. The final component of the consideration was acquired net working capital of $3.6 million.

The acquired developed technologies that have associated patents issued are classified as finite-lived intangible assets and are amortized on a straight-lined basis over their estimated remaining useful lives, generally between seven to 12 years. The Company also acquired indefinite-lived intangible asset consisting of in-process research and development. These assets will not be amortized until regulatory approval is obtained in a major market. At that time, the Company will determine the useful life of the asset and begin amortization. If the associated research and development effort is abandoned, the related in-process research and development assets will be written-off and an impairment charge recorded. As of September 30, 2019, there have been no such impairments. The estimated fair value of the intangible assets was determined using the replacement cost method. The excess of the purchase price over the estimated fair value of the net assets acquired was recorded as goodwill. None of the goodwill is expected to be deductible for income tax purposes. As of September 30, 2019, no goodwill impairment was identified.

Acquisition of Agenovir

In January 2018, the Company entered into an agreement and plan of merger (the "Agenovir Merger Agreement") with Agenovir Corporation ("Agenovir"), pursuant to which the Company purchased all equity interests of Agenovir. The primary assets purchased in the acquisition were in-process research and development programs in human papillomavirus ("HPV") and HBV using CRISPR/Cas9. The Company concluded that the assets acquired and liabilities assumed did not meet the definition of a business as a limited number of inputs were acquired but no substantive processes were acquired. As such, the acquisition was accounted for as an asset purchase.

As purchase consideration, the Company agreed to pay cash of $11.5 million and issued an aggregate of 555,537 shares of Series A-2 convertible preferred stock, valued at $1.8 million on the transaction date, to the former Agenovir stockholders. The Company also assumed certain liabilities of $1.3 million. The estimated fair value of the Company's Series A-2 convertible preferred stock was $3.15 per share as of the date of the transaction and was determined by management with the assistance of a third-party valuation specialist. The Company retained $2.0 million of the cash consideration as holdback to satisfy claims for indemnification, of which, $1.8 million was paid to Agenovir in April 2019. In addition to the equity, the Company incurred transaction costs of $0.7 million.

The Company allocated the purchase price of $15.3 million between property and equipment of $0.8 million and in-process research and development of $14.5 million, which was expensed as research and development expenses in the accompanying condensed consolidated statement of operations for the nine months ended September 30, 2018.

During a specified period following the closing of the Agenovir acquisition, the Company will be required to pay Agenovir's former stockholders up to $45.0 million in the aggregate for the achievement of specified development and regulatory milestones for the first HBV product, and if the Company elects to progress the HPV program, the Company will owe up to $45.0 million in the aggregate for the achievement of development and regulatory milestones for the first HPV product. In addition, during a specified period following the closing of the Agenovir acquisition, if the Company successfully commercializes one or more products arising from the HBV program or the HPV program, the Company will owe milestone payments for the achievement of specified levels of worldwide annual net sales of up to $90.0 million for products arising from each program, or up to $180.0 million in the aggregate, if the Company were to commercialize products from both the HBV program and the HPV program.

None of the milestones have been achieved as of September 30, 2019, therefore no amounts were recognized relating to the contingent consideration.

Acquisition of Statera

In February 2018, the Company entered into an agreement and plan of reorganization with Statera Health, LLC ("Statera"), pursuant to which the Company acquired all equity interests of Statera. The Company paid $0.9 million in cash and issued an aggregate of 188,333 shares of Series A-2 convertible preferred stock, valued at $0.6 million on the transaction date, to the former Statera stockholders as purchase consideration. The estimated fair value of the Company's Series A-2 convertible preferred stock was $3.15 per share as of the date of the transaction and was determined by management with the assistance of a third-party valuation specialist. The transaction was accounted for as an asset acquisition. The Company incurred transaction costs of $0.2 million.

The primary asset purchased was a cloud-based predictive analytics platform that translates clinical data into casual hypotheses of disease pathophysiology. The cloud-based predictive analytics platform was accounted for as developed technology and is classified as finite-lived intangible assets and is being amortized on a straight-lined basis over an estimated useful life of three years.

5. Grant, License and Collaboration Agreements

The Company is a party to various grant and customer contract agreements. Descriptions of the material agreements are included below.

Bill & Melinda Gates Foundation Grants

Campylo/EPEC/EAEC Grant

As part of the Company's acquisition of Humabs in August 2017, the Company acquired a grant agreement with the Bill & Melinda Gates Foundation pursuant to which it was awarded a grant totaling up to $4.7 million (the "2017 Grant"). The 2017 Grant supported the Company's discovery, characterization and selection of human monoclonal antibodies with pre-clinical efficacy against three enteric pathogens responsible for life-threatening diarrhea in neonates. The 2017 Grant expired on May 31, 2019.

Payments received in advance that were related to future research activities were deferred and recognized as revenue when the donor-imposed conditions were met, which was as the research and development activities were performed. The Company recognized grant revenue of nil and $0.8 million for the three months ended September 30, 2019 and 2018, and $0.9 million and $1.5 million for the nine months ended September 30, 2019 and 2018, respectively.

Human Immunodeficiency Virus ("HIV") Grant

On January 26, 2018, the Company entered into a grant agreement with the Bill & Melinda Gates Foundation pursuant to which it was awarded a grant totaling up to $12.2 million for its HIV program (the "HIV Grant"). The HIV Grant will remain in effect until June 30, 2020, unless earlier terminated by the Bill & Melinda Gates Foundation for the Company's breach, failure to progress the funded project, in the event of the Company's change of control, change in the Company's tax status, or significant changes in the Company's leadership that the Bill & Melinda Gates Foundation reasonably believes may threaten the success of the project.

Payments received in advance that are related to future research activities are deferred and recognized as revenue when the donor-imposed conditions are met, which is as the research and development activities are performed. The Company recognized grant revenue of $0.5 million and $0.8 million for the three months ended September 30, 2019 and 2018, respectively, and $3.4 million and $2.8 million for the nine months ended September 30, 2019 and 2018, respectively.

Tuberculosis ("TB") Grant

On March 16, 2018, the Company entered into a grant agreement with the Bill & Melinda Gates Foundation pursuant to which it was awarded a grant totaling up to $14.9 million for its TB program (the "TB Grant"). The TB Grant will remain in effect until June 30, 2020, unless earlier terminated by the Bill & Melinda Gates Foundation for the Company's breach, failure to progress the funded project, in the event of the Company's change of control, change in the Company's tax status, or significant changes in the Company's leadership that the Bill & Melinda Gates Foundation reasonably believes may threaten the success of the project.

Payments received in advance that are related to future research activities are deferred and recognized as revenue when the donor-imposed conditions are met, which is as the research and development activities are performed. The Company recognized grant revenue of $0.4 million and $1.0 million for the three months ended September 30, 2019 and 2018, respectively, and $1.8 million and $1.5 million for the nine months ended September 30, 2019 and 2018, respectively.

National Institutes of Health

As part of the Company's acquisition of TomegaVax in September 2016, the Company acquired grant agreements related to TomegaVax's research effort in infectious diseases and cancer that entitled them to several awards under the Small Business Innovation Research Program from the National Institutes of Health ("NIH"). Through September 30, 2019, the Company has acquired or been awarded grants from NIH totaling $5.1 million. These grants are cost plus fixed fee agreements in which the Company is reimbursed for its direct and indirect costs. Only costs that are allowable under certain government regulations and NIH's supplemental policy and procedure manual may be claimed for reimbursement, subject to government audit.

The Company recognized grant revenue of $0.2 million for each of the three months ended September 30, 2019 and 2018, and $0.7 million and $0.9 million for the nine months ended September 30, 2019 and 2018, respectively.

Brii Biosciences

In May 2018, the Company entered into an option and license agreement (the "Brii Agreement") with Brii Biosciences Limited (previously named BiiG Therapeutics Limited) ("Brii Bio Parent") and Brii Biosciences Offshore Limited ("Brii Bio"), pursuant to which the Company granted to Brii Bio, with respect to up to four of the Company's programs, an exclusive option to obtain exclusive rights to develop and commercialize compounds and products arising from such programs in China, Taiwan, Hong Kong and Macau (collectively, the "China Territory") for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection (the "Field of Use"). The Company's HBV small interfering ribonucleic acid ("siRNA") program being developed under the Alnylam Agreement (described below) is included within the Brii Agreement as a program for which Brii Bio may exercise one of its options. In partial consideration for the options granted by the Company to Brii Bio, Brii Bio Parent and Brii Bio granted the Company, with respect to up to four of Brii Bio Parent's or Brii Bio's programs, an exclusive option to be granted exclusive rights to develop and commercialize compounds and products arising from such Brii Bio programs in the United States for the Field of Use. The number of options that the Company may exercise for a Brii Bio program is limited to the corresponding number of options that Brii Bio exercises for a Vir program. As of September 30, 2019, no license option had been exercised.

As partial consideration for the Company's entry into the Brii Agreement, upon closing of Brii Bio Parent's Series A preferred stock financing, the Company received ordinary shares equal to 9.9% of the outstanding shares in Brii Bio Parent. As a result of Brii Bio's right to exercise one of its options for the Company's HBV siRNA program, under the terms of the Alnylam Agreement, as amended by a letter agreement with Alnylam, the Company will transfer to Alnylam a specified percentage of such equity consideration allocable to such program. The Company also received an option to purchase additional ordinary shares of Brii Bio Parent at a purchase price of $0.0001 per share in connection with additional Series A preferred stock issuances by Brii Bio Parent and an option to acquire shares of Brii Bio Parent's Series B preferred stock upon the occurrence of a Series B financing at the same purchase price paid by the other Series B investors.

With respect to programs for which Brii Bio exercises its options, Brii Bio will be required to pay the Company an option exercise fee for each such Vir program ranging from the mid-single-digit millions up to $20.0 million, determined based on the commercial potential of the licensed program. Brii Bio will also be required to pay regulatory milestone payments on a licensed product-by-licensed product basis ranging from the mid-single-digit millions up to $30.0 million, also determined based on the commercial potential of such program. Following commercialization, Brii Bio will be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products arising from each licensed program in the China Territory, up to an aggregate of $175.0 million per licensed program. Brii Bio also will pay royalties to the Company that range from the mid-teens to the high-twenties, as described below.

Upon exercise of each option for a Brii Bio program, the Company will be required to pay to Brii Bio an option exercise fee ranging from the low tens of millions to up to $50.0 million, determined based on the commercial potential of the licensed program. The Company will be required to make regulatory milestone payments to Brii Bio on a licensed product-by-licensed product basis ranging from the low tens of millions up to $100.0 million, also determined based on the commercial potential of such program. The Company will also be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products in the United States arising from each licensed program, up to an aggregate of $175.0 million per licensed program.

In addition, the Company is obligated under the Brii Agreement to pay Brii Bio tiered royalties based on net sales of products arising from the licensed programs in the United States, and Brii Bio is obligated to pay the Company tiered royalties based on net sales of products arising from the licensed programs in the China Territory. The rates of royalties payable by the Company to Brii Bio, and by Brii Bio to the Company, on net sales range from mid-teens to high-twenties. Each party's obligations to pay royalties expires, on a product-by-product and territory-by-territory basis, on the latest of 10 years after the first commercial sale of such licensed product in the United States or China Territory, as applicable; the expiration or abandonment of licensed patent rights that cover such product in the United States or China Territory, as applicable; and the expiration of regulatory exclusivity in the United States or the China Territory, as applicable. Royalty rates are subject to specified reductions and offsets.

The Brii Agreement will remain in force until expiration of all options or, if any option is exercised, expiration of all royalty payment obligations for all licensed products within such licensed program, unless terminated in its entirety or on a program-by-program basis by either party. Each party may terminate for convenience all rights and obligations with respect to any program for which it has an option, with 30 days' written notice (if the terminating party has not exercised an option for such program) or 180 days' notice (following the exercise of an option for such program). The Brii Agreement may also be terminated by either party for insolvency of the other party, and either party may terminate the Brii Agreement in its entirety or on a program-by-program basis for the other party's uncured material breach on 60 days' written notice (or 30 days' notice following failure to make payment).

The Company has determined that Brii Bio Parent and its wholly owned subsidiary Brii Bio are variable interest entities due to their reliance on future financing and having insufficient equity at risk. However, the Company does not have the power to direct activities which most significantly impact the economic success of these entities and is not considered the primary beneficiary of these entities. Therefore, the Company does not consolidate Brii Bio Parent or Brii Bio. The Company also determined that it does not exercise significant influence over Brii Bio Parent or Brii Bio. The investment in Brii Bio Parent was recorded at its initial estimated fair value of $6.6 million within other assets on the consolidated balance sheet and is subsequently accounted for under the cost method. The Company also recorded a contract liability of $6.6 million within deferred revenue, noncurrent; which represents the four options that the Company granted to Brii Bio. Revenue will be recognized when Brii Bio exercises its options or the options expire. As of September 30, 2019 and December 31, 2018, the carrying value of the investment in Brii Bio is $6.6 million, which is included in other assets on the consolidated balance sheets.

The Company's maximum exposure to loss under the Brii Agreement is represented by options to acquire licenses to develop and commercialize potential products and future milestone payments. The ultimate expense that the Company incurs under the Brii Agreement cannot be quantified at this time as the amount will vary based on the timing and outcome of research activities.

Alnylam

In October 2017, the Company entered into a collaboration and license agreement (the "Alnylam Agreement") with Alnylam Pharmaceuticals, Inc. ("Alnylam") for the development of siRNA products for the treatment of HBV and following the exercise of certain program options, the development and commercialization of siRNA therapeutic products directed to up to four other infectious disease targets selected by the Company. The technology licensed under the Alnylam Agreement forms the basis of the Company's siRNA technology platform.

Pursuant to the Alnylam Agreement, the Company obtained a worldwide, exclusive license to develop, manufacture and commercialize the HBV siRNA product candidates, including VIR-2218, for all uses and purposes other than agricultural, horticultural, forestry, aquaculture and other residential applications, such excluded fields, the Excluded Fields. In addition, Alnylam granted us an exclusive option, for each of the infectious disease siRNA programs directed to the Company's selected targets, to obtain a worldwide, exclusive license to develop, manufacture and commercialize siRNA products directed to the target of each such program for all uses and purposes other than the Excluded Fields. On a product-by-product basis for each product arising from the HBV and, following the Company's option exercise, the infectious disease programs, Alnylam has an exclusive option, exercisable during a specified period prior to the initiation of a Phase 3 clinical trial for each such product, to negotiate and enter into a profit-sharing agreement for such product.

The Company and Alnylam are jointly responsible for funding the initial research and development activities for VIR-2218 through completion of proof of concept studies. Prior to the exercise of the Company's option for each siRNA program directed to one of the Company's selected infectious disease targets, Alnylam is responsible for conducting all development activities, at the Company's expense, in accordance with an agreed upon development plan. Following the Company's exercise of an option for a program and payment of the program option exercise fee and any outstanding program costs due to Alnylam, the Company is solely responsible, at the Company's expense (subject to Alnylam's exercise of a profit-sharing option), for conducting all development, manufacture and commercialization activities for products arising from each such program. If Alnylam exercises a profit-sharing option for a product, the Company will negotiate the terms of such profit-sharing agreement, which will include sharing equally with Alnylam all subsequent costs associated with the development of such product, as well as the profits and losses in connection with such product, subject to reimbursement by Alnylam of a portion of specified development costs in certain circumstances.

Pursuant to the Alnylam Agreement, the Company paid Alnylam an upfront fee of $10.0 million and issued to Alnylam 1,111,111 shares of the Company's common stock. Both the upfront fee and the estimated fair value of the common stock were recognized as research and development expenses in 2017. Additionally, the receipt of consideration from Brii Bio as discussed above triggered a requirement under the Alnylam Agreement to transfer a portion of the consideration, consisting of equity in Brii Bio, to Alnylam. Accordingly, the Company recognized a liability of $0.8 million as of December 31, 2018, and a corresponding charge to research and development expenses. The liability of $0.8 million remained outstanding as of September 30, 2019.

Upon the achievement of a certain development milestone, the Company will also issue shares of the Company's common stock equal to the lesser of (i) 1,111,111 shares or (ii) a certain number of shares based on the Company's stock price at the time such milestone is achieved. The Company will be required to pay Alnylam up to $190.0 million in the aggregate for the achievement of specified development and regulatory milestones by the first siRNA product directed to HBV, and up to $115.0 million for the achievement of specified development and regulatory milestones by the first product directed to the target of each infectious disease siRNA program for which the Company exercised its option. Following commercialization, the Company will be required to pay to Alnylam up to $250.0 million in the aggregate for the achievement of specified levels of net sales by siRNA products directed to HBV and up to $100.0 million for the achievement of specified levels of net sales by products directed to the target of each infectious disease siRNA program for which the Company exercised its option. The Company may also be required to pay Alnylam tiered royalties at percentages ranging from the low double-digits to mid-teens on annual net sales of HBV products, and tiered royalties at percentages ranging from the high single-digits to the sub-teen double-digits on annual net sales of licensed infectious disease products, in each case subject to specified reductions and offsets. The royalties are payable on a product-by-product and country-by-country basis until the later of the expiration of all valid claims of specified patents covering such product in such country and 10 years after the first commercial sale of such product in such country. No such liabilities have been recorded as of September 30, 2019.

The term of the Alnylam Agreement will continue, on a product-by-product and country-by-country basis, until expiration of all royalty payment obligations under the Alnylam Agreement. If the Company does not exercise its option for an infectious disease program directed to one of its selected targets, the Alnylam Agreement will expire upon the expiration of the applicable option period with respect to such program. However, if Alnylam exercises its profit-sharing option for any product, the term of the Alnylam Agreement will continue until the expiration of the profit-sharing arrangement for such product. The Company may terminate the Alnylam Agreement on a program-by-program basis or in its entirety for any reason on 90 days' written notice. Either party may terminate the agreement for cause for the other party's uncured material breach on 60 days' written notice (or 30 days' notice for payment breach), or if the other party challenges the validity or enforceability of any patent licensed to it under the Alnylam Agreement on 30 days' notice.

The Company incurred $7.5 million and $1.6 million of expenses under the Alnylam Agreement during the three months ended September 30, 2019 and 2018, respectively, and $10.7 million and $7.1 million during the nine months ended September 30, 2019 and 2018, respectively.

Visterra

In August 2017, the Company entered into a collaboration, license and option agreement (the "Visterra Agreement") with Visterra, Inc. ("Visterra") to license Visterra's proprietary technology and to research, develop, and commercialize certain product candidates. Under the Visterra Agreement, the Company paid an upfront fee of $25.0 million, which was recognized as research and development expenses in 2017. The Company incurred $0.3 million and $2.6 million for the research and development activities under the Visterra Agreement during the three and nine months ended September 30, 2018. No expense was incurred under the Visterra Agreement during the three and nine months ended September 30, 2019. In July 2019, the Company notified Visterra of its intention to terminate the Visterra Agreement and return the rights to Visterra. The termination will be effective in November 2019.

Rockefeller University

In July 2018, the Company entered into an exclusive license agreement with The Rockefeller University ("Rockefeller"), which was amended in May 2019 (the "Rockefeller Agreement"). Pursuant to the Rockefeller Agreement, Rockefeller granted the Company a worldwide exclusive license under certain patent rights, and a worldwide non-exclusive license under certain materials and know-how covering certain antibody variants relating to a specified mutation leading to enhanced antibody function and utility, to develop, manufacture and commercialize infectious disease products covered by the licensed patents, or that involve the use or incorporation of the licensed materials and know-how, in each case for all uses and purposes for infectious diseases. The Company uses technology licensed under the Rockefeller Agreement in the Company's antibody platform and in the Company's product candidate VIR-3434.

The Company paid Rockefeller an upfront fee of $0.3 million for entry into the Rockefeller Agreement, and is required to pay annual license maintenance fees of $1.0 million, which will be creditable against royalties following commercialization. In addition, for achievement of specified development and regulatory milestone events, the Company will be required to pay up to $8.5 million with respect to the first infectious disease product for the HIV indication, up to $7.0 million with respect to each of the first four other infectious disease products with specified projected peak worldwide annual net sales, and up to $3.6 million with respect to any other infectious disease product. Following regulatory approval, the Company will be required to pay commercial success milestones of up to $40.0 million in the aggregate for the achievement of specified aggregate worldwide annual net sales of the first infectious disease product for the HIV indication and the first four infectious disease products with specified projected peak worldwide annual net sales. The Company will also be required to pay to Rockefeller a royalty at a low single-digit percentage rate on net sales of licensed products, subject to certain adjustments. The Company's obligation to pay royalties to Rockefeller will terminate, on a product-by-product and jurisdiction-by-jurisdiction basis, upon the latest of the expiration of the last valid claim of a licensed patent in such jurisdiction, the expiration of all regulatory exclusivity in such jurisdiction or 12 years following the first commercial sale of the applicable licensed product in such jurisdiction. The Company recognized $1.0 million of annual license maintenance fee as research and development expense during the nine months ended September 30, 2019.

The Rockefeller Agreement will remain in force, absent earlier termination, until the expiration of all of the Company's obligations to pay royalties to Rockefeller in all jurisdictions. The Company has the right to terminate the Rockefeller Agreement in its entirety, or in part, for any reason on 60 days' written notice to Rockefeller. Rockefeller may terminate the Rockefeller Agreement on 90 days' written notice for the Company's uncured material breach, or if the Company challenges the validity or enforceability of any of the licensed patents, or immediately in the event of the Company's insolvency. Rockefeller may also terminate the Rockefeller Agreement if the Company ceases to carry on business with respect to the rights granted to the Company under the agreement.

MedImmune

In September 2018, the Company entered into a license agreement ("2018 MedImmune Agreement") with MedImmune, LLC ("MedImmune"), pursuant to which the Company obtained a worldwide, exclusive license to develop and commercialize half-life extended versions of two specified antibodies under development by MedImmune that target influenza A and influenza B, respectively, for all uses in humans and animals. The Company is developing VIR-2482 using technology licensed under the 2018 MedImmune Agreement.

In consideration for the grant of the licenses under the 2018 MedImmune Agreement, the Company made an upfront payment to MedImmune of $10.0 million. The upfront fee was recognized as research and development expenses in the third quarter of 2018.

The Company will be obligated to make development, regulatory, and commercial milestone payments of up to $343.3 million in the aggregate relating to influenza A and influenza B products. MedImmune will also be entitled to receive tiered royalties based on net sales of products containing half-life extended versions of antibodies directed to influenza A and/or influenza B at percentages ranging from the mid-single-digits to sub-teen double-digits.

The 2018 MedImmune Agreement will remain in force until the expiration on a country-by-country and product-by-product basis of all of the Company's obligations to pay royalties to MedImmune. The Company may terminate the 2018 MedImmune Agreement in its entirety or on a product-by-product basis, for convenience, upon 120 days' notice. Either party may terminate the 2018 MedImmune Agreement for cause for the other party's uncured material breach on 60 days' notice or immediately in the event of bankruptcy of the other party. Additionally, MedImmune may terminate the 2018 MedImmune Agreement for cause on 30 days' written notice if the Company challenges the validity or enforceability of the patents to which the Company has obtained a license under the 2018 MedImmune Agreement.

In August 2019, the Company achieved one of the specified development milestones relating to influenza A pursuant to the 2018 MedImmune Agreement. As such, the Company paid $5.0 million related to this milestone event in September 2019. The milestone payment was expensed to research and development in the three and nine months ended September 30, 2019.

Xencor

In August 2019, the Company entered into a patent license agreement (the "Xencor Agreement") with Xencor, Inc., ("Xencor"). Pursuant to the Xencor Agreement, the Company obtained a non-exclusive, sublicensable (only to its affiliates and subcontractors) license to incorporate Xencor's half-life extension Fc region-related technologies into, and to evaluate, antibodies that target influenza A and HBV, and a worldwide, non-exclusive, sublicensable license to develop and commercialize products containing such antibodies incorporating such technologies for all uses, including the treatment, palliation, diagnosis and prevention of human or animal diseases, disorders or conditions. The Company is obligated to use commercially reasonable efforts to develop and commercialize an antibody product that incorporates Xencor's half-life extension Fc-related technologies, for each of the influenza A and HBV research programs. These technologies are used in the Company's VIR-2482 and VIR-3434 product candidates.

In consideration for the grant of the license, the Company paid Xencor an upfront fee. The upfront fee was recognized as research and development expenses in the third quarter of 2019. For each of the influenza A and HBV research programs, the Company will be required to pay Xencor development and regulatory milestone payments of up to $17.8 million in the aggregate, and commercial sales milestone payments of up to $60.0 million in the aggregate, for a total of up to $77.8 million in aggregate milestones for each program and $155.5 million in aggregate milestones for both programs. On a product-by-product basis, the Company will also be obligated to pay tiered royalties based on net sales of licensed products in the low single-digits. The royalties are payable, on a product-by-product and country-by-country basis, until the expiration of the last to expire valid claim in the licensed patents covering such product in such country.

The Xencor Agreement will remain in force, on a product-by-product and country-by-country basis, until expiration of all royalty payment obligations under the Xencor Agreement. The Company may terminate the Xencor Agreement in its entirety, or on a target-by-target basis, for convenience upon 60 days' written notice. Either party may terminate the Xencor Agreement for the other party's uncured material breach upon 60 days' written notice (or 30 days in the case of non-payment) or in the event of bankruptcy of the other party immediately upon written notice. Xencor may terminate the Xencor Agreement immediately upon written notice if the Company challenges, or upon 30 days' written notice if any of the Company's sublicensees challenge, the validity or enforceability of any patent licensed to the Company under the Xencor Agreement.

In August 2019, the Company achieved one of the specified development milestones pursuant to the Xencor Agreement. As such, the Company paid $0.8 million related to the upfront fee and this milestone event in September 2019. The milestone payment was expensed to research and development in the three and nine months ended September 30, 2019.

6. Balance Sheet Components

Property and Equipment, net

Property and equipment, net consists of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Lab equipment	$ 10,559	$ 7,538
Computer equipment	548	518
Furniture and fixtures	1,330	943
Leasehold improvements	7,162	3,114
Construction in progress	—	1,893
Property and equipment, gross	19,599	14,006
Less accumulated depreciation and amortization	(4,151)	(1,716)
Total property and equipment, net	$ 15,448	$ 12,290

Depreciation and amortization expenses was $0.9 million and $0.4 million for the three months ended September 30, 2019 and 2018, respectively, and $2.4 million and $1.0 million for the nine months ended September 30, 2019 and 2018, respectively.

Sale-Leaseback Transaction

In August 2019, the Company entered into a lease agreement whereby the Company sold various laboratory instruments, furniture, and other equipment for gross proceeds of $1.2 million to a bank and leased them back for a five-year term, collateralized by the underlying equipment. The Company determined it did not relinquish control of the assets to the buyer-lessor. Therefore, the Company accounted for the transaction as a failed sale-leaseback whereby the Company continues to depreciate the assets and recorded a financing obligation for the consideration received from the buyer-lessor. As of September 30, 2019, the current and long-term portions of the financing obligation were $0.2 million and $0.9 million, respectively. The current and long-term portions of the financing obligation are included within accrued liabilities and other long-term liabilities, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Payroll and related expenses	$ 6,813	$ 6,165
Research and development expenses	11,536	5,016
Restricted stock liability	1,672	—
Other professional and consulting expenses	1,199	694
Other accrued expenses	1,733	2,659
Total accrued liabilities	$ 22,953	$ 14,534

7. Commitments and Contingencies

Facility Leases

The Company has various lease arrangements for office and laboratory space located in California, Oregon and Switzerland with contractual lease periods expiring between 2020 and 2028. In April 2019, the Company executed an amendment to the lease related to the San Francisco facility and in June 2019, the Company executed a noncancelable operating lease for the South San Francisco facility. In addition, the Company entered into a sale-leaseback transaction in August 2019. See further discussion in Note 6—Balance Sheet Components.

Rent expense is recognized on a straight-line basis over the terms of the operating leases accordingly and the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability.

The following are the aggregate non-cancelable future minimum lease payments under operating and financing leases as of September 30, 2019 (in thousands):

Year Ending December 31:	Amounts
2019 (remaining three months)	$ 1,105
2020	4,273
2021	4,053
2022	4,138
2023 and thereafter	8,240
Total	$ 21,809

Rent expense for the three months ended September 30, 2019 and 2018 was $1.2 million and $0.9 million, respectively, and for the nine months ended September 30, 2019 and 2018 was $3.2 million and $3.1 million, respectively.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. In addition, the Company has entered into indemnification agreements with its directors and certain officers that may require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, no demands have been made upon the Company to provide indemnification under these agreements, and thus, there are no indemnification claims that the Company is aware of that could have a material effect on the Company's consolidated balance sheets, consolidated statements of operations, or consolidated statements of cash flows.

8. Related Party Transactions

In January 2017, the Company issued a promissory note to an executive officer and a promissory note to a director for an aggregate principal amount of $3.1 million with an interest rate of 1.97% per annum. Principal and interest under these notes were due the earlier of (i) December 31, 2025 or (ii) in an event of default. The entire principal amount was used to purchase 3,624,355 shares of restricted stock. The outstanding balance of these notes was $3.2 million as of December 31, 2018. In August 2019, in accordance with the terms of the notes, the Company received $3.3 million as repayment of the outstanding promissory notes and accrued interest. As the promissory notes were non-recourse in nature, they were accounted for as in-substance stock options. See further discussion in Note 11—Stock-Based Awards.

As a result of the Brii Agreement in May 2018, the Company holds a minority equity interest in Brii Bio through its parent company, Brii Bio Parent. Additionally, the Company's Chief Executive Officer and member of the board of directors as well as another member of the Company's board of directors serve on Brii Bio Parent's board of directors.

In January 2019, the Company issued 18,202,213 shares of Series B convertible preferred stock to existing Series A-1 preferred stockholders. See further discussion in Note 9—Convertible Preferred Stock.

9. Convertible Preferred Stock

Prior to the IPO, under the Company's amended and restated certificate of incorporation in effect as of September 30, 2019, the Company was authorized to issue two classes of shares: preferred stock and common stock. The preferred stock was issued in a series.

In June 2018, the Amended and Restated Series A-1 and B Purchase Agreement was amended (as amended, the "Amended A&R Series A-1 and B Purchase Agreement"), pursuant to which the Company sold an aggregate of 3,222,220 shares of Series A-1 convertible preferred stock at $4.50 per share for gross proceeds of $14.5 million in three closings (the "Additional Closings"): (i) 2,777,776 shares in two closings in June 2018; and (ii) 444,444 shares in July 2018. Pursuant to the Amended A&R Series A-1 and B Purchase Agreement, after the Additional Closings, the Company was authorized to sell up to 1,111,121 additional shares of Series A-1 convertible preferred stock in one or more additional closings.

In January 2019, pursuant to the Amended A&R Series A-1 and B Purchase Agreement, the Company sold an aggregate of 18,202,213 shares of Series B convertible preferred stock at $18.00 per share for gross proceeds of $327.6 million in two closings (the "Series B Closing"). The Company is authorized to sell up to 4,020,009 additional shares of Series B convertible preferred stock in one or more additional closings.

At September 30, 2019, convertible preferred stock consisted of the following (in thousands, except share and per share amounts):

	September 30, 2019				
	Shares Authorized	Shares Issued and Outstanding	Issuance Price per Share	Carrying Value	Liquidation Preference
Series A-1	310,350,000	67,611,100	$ 4.50	$ 303,224	$ 322,505
Series A-2	11,100,000	2,299,420	$ 2.57	5,913	10,968
Series B	100,000,000	18,202,213	$ 18.00	327,475	342,094
	421,450,000	88,112,733		$ 636,612	$ 675,567

At December 31, 2018, convertible preferred stock consisted of the following (in thousands, except share and per share amounts):

	December 31, 2018				
	Shares Authorized	Shares Issued and Outstanding	Issuance Price per Share	Carrying Value	Liquidation Preference
Series A-1	310,350,000	67,611,100	$ 4.50	$ 303,224	$ 322,100
Series A-2	11,100,000	2,299,420	$ 2.57	5,913	10,958
Series B	100,000,000	—	—	—	—
	421,450,000	69,910,520		$ 309,137	$ 333,058

The Company recorded its convertible preferred stock at the issuance price on the dates of issuance, net of issuance costs.

Certain purchasers of Series A-1 convertible preferred stock committed to purchase a pre-determined number of shares of Series B convertible preferred stock at a purchase price of $18.00 per share. In the event that any purchaser of Series A-1 convertible preferred stock did not purchase such number of shares of Series B convertible preferred stock it agreed to purchase pursuant to the Amended A&R Series A-1 and B Purchase Agreement, other than as a result of the nonfulfillment of conditions to such purchaser's obligation to purchase such shares, then (i) each share of Series A-1 convertible preferred stock and Series B convertible preferred stock (collectively, "Senior Preferred Stock") originally purchased by such purchaser would have automatically converted into 5% of the number of shares of common stock that would otherwise have been issuable upon conversion of such shares if the purchaser had elected to convert the shares to common stock and (ii) with respect to any shares of common stock outstanding at the time of a Series B Closing that were issued to the purchaser upon its conversion election of Senior Preferred Stock, 95% of the shares of common stock issued upon such conversion would have been canceled by the Company for no consideration. No such conversions have taken place because the relevant purchasers of Series A-1 convertible preferred stock had purchased the number of Series B convertible preferred stock as committed pursuant to the Amended A&R Series A-1 and B Purchase Agreement.

The convertible preferred stock is an equity instrument with various features, including convertibility and dividends. The Company determined that none of the features required bifurcation from the underlying shares, either because they are clearly and closely related to the underlying shares or because they do not meet the definition of a derivative. The Company did not separately account for the purchase rights of the shares of Series B convertible preferred stock described above as they were not freestanding from the associated shares of Series A-1 convertible preferred stock.

The holders of the convertible preferred stock had the following rights and preferences:

Dividend Rights

The holders of preferred stock were entitled to receive dividends, if and when declared by the Company's board of directors, at the rate of $0.27 per share per annum for each of Series A-1 convertible preferred stock and Series A-2 convertible preferred stock and $1.08 per share per annum for Series B convertible preferred stock, from and after the date of issuance of such shares. As of September 30, 2019, no such dividends were declared or accrued.

Conversion Rights

Each share of Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series B convertible preferred stock was convertible, at the option of the holder, into one share of common stock, subject to certain adjustments for dilution, if any, resulting from future stock issuances. Each share of Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series B convertible preferred stock automatically converted into shares of common stock at the then-effective conversion rate for such share either: (i) upon the closing of a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act, resulting in gross proceeds to the Company of not less than $200.0 million; or (ii) by vote or written consent of the holders of at least 60% of the then outstanding shares of Series A-1 convertible preferred stock and Series B convertible preferred stock. Additionally, in the event that any purchaser of Series A-1 convertible preferred stock did not purchase such number of shares of Series B convertible preferred stock it agreed to purchase pursuant to the Amended A&R Series A-1 and B Purchase Agreement, other than as a result of the nonfulfillment of conditions to such purchaser's obligation to purchase such shares, then (i) each share of Senior Preferred Stock originally purchased by such purchaser automatically converted into 5% of the number of shares of common stock that would otherwise have been issuable upon conversion of such shares should the purchaser have elected to convert the shares to common stock and (ii) with respect to any shares of common stock outstanding at the time of a Series B Closing that were issued to the purchaser upon its conversion election of Senior Preferred Stock, 95% of the shares of common stock issued upon such conversion would have been canceled by the Company for no consideration.

The conversion price for each series of preferred stock was subject to an adjustment in the event of stock split, stock dividend, combination or other similar recapitalization with respect to the common stock.

Voting Rights

Each holder of outstanding shares of preferred stock had voting rights equal to the whole number of shares of common stock into which such shares could have been converted as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Company's amended and restated certificate of incorporation, the holders of the Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series B convertible preferred stock voted together with the holders of common stock as a single class. Holders of shares of Series A-1 convertible preferred stock, voting as a separate class, were entitled to elect three directors of the Company prior to the date shares of Series B convertible preferred stock were issued (the "Series B Issuance Date") and were entitled to elect two directors of the Company after the Series B Issuance Date. The holders of shares of Series A-2 convertible preferred stock, voting as a separate class, were entitled to elect one director of the Company. The holders of shares of Series B convertible preferred stock, voting as a separate class, were entitled to elect one director of the Company. Holders of a majority of the outstanding shares of common stock and preferred stock, voting as a single class on an as-converted basis, were entitled to elect any remaining directors.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, as further defined in the Company's amended and restated certificate of incorporation, the holders of shares of Senior Preferred Stock then outstanding were entitled to be paid out of the assets of the Company available for distribution to its stockholders, on a *pari passu* basis and before any payment shall be made to the holders of Series A-2 convertible preferred stock and common stock, an amount per share equal to the greater of: (i) the original issue price of Senior Preferred Stock held plus any dividends accrued but unpaid, whether or not declared, together with any other dividends declared but unpaid thereon; or (ii) such amount per share as would have been payable if all shares of Senior Preferred Stock had been converted to common stock immediately prior to such liquidation, dissolution, winding up or deemed liquidation event. If assets of the Company available were insufficient to pay holders of Senior Preferred Stock the full amount they were entitled to, the holders of Senior Preferred Stock would have shared ratably in any distribution of the assets available for distribution in proportion to the amounts due such holders. After the payments of all preferential amounts required to the holders of shares of Senior Preferred Stock, the remaining assets of the Company would have been distributed among the holders of the shares of Series A-2 convertible preferred stock using the same distribution method as the Senior Preferred Stockholders. After the payments of all preferential amounts required to the holders of shares of Senior Preferred Stock and Series A-2 convertible preferred stock, the remaining assets of the Company available for distribution would have been distributed among the holders of the shares of common stock, pro rata based on the number of shares held by each such holder.

Redemption

The preferred stock was not redeemable at the option of the holder.

Classification

The Company has classified the convertible preferred stock as temporary equity on the consolidated balance sheets as the shares could have been redeemed upon the occurrence of certain change in control events that are outside the Company's control, including liquidation, sale or transfer of the Company. The Company has elected not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because it was uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences would have been made only when it became probable that such a liquidation would occur.

10. Convertible Preferred Stock Warrant Liability

In September 2016, the Company issued a warrant to purchase an aggregate of244,444 shares of the Company's Series A-1 convertible preferred stock with an exercise price of $4.50 per share in connection with the termination of a sponsor research agreement. The warrant was fully vested upon the issuance date and has an expiration date of September 11, 2026. The initial fair value of the warrant was calculated using the Black-Scholes pricing model and the following assumptions: volatility of 99.32%, expected term of 10 years, risk-free interest rate of1.68%, exercise price of $4.50 and dividend rate of0%. The fair value of the warrant was determined to be $4.4 million and $1.0 million as of September 30, 2019 and December 31, 2018, respectively. Upon the completion of the IPO in October 2019, the warrant automatically converted into a warrant to purchase 244,444 shares of common stock.

11. Stock-Based Awards

2016 Equity Incentive Plan

In September 2016, the Company adopted the 2016 Equity Incentive Plan (the "2016 Plan") for the issuance of incentive stock options ("ISO"), non-qualified stock options ("NSO"), stock appreciation rights ("SARs"), restricted stock and other stock awards, to employees, non-employee directors, and consultants under terms and provisions established by the Company's board of directors and approved by the stockholders.

Awards granted under the 2016 Plan expire no later than ten years from the date of grant. For ISO and NSO, the option price shall not be less than 100% of the estimated fair value on the date of grant. Options granted typically vest over a four-year period but may be granted with different vesting terms. For all stock options granted between July 2018 and July 2019, the Company incorporated reassessed fair values using hindsight for calculating stock-based compensation expense.

As of September 30, 2019, there were 1,880,604 shares available for the Company to grant under the 2016 Plan.

2019 Equity Incentive Plan

In September 2019, the Company's board of directors adopted, with the approval of its stockholders, the 2019 Equity Incentive Plan (the "2019 Plan") for the issuance of ISO, NSO, SARs, restricted stock, other stock awards and performance cash awards, to employees, non-employee directors, and consultants. The 2019 Plan became effective concurrent with the IPO.

Awards granted under the 2019 Plan expire no later than ten years from the date of grant. For ISO and NSO, the option price shall not be less than 100% of the estimated fair value on the date of grant. Options granted typically vest over a four-year period but may be granted with different vesting terms. There are 5,800,000 shares reserved for issuance under the 2019 Plan.

2019 Employee Stock Purchase Plan

In September 2019, the Company's board of directors adopted, with the approval of its stockholders, the 2019 Employee Stock Purchase Plan (the "2019 ESPP"). The 2019 ESPP Plan became effective on the completion of the Company's IPO.

The 2019 ESPP authorizes the issuance of 1,280,000 shares of the Company's common stock under purchase rights granted to its employees or to employees of any of the Company's designated affiliates. The number of shares of the Company's common stock reserved for issuance is subject to automatic increase at each calendar year pursuant to the terms of the 2019 ESPP.

Stock Option Activity

The following table summarizes option award activity under the 2016 Plan:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	5,044,924	$ 1.50	9.13	
Granted	2,331,293	7.49		
Exercised	(706,579)	1.50		
Forfeited	(352,694)	1.71		
Outstanding at September 30, 2019	6,316,944	3.70	8.86	$ 97,018
Vested and expected to vest at September 30, 2019	6,316,944	3.70	8.86	97,018
Vested and exercisable at September 30, 2019	1,479,126	$ 2.35	8.54	$ 24,714

Aggregate intrinsic value represents the difference between the Company's reassessed fair value of its common stock and the exercise price of outstanding options. During the three months ended September 30, 2019 and 2018, the estimated weighted-average grant date fair value of options granted was $7.64 and $1.82, respectively, and during the nine months ended September 30, 2019 and 2018, was $6.51 and $1.36 per share, respectively.

As of September 30, 2019, the Company expects to recognize the remaining unamortized stock-based compensation expense of $16.2 million related to stock options, over an estimated weighted average period of 3.3 years.

Stock Options Granted to Employees

The fair value of stock options granted to employees was estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Expected term of options (in years)	6.0	6.0	5.9 - 6.0	6.0
Expected stock price volatility	88.5%	87.6%	88.5% - 89.4%	87.6% - 88.1%
Risk-free interest rate	1.9%	2.8%	1.9% - 2.5%	2.5% - 2.9%
Expected dividend yield	—	—	—	—

The valuation assumptions were determined as follows:

Expected Term—The expected term represents the period that the options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term.

Expected Volatility—The expected volatility was determined by examining the historical volatilities for industry peers and using an average of historical volatilities of these industry peers as the Company's stock is not actively traded on any public markets during these periods.

Risk-Free Interest Rate—The Company based the risk-free interest rate over the expected term of the options based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant.

Expected Dividend Rate—The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its profit interest units in the foreseeable future.

Restricted Stock Activity

The following table summarizes restricted stock activity:

	Number of Shares	Weighted Average Fair Value at Date of Grant per Share
Unvested as of December 31, 2018	4,814,733	$ 1.15
Vested	(2,123,966)	1.01
Unvested as of September 30, 2019	2,690,767	$ 1.13

The unvested shares of restricted stock have not been included in the shares issued and outstanding.

In January 2017, the Company entered into a restricted stock purchase agreement with an executive officer and a restricted stock purchase agreement with a director whereby the executive officer and the director purchased an aggregate of 3,624,355 shares of restricted stock. The consideration for the restricted stock was the issuance of promissory notes which are non-recourse in nature and are accounted for as in-substance stock options. The Company measured compensation cost for these in-substance options based on their estimated fair value on the grant date using the Black-Scholes pricing model. The Company is recognizing compensation cost over the requisite service period with an offsetting credit to additional paid-in capital. In August 2019, in accordance with the terms of the notes, the Company received $3.3 million as repayment of the outstanding promissory notes and accrued interest. The Company recognized a liability of $1.8 million for the portion of the promissory note repayment which relates to restricted common stock subject to future vesting as of September 30, 2019. The Company will reduce the restricted stock liability as the common stock vests.

As of September 30, 2019, there was $1.6 million of total unrecognized compensation cost related to unvested restricted stock, all of which is expected to be recognized over a remaining weighted-average period of 1.1 years.

Stock-Based Compensation Expense

The following table sets forth the total stock-based compensation expense for all awards granted to employees and non-employees, including shares sold through the issuance of non-recourse promissory notes of which all the shares are considered to be options for accounting purposes in the Company's statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Research and development	$ 926	$ 279	$ 1,925	$ 735
General and administrative	1,262	1,170	4,115	3,366
Total stock-based compensation	$ 2,188	$ 1,449	$ 6,040	$ 4,101

12. Net Loss Per Share

As the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common securities outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	September 30,	
	2019	2018
Convertible preferred stock	88,112,733	69,910,520
Options issued and outstanding	6,316,944	4,800,440
Restricted shares subject to future vesting	2,690,767	5,151,810
Warrants to purchase convertible preferred stock	244,444	244,444
Total	97,364,888	80,107,214

13. Defined Benefit Pension and Other Postretirement Plans

Postretirement Benefits (Pension Plans) for Humabs

The Company's subsidiary, Humabs, provides its Swiss employees with mandatory cash balance pension benefits whereby employer and employee contributions are accumulated in individual accounts with interest to retirement or withdrawal, if earlier. The benefits are financed through the Swiss Life Collective BVG Foundation with Swiss Life Asset Management through two separate plans.

The expected rate of return on assets corresponds to the return on benefits expected to be provided under the insurance contractNet periodic pension cost includes the following components (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Service cost	$ 66	$ 65	$ 197	$ 196
Interest cost	8	5	24	17
Expected return on plan assets	(6)	(5)	(17)	(15)
Net funded status	$ 68	$ 65	$ 204	$ 198

14. Income Taxes

The Company's income tax provision for interim periods is determined using an estimate of the Company's annual effective tax rate, adjusted for discrete items arising in the quarter. The Company's effective tax rate differs from the U.S. statutory tax rate primarily due to valuation allowances on our deferred tax assets in all jurisdictions as it is more likely than not that the Company's deferred tax assets will not be realized.

During the three and nine months ended September 30, 2019, the Company recorded an immaterial tax provision related to international income taxes.

During the nine months ended September 30, 2018, the Company recorded a tax benefit of $0.5 million related to the reversal of deferred tax liability associated with the developed technology acquired from Statera.

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 in conjunction with our unaudited condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and notes thereto and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in the prospectus dated October 10, 2019 that forms a part of our Registration Statement on Form S-1 (File No. 333-233604), as filed with the Securities and Exchange Commission, or the SEC, pursuant to Rule 424(b) under the Securities Act of 1933, as amended, or the Securities Act, on October 11, 2019, or the Prospectus. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to the "Company", "Vir," "we," "us" and "our" refer to Vir Biotechnology, Inc. and its consolidated subsidiaries.

Overview

We are a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Infectious diseases are one of the leading causes of death worldwide and cause hundreds of billions of dollars of economic burden each year. We believe that now is the time to apply the recent and remarkable advances in immunology to combat infectious diseases. Our approach begins with identifying the limitations of the immune system in combating a particular pathogen, the vulnerabilities of that pathogen and the reasons why previous approaches have failed. We then bring to bear powerful technologies that we believe, individually or in combination, will lead to effective therapies.

We have assembled four technology platforms, focused on antibodies, T cells, innate immunity and small interfering ribonucleic acid, or siRNA, through internal development, collaborations and acquisitions. Our current development pipeline consists of product candidates targeting hepatitis B virus, or HBV, influenza A, human immunodeficiency virus, or HIV, and tuberculosis, or TB. VIR-2218, an HBV-targeting siRNA, is in an ongoing Phase 1/2 clinical trial and initial data have demonstrated substantial reduction of hepatitis B virus surface antigen, or HBsAg. Based on initial data, VIR-2218 has been generally well tolerated. Additionally, we have initiated a Phase 1/2 clinical trial for VIR-2482, a monoclonal antibody, or mAb, designed for the prevention of influenza A. We have built an industry-leading team that has deep experience in immunology, infectious diseases and product development. Given the global impact of infectious diseases, we are committed to developing cost-effective treatments that can be delivered at scale.

We were incorporated in April 2016 and commenced principal operations later that year. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, identifying, acquiring, developing and in-licensing our technology platforms and product candidates, and conducting preclinical studies and early clinical trials.

Prior to our initial public offering, or IPO, we funded our operations to date primarily from the issuance and sale of convertible preferred stock, and to a lesser extent from revenue from grant agreements with government-sponsored and private organizations, as well as research and development services. From our inception through September 30, 2019, we have raised aggregate net cash proceeds of $630.7 million from the sale of our convertible preferred stock. As of September 30, 2019, we had $320.2 million in cash, cash equivalents and short-term investments. In October 2019, we completed our IPO pursuant to which we issued 7,142,858 shares of our common stock at a price of $20.00 per share. We received net proceeds of $127.2 million from the IPO, after deducting underwriting discounts, commissions and estimated offering expenses. Based upon our current operating plan, we believe that the net proceeds from the IPO, together with our existing cash, cash equivalents and short-term investments as of September 30, 2019 will enable us to fund our operating expenses and capital expenditure requirements through at least the next 18 months from the issuance date of the condensed consolidated financial statements.

We have incurred significant operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future. We do not have any products approved for sale, we have not generated any revenue from the sale of products, and we do not expect to generate revenue from the sale of our product candidates until we complete clinical development, submit regulatory filings and receive approvals from the applicable regulatory bodies for such product candidates, if ever. Our net losses were $48.3 million and $33.5 million for the three months ended September 30, 2019 and 2018, respectively, and $110.9 million and $89.5 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $304.7 million. Our primary use of our capital resources is to fund our operating expenses, which consist primarily of expenditures related to identifying, acquiring, developing and in-licensing our technology platforms and product candidates, and conducting preclinical studies and early clinical trials, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We expect to continue to incur net operating losses for at least the next several years. In particular, we expect our expenses and losses to increase as we continue our research and development efforts, advance our product candidates through preclinical and clinical development, seek regulatory approval, prepare for commercialization, as well as hire additional personnel, protect our intellectual property and incur additional costs associated with being a public company. We also expect to increase the size of our administrative function to support the growth of our business. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We are currently manufacturing product candidates from three different platforms: antibodies, T cells and siRNAs. We have established our own internal chemistry, manufacturing and control, or CMC, capabilities and are working with contract development and manufacturing organizations, or CDMOs to supply our early stage product candidates in the near-term. We have completed our internal capacity build in process development, analytical development, quality, manufacturing and supply chain. Specifically, our San Francisco, California and Portland, Oregon facilities include laboratories that support process development, production of human cytomegalovirus, or HCMV research viral seed stock and selected quality control testing for our product candidates. We have established relationships with multiple CDMOs and have produced material to support preclinical studies and Phase 1 and Phase 2 clinical trials. Material for Phase 3 clinical trials and commercial supply will require large-volume, low-cost-of-goods production, and we are in discussions with additional large-scale CDMOs to plan for future scale-up and capacity.

Our License, Collaboration and Grant Agreements

We have entered into grant, license and collaboration arrangements with various third parties. For details regarding these and other agreements, see Note5 —Grant, License and Collaboration Agreements to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Our Acquisitions

We have completed various acquisitions. For details regarding our acquisitions, see Note 4—Acquisitions to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Components of Operating Results

Revenue

We do not have any products approved for sale, we have not generated any revenue from the sale of our products, and we do not expect to generate revenue from the sale of our product candidates until we complete clinical development, submit regulatory filings and receive approvals from the applicable regulatory bodies for such product candidates, if ever.

Our revenue consists of: (i) grant revenue; and (ii) contract revenue. Grant revenue is comprised of revenue derived from grant agreements with government-sponsored and private organizations. Contract revenue is comprised of revenue generated from research and development services.

Operating Expenses

Research and Development

To date, our research and development expenses have related primarily to discovery efforts and preclinical and clinical development of our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. We do not track research and development expenses by product candidate.

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- expenses related to license and collaboration agreements;
- personnel-related expenses, including salaries, benefits and stock-based compensation for personnel contributing to research and development activities;
- expenses incurred under agreements with third-party contract manufacturing organizations, contract research organizations, and consultants;
- clinical costs, including laboratory supplies and costs related to compliance with regulatory requirements; and
- other allocated expenses, including expenses for rent and facilities maintenance, and depreciation and amortization.

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance our product candidates into and through preclinical studies and clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors including: the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our clinical development costs may vary significantly based on factors such as:

- whether a collaborator is paying for some or all of the costs;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates; and
- the efficacy and safety profile of our product candidates.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses for personnel in executive, finance and other administrative functions, facilities and other allocated expenses, transaction costs associated related to acquisitions and other expenses for outside professional services, including legal, audit and accounting services, and insurance costs. Personnel-related expenses consist of salaries, benefits and stock-based compensation.

We expect our general and administrative expenses to increase substantially in absolute dollars for the foreseeable future as we continue to support our continued research and development activities, grow our business and, if any of our product candidates receive marketing approval, commercialization activities. We also anticipate incurring additional expenses associated with operating as a public company, including increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with the rules and regulations of the SEC and standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities and other administrative and professional services.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents and short-term investments.

Other Income (Expense), Net

Other income (expense), net consists of foreign currency transaction gains and losses and remeasurement gains and losses related to the convertible preferred stock warrant liability.

Benefit from (Provision for) Income Taxes

Benefit from income taxes consists of the partial release of the valuation allowance on net deferred tax assets triggered by the deferred tax liabilities recorded as a result of the acquisition of Statera in 2018. Provision for income taxes in 2019 consisted of immaterial international income tax.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the periods presented:

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2019	2018		2019	2018	
	(in thousands)					
Revenue:						
Grant revenue	$ 1,166	$ 2,771	$ (1,605)	$ 6,771	$ 6,680	$ 91
Contract revenue	237	114	123	340	862	(522)
Total revenue	1,403	2,885	(1,482)	7,111	7,542	(431)
Operating expenses:						
Research and development	39,863	29,837	10,026	95,541	78,256	17,285
General and administrative	9,220	7,394	1,826	25,790	21,182	4,608
Total operating expenses	49,083	37,231	11,852	121,331	99,438	21,893
Loss from operations	(47,680)	(34,346)	(13,334)	(114,220)	(91,896)	(22,324)
Other income (expense):						
Interest income	2,012	712	1,300	6,564	1,919	4,645
Other income (expense), net	(2,659)	178	(2,837)	(3,251)	(14)	(3,237)
Total other income (expense), net	(647)	890	(1,537)	3,313	1,905	1,408
Loss before benefit from (provision for) income taxes	(48,327)	(33,456)	(14,871)	(110,907)	(89,991)	(20,916)
Benefit from (provision for) income taxes	13	—	13	(5)	500	(505)
Net loss	$ (48,314)	$ (33,456)	$ (14,858)	$ (110,912)	$ (89,491)	$ (21,421)

Revenue

Total revenue was $1.4 million and $2.9 million for the three months ended September 30, 2019 and 2018, respectively and $7.1 million and $7.5 million for the nine months ended September 30, 2019 and 2018, respectively. The decrease in total revenue for the three months ended September 30, 2019 was primarily due to a decrease in revenue recognized under the Campylo/EPEC/EAEC grant with the Bill & Melinda Gates Foundation, which expired in May 2019, and the HIV and TB grants with the Bill & Melinda Gates Foundation due to timing of research activities under these grants. The decrease in total revenue for the nine months ended September 30, 2019 was primarily due to a decrease in contract revenue recognized for research and development services.

Research and Development Expenses

The following table shows the primary components of our research and development expenses for the periods presented:

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2019	2018		2019	2018	
			(in thousands)			
Licenses and collaborations	$ 12,666	$ 10,268	$ 2,398	$ 12,356	$ 32,964	$ (20,608)
Personnel	11,762	6,359	5,403	31,879	16,439	15,440
Contract manufacturing	2,193	4,595	(2,402)	14,987	7,802	7,185
Clinical costs	3,080	376	2,704	5,912	732	5,180
Other	10,162	8,239	1,923	30,407	20,319	10,088
Total research and development	$ 39,863	$ 29,837	$ 10,026	$ 95,541	$ 78,256	$ 17,285

Comparison of three months ended September 30, 2019 and 2018

Research and development expenses were $39.9 million and $29.8 million for the three months ended September 30, 2019 and 2018, respectively. This increase was primarily due to:

- personnel-related expenses increased by $5.4 million, which was primarily attributable to an increase in our headcount;
- clinical costs increased $2.7 million, which was primarily attributable to initiation of our first HBV clinical trial in November 2018 and preparation for our influenza A clinical trial;
- licenses and collaboration expenses increased by $2.4 million, which was attributable to an increase of $7.4 million related to our collaboration with Alnylam Pharmaceuticals, Inc., or Alnylam, the change in fair value of the contingent consideration from our acquisition of Humabs Biomed SA, and the issuance of common stock in connection with a license agreement in the third quarter of 2019, partially offset by a decrease of $5.0 million related to payments under our 2018 license agreement, or the 2018 MedImmune Agreement, with MedImmune, LLC; and
- other research and development expenses increased by $1.9 million, which was attributable to increases of $0.7 million in external research costs, $1.0 million in the allocation of facilities costs, and $0.2 million in supplies and equipment costs to support an increase in our headcount.

The increase was partially offset by a decrease of $2.4 million in contract manufacturing expense, which was primarily attributable to the manufacturing for HBV and influenza A drug products initiated in the first half of 2018 and completed in the second quarter of 2019.

Comparison of nine months ended September 30, 2019 and 2018

Research and development expenses were $95.5 million and $78.2 million for the nine months ended September 30, 2019 and 2018, respectively. This increase was primarily due to:

- personnel-related expenses increased by $15.4 million, which was primarily attributable to an increase in our headcount;
- other research and development expenses increased by $10.1 million, which was primarily attributable to increases of $4.8 million in external research costs, $2.8 million in the allocation of facilities costs, and $0.9 million in supplies and equipment costs to support an increase in our headcount;
- contract manufacturing expenses increased by $7.2 million, which was primarily attributable to an increase of manufacturing cost related to HBV and influenza A production of clinical materials for use in our preclinical studies and clinical trials; and
- clinical costs increased $5.2 million, which was primarily attributable to initiation of our first HBV clinical trial in November 2018 and preparation for our influenza A clinical trial.

This increase was partially offset by a decrease of $20.6 million in licenses and collaborations expense primarily attributable to decreases of $14.5 million related to our acquisition of Agenovir Corporation, or Agenovir, in the third quarter of 2018 and $5.0 million related to payments under the 2018 MedImmune Agreement.

General and Administrative Expenses

General and administrative expenses were $9.2 million and $7.4 million for the three months ended September 30, 2019 and 2018, respectively, and $25.8 million and $21.2 million for the nine months ended September 30, 2019 and 2018, respectively. The increase in both periods was primarily due to an increase in personnel-related expenses related to additional headcount and professional fees.

Interest Income

Interest income was $2.0 million and $0.7 million for the three months ended September 30, 2019 and 2018, respectively, and $6.6 million and $1.9 million for the nine months ended September 30, 2019 and 2018, respectively. The increase was due to higher cash, cash equivalents and short-term investment balances in the three and nine months ended September 30, 2019 compared to the same periods in 2018.

Other Income (Expense), Net

Other expense, net was $2.7 million for the three months ended September 30, 2019 compared to other income, net of $0.2 million for the three months ended September 30, 2018. We had other expense, net, of $3.3 million and $14,000 for the nine months ended September 30, 2019 and 2018, respectively. The increase in expense in both periods was related to the revaluation of the convertible preferred stock warrant liability.

Liquidity, Capital Resources and Capital Requirements

Sources of Liquidity

Prior to our IPO in October 2019, we funded our operations primarily through the sale and issuance of convertible preferred stock, and to a lesser extent from revenue from grant agreements with government-sponsored and private organizations, as well as research and development services. From our inception through September 30, 2019, we have raised aggregate net cash proceeds of $630.7 million from the sale of our convertible preferred stock. As of September 30, 2019, we had $320.2 million in cash, cash equivalents and short-term investments. Subsequently, on October 10, 2019, our registration statement on Form S-1 was declared effective by the SEC and our shares began trading on the Nasdaq Global Select Market on October 11, 2019. We sold an aggregate of 7,142,858 shares of our common stock at an initial offering price of $20.00 per share. As a result of the IPO, we received $127.2 million in net proceeds, after deducting underwriting discounts and commissions of approximately $10.0 million and offering expenses of approximately $5.6 million.

Our primary use of our capital resources is to fund our operating expenses, which consist primarily of expenditures related to identifying, acquiring, developing and in-licensing our technology platforms and product candidates, and conducting preclinical studies and early clinical trials, and to a lesser extent, general and administrative expenditures.

Future Funding Requirements

Based upon our current operating plan, we believe that the net proceeds from the IPO, together with our existing cash, cash equivalents and short-term investments as of September 30, 2019, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 18 months from the issuance date of the condensed consolidated financial statements. However, we will still need to raise substantial additional capital to fund the development of our product candidates. We anticipate raising additional capital through the sale of our equity securities, incurring debt, entering into collaboration, licensing or similar arrangements with third parties, or receiving research contributions, grants or other sources of financing to fund our operations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. There can be no assurance that sufficient funds will be available to us on attractive terms or at all. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of biotechnology products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing, progress and results of our ongoing preclinical studies and clinical trials of our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- our ability to establish and maintain collaboration, license, grant and other similar arrangements, and the financial terms of any such arrangements, including the timing and amount of any future milestone, royalty or other payments due thereunder;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- any expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other companies' product candidates and technologies.

Cash Flows

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

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (90,747)	$ (64,588)
Investing activities	(182,389)	(76,539)
Financing activities	319,144	14,540
Net increase (decrease) in cash and cash equivalents and restricted cash and cash equivalents	$ 46,008	$ (126,587)

Operating Activities

During the nine months ended September 30, 2019, net cash used in operating activities was $90.7 million. This consisted primarily of a net loss of $110.9 million, partially offset by a decrease in our net operating assets of $6.4 million and non-cash charges of $13.7 million. The change in our net operating assets of $6.4 million was primarily driven by an increase in accrued liabilities related to expenses incurred under the Alnylam Agreement. The non-cash charges of $13.7 million primarily consisted of $6.0 million for stock-based compensation expense, $3.4 million for revaluation of convertible preferred stock liability, and $3.4 million for depreciation and amortization expense.

During the nine months ended September 30, 2018, net cash used in operating activities was $64.6 million. This consisted primarily of a net loss of $89.5 million, partially offset by a decrease in our net operating assets of $16.0 million and non-cash charges of $8.9 million. The change in our net operating assets of $16.0 million was primarily due to an increase in deferred revenue of $10.8 million related to upfront payments received from the Bill & Melinda Gates Foundation grants and increases in accounts payable, accrued liabilities and other long-term liabilities of $8.8 million as we expanded our operations, which was partially offset by an increase of $3.3 million in prepaid and other current assets primarily related to prepaid research expenses. The non-cash charges of $8.9 million primarily consisted of $4.1 million for stock-based compensation expense, $1.9 million for change in fair value of contingent consideration and $1.8 million for the preferred stock issued in connection with our acquisition of Agenovir.

Investing Activities

During the nine months ended September 30, 2019, cash used in investing activities was $182.4 million. This consisted of purchases of short-term investments of $495.9 million and purchases of property and equipment of $7.4 million, partially offset by $320.9 million in proceeds received from short-term investments which matured during the period.

During the nine months ended September 30, 2018, cash used in investing activities was $76.5 million. This consisted primarily of purchases of short-term investments of $105.2 million and purchases of property and equipment of $5.4 million, partially offset by $35.8 million in proceeds received from short-term investments which matured during the period.

Financing Activities

During the nine months ended September 30, 2019, cash provided in financing activities was $319.1 million. This consisted primarily of net proceeds received from the issuance of our Series B convertible preferred stock of $317.3 million in January 2019.

During the nine months ended September 30, 2018, cash provided in financing activities was $14.5 million. This consisted primarily of net proceeds received from the issuance of our Series A-1 convertible preferred stock of $14.2 million.

Contractual Obligations and Commitments

Except as discussed in Note 7—Commitments and Contingencies, there have been no material changes from the contractual obligations previously disclosed in our Prospectus.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules of the SEC. Brii Biosciences Limited, or Brii Bio Parent, and its wholly owned subsidiary Brii Biosciences Offshore Limited, or Brii Bio, are variable interest entities due to their reliance on future financing and insufficient equity at risk. However, we do not have the power to direct activities which most significantly impact the economic success of these entities and are not the primary beneficiary, and therefore we do not consolidate Brii Bio Parent or Brii Bio.

JOBS Act Accounting Election

We are an "emerging growth company," as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

We have elected to use this extended transition period to enable us to get comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Critical Accounting Policies and Estimates

Our unaudited condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of our unaudited condensed consolidated financial statements requires us to make assumptions and estimates about future events and apply judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the related disclosures. We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

There have been no material changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in the Prospectus.

Recent Accounting Pronouncements Not Yet Adopted

See Note 2—Summary of Significant Accounting Policies to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities.

Interest Rate Risk

We had cash and cash equivalents and restricted cash and cash equivalents of $105.4 million as of September 30, 2019, which consisted of bank deposits and money market funds. We also had short-term investments of $226.5 million as of September 30, 2019. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We had no debt outstanding as of September 30, 2019.

Foreign Currency

The functional currency of our foreign subsidiaries is the U.S. dollar. Monetary assets and liabilities of our foreign subsidiaries are translated into U.S. dollars at period-end exchange rates and non-monetary assets and liabilities are translated to U.S. dollars using historical exchange rates. Revenue and expenses are translated at average rates throughout the respective periods. As of the date of this Quarterly Report on Form 10-Q, we are exposed to foreign currency risk related to the operations of our Swiss subsidiary and consequently the Swiss Franc. Transaction gains and losses are included in other income (expenses), net on the condensed consolidated statements of operations and were not material for the three and nine months ended September 30, 2019 and 2018.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until after the filing of our Annual Report on Form 10-K for the year ended December 31, 2020. As a result, this Quarterly Report on Form 10-Q does not address whether there have been any changes in our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and/or prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. You should consider all of the risk factors described when evaluating our business.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future and may never achieve or maintain profitability.

Since inception in April 2016, we have incurred significant net losses and have never generated any revenue from product sales. Our net loss was $110.9 million and $89.5 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $304.7 million. Although we completed our IPO in October 2019 raising net proceeds of $127.2 million after deducting underwriting discounts, commissions and estimated offering expenses, we expect to continue to incur significant expenses and increasing net losses for the foreseeable future. Since inception, we have devoted substantially all of our efforts to identifying, researching and conducting preclinical and clinical activities of our product candidates, acquiring and developing our technology platforms and product candidates, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio. To date, we have never obtained regulatory approval for, or commercialized, any products. It could be several years, if ever, before we have a commercialized product. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue the ongoing and planned development of our product candidates;
- initiate, conduct and complete any ongoing, anticipated or future preclinical studies and clinical trials for our current and future product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any current or future product candidate for which we may obtain marketing approval;
- seek to discover and develop additional product candidates;
- continue to build a portfolio of product candidates through the acquisition or in-license of products, product candidates or technologies;
- maintain, protect and expand our intellectual property portfolio;
- make milestone payments if we successfully achieve certain predetermined milestones under existing or future agreements;
- hire additional clinical, regulatory and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional costs associated with operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our current and future product candidates, obtaining regulatory approval, procuring commercial-scale manufacturing, marketing and selling any products for which we obtain regulatory approval (including through third parties), as well as discovering or acquiring and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is sufficient to offset our expenses and achieve profitability.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage company founded in April 2016 and our operations to date have been largely focused on identifying, researching and conducting preclinical and clinical activities of our product candidates, acquiring and developing our technology platforms and product candidates, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio. As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization or arrange for a third party to conduct these activities on our behalf. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We currently have four technology platforms and five product candidates in our development pipeline. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives, including with respect to our technology platforms and product candidates. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Even after IPO, we will require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

As of September 30, 2019, we had cash, cash equivalents and short-term investments of $320.2 million. We believe that the net proceeds from the IPO, together with our existing cash, cash equivalents and short-term investments as of September 30, 2019, will fund our current operating plans through at least the next 18 months from the issuance date of the condensed consolidated financial statements. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. We expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. Our future capital requirements will depend on many factors, including:

- the timing, progress and results of our ongoing preclinical studies and clinical trials of our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- our ability to establish and maintain collaboration, license, grant and other similar arrangements, and the financial terms of any such arrangements, including timing and amount of any future milestones, royalty or other payments due thereunder;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- any expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other companies' product candidates and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether terminate our research and development programs or future commercialization efforts, which may adversely affect our business, financial condition, results of operations and prospects. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and collaborations and strategic alliances, or any combination of these approaches. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest in our company may be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations or strategic alliances, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Risks Related to the Development and Commercialization of Our Product Candidates

Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of our product candidates in a timely manner. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate product revenue will be adversely affected.

We have invested a significant portion of our time and financial resources in the development of VIR-2218, VIR-3434, VIR-2482, VIR-1111 and VIR-2020. Our business is dependent on our ability to successfully complete development of, obtain regulatory approval for, and, if approved, successfully commercialize our product candidates in a timely manner. We may face unforeseen challenges in our product development strategy, and we can provide no assurances that our product candidates will be successful in clinical trials or will ultimately receive regulatory approval.

We have only recently initiated clinical trials for two product candidates. We have not obtained regulatory approval for any product candidate, and it is possible that any product candidates we may seek to develop in the future will not obtain regulatory approval. Neither we nor any current or future collaborator is permitted to market any product candidates in the United States or abroad until we receive regulatory approval from the U.S. Food and Drug Administration, or the FDA, or applicable foreign regulatory agency. The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign regulatory authorities is unpredictable and typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Prior to obtaining approval to commercialize any product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidate is safe and effective for its intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program, requiring their alteration.

Of the large number of products in development, only a small percentage successfully complete the FDA's or comparable foreign regulatory authorities' approval processes and are commercialized. The lengthy approval or marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval or marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical testing and receive approval of a new drug application, or NDA, biologics license application, or BLA, or foreign marketing application for our product candidates, the FDA or the comparable foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

In addition, the FDA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Furthermore, even if we obtain regulatory approval for our product candidates, we may still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors, including government health administration authorities. If we are unable to successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

The development of additional product candidates is risky and uncertain, and we can provide no assurances that we will be able to replicate our approach for other diseases.

A core element of our business strategy is to expand our product pipeline. Efforts to identify, acquire or in-license, and then develop product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our efforts may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development, approved products or commercial revenue for many reasons, including the following:

- the methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render any product candidates we develop obsolete;
- any product candidates we develop may be covered by third parties' patents or other exclusive rights;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by physicians, patients, the medical community or third-party payors.

We have limited financial and management resources and, as a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in circumstances under which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, we may not be successful in replicating our approach to development for other disease indications. If we are unsuccessful in identifying and developing additional product candidates or are unable to do so, our business may be harmed.

We are developing, and in the future may develop, other product candidates in combination with other therapies, which exposes us to additional risks.

We are developing VIR-2218 and VIR-3434 for the functional cure of hepatitis B virus, or HBV. Each of these product candidates has the potential to stimulate an effective immune response and also has direct antiviral activity against HBV. We believe that a functional cure for HBV will require an effective immune response, in addition to antiviral activity, based on the observation that severe immunosuppression can reactivate HBV disease. Monotherapy with each of these agents may provide a functional cure in some patients, while combination therapy may be necessary for others. We are planning trials that combine VIR-2218 with VIR-3434, as well as combine VIR-2218 with other immunotherapy agents and direct acting antiviral agents. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate. There is also a risk that safety, efficacy, manufacturing or supply issues could arise with these other existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals.

Success in preclinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical studies and Phase 1 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired characteristics in clinical development sufficient to obtain regulatory approval, despite positive results in preclinical studies or having successfully advanced through earlier clinical trials.

A trial design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of trials with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, making the trial results less reliable than trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct clinical trials with a small number of patients, we may not achieve a statistically significant result or the same level of statistical significance, if any, that would have been possible to achieve in a larger trial.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Clinical product development involves a lengthy and expensive process. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA or other comparable regulatory authority, and we may never receive such approvals. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including the following:

- delays in reaching a consensus with regulatory authorities on the design or implementation of our clinical trials;
- regulators or institutional review boards and ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites;
- delays of failures by our manufacturing partners to comply with current good manufacturing practices, or cGMP;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or fail to return for post-treatment follow-up or we may fail to recruit suitable patients to participate in a trial;
- clinical trials of our product candidates may produce negative or inconclusive results;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical trial operations, trial sites or manufacturing facilities;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs.

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

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

- be delayed in obtaining marketing approval, or not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;

- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

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

Furthermore, our product candidates are based on certain innovative technology platforms, which makes it even more difficult to predict the time and cost of product candidate development and obtaining regulatory approval, particularly for our small interfering ribonucleic acid, or siRNA, and cytomegalovirus, or CMV, vector technologies. Relatively few siRNA product candidates have ever been tested in humans and to date, we are only aware of one siRNA, ONPATTRO (*patisiran*) in 2018 (developed by Alnylam Pharmaceuticals, Inc., or Alnylam), that has received regulatory approval. In addition, the compounds we are developing may not demonstrate in patients the chemical and pharmacological properties ascribed to them in preclinical studies, and they may interact with human biological systems in unforeseen, ineffective or harmful ways.

As part of our T cell platform, our approach is to use human cytomegalovirus, or HCMV, as a vaccine vector to potentially treat and prevent pathogens refractory to current vaccine technologies because HCMV may induce potent and long-lasting T cell responses to a broader range of epitopes than observed for other viral vaccines. Safety and toxicity studies for this technology have so far only been conducted in animal species, in which HCMV has limited ability to replicate. If our first clinical trial for VIR-1111 or VIR-2020 causes unexpected side effects that are not tolerable in the treatment of the relevant patient group, the further development of the product candidates and any other potential products based on HCMV-vector technology may be significantly limited or become impossible. Also, because our HCMV-vector technology is novel, regulatory agencies may lack experience with product candidates such as VIR-1111 and VIR-2020, which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. In addition, our HCMV-vector technology utilizes live-attenuated, genetically-modified organisms for which the FDA, the European Medicines Agency, or the EMA, and other comparable foreign regulatory authorities and other public health authorities, such as the Centers for Disease Control and Prevention and hospitals involved in clinical studies, have established additional safety and contagion rules and procedures, which could establish additional hurdles for the development, manufacture or use of our vectors. These hurdles may lead to delays in the conduct of clinical trials or in obtaining regulatory approvals for further development, manufacturing or commercialization of our product candidates.

Further, we, the FDA, a foreign regulatory authority or an institutional review board may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA or foreign regulatory authority finds deficiencies in our investigational new drug applications, or INDs, or clinical trial applications, or CTAs, respectively, or the conduct of these trials. Moreover, we may not be able to file INDs to commence additional clinical trials on the timelines we expect because our filing schedule is dependent on further preclinical and manufacturing progress. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenue from our product candidates may be delayed.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. We are developing VIR-2218 and VIR-3434 for the treatment of HBV, VIR-2482 for the prevention of influenza A, VIR-1111 for the prevention of human immunodeficiency virus, or HIV, and VIR-2020 for the prevention of tuberculosis, or TB. In particular, clinical trials for prophylaxes tend to require enrollment of a larger number of subjects than clinical trials for treatments. We may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our product candidates. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the trial.

Our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. Any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we may rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to ensure their actual performance.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur.

In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects or patients. Many times, side effects are only detectable after investigational products are tested in large-scale pivotal trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates have side effects or cause serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, financial condition, results of operations and prospects.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, "top-line" or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

We are a party to strategic collaboration and license agreements pursuant to which we are obligated to make substantial payments upon achievement of milestone events and, in certain cases, have relinquished important rights over the development and commercialization of certain current and future product candidates. We also intend to explore additional strategic collaborations, which may never materialize or may require that we relinquish rights to and control over the development and commercialization of our product candidates.

We are a party to various strategic collaboration and license agreements that are important to our business and to our current and future product candidates. For example, we license a number of technologies to form our antibody platform, including technology from the Institute for Research in Biomedicine, or IRB, The Rockefeller University, or Rockefeller, and Xencor, Inc., or Xencor, pursuant to our exclusive license agreement with IRB, or the IRB Agreement, our exclusive license agreement with Rockefeller, or the Rockefeller Agreement, and our patent license agreement with Xencor, or the Xencor Agreement. We also license technology from Oregon Health & Science University, or OHSU, pursuant to our master exclusive license agreement with OHSU, or the OHSU Agreement, to form our T cell platform. In addition, the technology we use in our siRNA technology platform is licensed from Alnylam pursuant to a collaboration and license agreement, or the Alnylam Agreement. These agreements contain obligations that require us to make substantial payments in the event certain milestone events are achieved.

Our agreements with Alnylam, OHSU, MedImmune, LLC, or MedImmune, Rockefeller and Xencor include the following milestone payment obligations: up to $1.3 billion in milestone payments under the Alnylam Agreement, up to $1.3 million in milestone payments per product and up to $2.0 million in the aggregate for all products under the OHSU Agreement, up to $343.3 million in milestone payments under the 2018 MedImmune Agreement, up to $48.5 million in milestone payments per product under the Rockefeller Agreement and up to $155.5 million in milestone payments for all licensed products under the Xencor Agreement. We may in the future be required to make these payments, which could adversely affect our financial condition. In addition, upon the achievement of a certain development milestone, we will be required to issue Alnylam shares of our common stock equal to the lesser of (i) 1,111,111 shares or (ii) a certain number of shares based on our stock price at the time such milestone is achieved.

Furthermore, pursuant to the Alnylam Agreement, Alnylam granted us an exclusive option for each of the infectious disease siRNA programs directed to our selected targets, to obtain a worldwide, exclusive license to develop, manufacture, and commercialize siRNA products directed to the target of each such program. Our options are each exercisable during a specified period following selection of candidates for each program, or two years following the initiation of certain activities under an agreed upon development plan, if earlier. On a product-by-product basis for each product arising from the HBV and, following our option exercise, the infectious disease programs, Alnylam has an option, exercisable during a specified period during development of each such product, to negotiate and enter into a profit-sharing agreement for such product. If we do not exercise our options with respect to a particular program in a timely manner or at all, Alnylam will retain such rights and may offer such exclusive rights to other third parties. If Alnylam exercises its profit-sharing option for a product, including VIR-2218, we will be required to negotiate the terms of a profit-sharing agreement with Alnylam, which will include sharing equally with Alnylam the profits and losses in connection with such product, subject to reimbursement by Alnylam of a portion of specified development costs in certain circumstances. Because of the uncertainty associated with Alnylam's decision to exercise its profit-sharing option for VIR-2218, we are unable to accurately predict the timing or amount of expenses related to the development of VIR-2218 after the specified period that Alnylam is allowed to exercise its option. Furthermore, if Alnylam does not exercise its profit-sharing option, it could damage public perceptions of VIR-2218, which could have a substantial adverse effect on the price of our common stock.

In addition, in May 2018, we entered into an option and license agreement, or the Brii Agreement, with Brii Biosciences Limited (previously named BiiG Therapeutics Limited), or Brii Bio Parent, and Brii Biosciences Offshore Limited, or Brii Bio, pursuant to which we granted to Brii Bio, with respect to up to four of our programs, an exclusive option to obtain exclusive rights to develop and commercialize compounds and products arising from such programs in China, Taiwan, Hong Kong and Macau, or collectively the China Territory, for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection, or the Field of Use. In partial consideration for the options granted by us to Brii Bio, Brii Bio Parent and Brii Bio granted us, with respect to up to four of Brii Bio Parent's or Brii Bio's programs, an exclusive option to be granted exclusive rights to develop and commercialize compounds and products arising from such Brii Bio programs in the United States for the Field of Use. Neither we nor Brii Bio has exercised an option under the Brii Agreement. We cannot be certain that, following the exercise of an option by Brii Bio or by us, we will achieve any benefits from our collaboration with Brii Bio.

A core element of our business strategy also includes continuing to acquire or in-license additional technologies or product candidates for the treatment and prevention of serious infectious diseases. As a result, we intend to periodically explore a variety of possible strategic collaborations or licenses in an effort to gain access to additional product candidates, technologies or resources.

At this time, we cannot predict what form such strategic collaborations or licenses might take in the future. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations and licenses can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations or licenses because of the numerous risks and uncertainties associated with establishing them. Any delays in entering into new strategic collaborations or licenses related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our current and future collaborations and licenses could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our stockholders' percentage ownership of our company;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;

- we may not have the right to control the preparation, filing, prosecution and maintenance of patents and patent applications covering the technology that we license, and we cannot always be certain that these patents and patent applications will be prepared, filed, prosecuted and maintained in a manner consistent with the best interests of our business;
- strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenue from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Furthermore, license agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

If the market opportunities for our product candidates are smaller than we believe they are or any approval we obtain is based on a narrower definition of the patient population, our business may suffer.

We currently focus our product development on product candidates for the treatment and prevention of serious infectious diseases. Our eligible patient population, pricing estimates and available coverage and reimbursement may differ significantly from the actual market addressable by our product candidates. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and analyses. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be receptive to treatment with our product candidates, and new patients may become increasingly difficult to identify or access. If the market opportunities for our product candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

We face substantial competition, which may result in others developing or commercializing products before or more successfully than us.

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and an emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future. In addition, regulatory incentives to develop products for treatment of infectious diseases have increased interest and activity in this area and may lead to increased competition for clinical investigators and clinical trial subjects, as well as for future prescriptions, if any of our product candidates are successfully developed and approved.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

As a result of these factors, our competitors may achieve patent protection or obtain regulatory approval of their products before we are able to, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop therapies that are safer, more effective, more widely accepted or less expensive than ours, and may also be more successful than we are in manufacturing and marketing their products. These advantages could render our product candidates obsolete or non-competitive before we can recover the costs of such product candidates' development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

Even if any product candidates receive marketing approval, they may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. If such product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the convenience and ease of administration compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the efficacy and potential advantages compared to alternative treatments and therapies;
- the effectiveness of sales and marketing efforts;
- the strength of our relationships with patient communities;
- the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments;
- our ability to offer such product for sale at competitive prices;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the product together with other medications.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complex and distinctive nature of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business.

For example, we are developing VIR-2482 as a universal prophylaxis for influenza A. VIR-2482 is designed to overcome the limitations of influenza vaccines and lead to meaningfully higher levels of protection. In order for VIR-2482 to be successful, not only will it need to be approved for commercial sale, but it will also need to demonstrate a higher efficacy compared to influenza vaccines and be offered at a competitive price in order to receive favorable coverage and reimbursement from third-party payors and in order for physicians to prescribe the product in lieu of the standard of care treatment.

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

Even if we obtain regulatory approvals for our product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the product. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval.

In addition, biopharmaceutical manufacturers and their facilities are subject to ongoing review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA, BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA, BLA or comparable foreign marketing application or any supplements thereto submitted by us or our partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug and biologic products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and harm our business, financial condition, results of operations and prospects.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the executive orders, will be implemented and the extent to which they will affect the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business, financial condition, results of operations and prospects may be negatively impacted.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing them, if and when they are approved.

To successfully commercialize any product candidate that may result from our development programs, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any product candidate we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability, and have no experience as a company in commercializing products. Establishing sales and marketing capabilities will be particularly important to the commercial success of our product candidates that target diseases with large patient populations throughout the world. We may seek to enter into collaborations with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any current or future collaborators do not commit sufficient time or resources to commercialize our product candidates, or we are unable to develop the necessary capabilities on our own, we may be unable to generate sufficient revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel, and will have to compete with those companies to recruit, hire, train and retain any of our own marketing and sales personnel. We will likely also face competition if we seek third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval outside the United States, which would limit our market opportunities.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our product candidates outside the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable foreign regulatory authorities also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any product candidates, if approved, is also subject to approval. Obtaining approval for our product candidates in the European Union, or EU, from the European Commission following the opinion of the EMA if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a product candidate is approved, the EMA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Approval of certain product candidates outside of the United States, particularly those that target diseases that are more prevalent outside of the United States will be particularly important to the commercial success of such product candidates. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for our product candidates may be withdrawn. If we fail to comply with the applicable regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects could be harmed.

Additionally, in June 2016, the electorate in the United Kingdom voted in favor of leaving the EU, commonly referred to as Brexit, and in March 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty either on the effective date of a withdrawal agreement (which requires UK parliamentary approval) or, failing that, two years following the United Kingdom's notification of its intention to leave the EU, unless extended. Given that no formal withdrawal agreements have been agreed and there have been several extensions granted, the United Kingdom has yet to formally leave the EU, and it is uncertain as to when it will occur, if ever. Because a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the EU. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or EU for our product candidates, which could significantly and materially harm our business, financial condition, results of operations and prospects.

If we commercialize our product candidates outside the United States, a variety of risks associated with international operations could harm our business.

We intend to seek approval to market our product candidates outside the United States, and may also do so for future product candidates. If we market approved products outside the United States, we expect that we will be subject to additional risks in commercialization, including:

- different regulatory requirements for approval of therapies in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in which we may operate, with which we will need to comply. Many biopharmaceutical companies have found the process of marketing their products in foreign countries to be challenging.

Negative developments and negative public opinion of new technologies on which we rely may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

The clinical and commercial success of our product candidates will depend in part on public acceptance of the use of new technologies for the prevention or treatment of human diseases. For example, we use CMV, a commonly occurring virus in humans, as a vaccine vector to prevent and treat pathogens refractory to current vaccine technologies. We also use CRISPR gene-editing technology as a research tool to systematically identify human genes that control infection.

Public perception may be influenced by claims that CMV technology is unsafe and products incorporating this technology may not gain the acceptance of the public or the medical community, or that CRISPR gene-editing technology is unethical or immoral. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in our targeted diseases prescribing, and their patients being willing to receive, our product candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of the technologies that we rely on may result in fewer physicians prescribing our products or may reduce the willingness of patients to utilize our products or participate in clinical trials for our product candidates.

Increased negative public opinion or more restrictive government regulations in response thereto, would have a negative effect on our business, financial condition, results of operations or prospects and may delay or impair the development and commercialization of our product candidates or demand for such product candidates. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing similar technologies, even if not ultimately attributable to product candidates we may discover and develop, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved, a decrease in demand for any such product candidates and a suspension or withdrawal of approval by regulatory authorities of our product candidates.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- increased insurance costs;
- the inability to commercialize any product candidate that we may develop; and
- injury to our reputation and significant negative media attention.

Any such outcomes could negatively impact our business, financial condition, results of operations and prospects.

Our insurance policies may be inadequate and potentially expose us to unrecoverable risks.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Conditions in the insurance markets relating to nearly all areas of traditional corporate insurance change rapidly and may result in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

Risks Related to Regulatory Compliance

If any of our future small molecule product candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such products, which may result in a material decline in sales of affected products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic version of an approved, small molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for a product, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if any of our future small molecule product candidates are approved, competitors could file ANDAs for generic versions of these products or 505(b)(2) NDAs that reference our products. If there are patents listed for such small molecule drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially.

Any biologic, or large molecule, product candidates for which we intend to seek approval may face competition sooner than anticipated.

If we are successful in achieving regulatory approval to commercialize any biologic product candidate faster than our competitors, such product candidates may face competition from biosimilar products. In the United States, large molecule product candidates are regulated by the FDA as biologic products subject to approval under the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated pathway for the approval of biosimilar and interchangeable biologic products following the approval of an original BLA. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical studies. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

If competitors are able to obtain marketing approval for biosimilars referencing our large molecule product candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

Our relationships with customers, physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws.

These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information on their behalf;
- the Federal Food Drug or Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, or GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU (including health data).

We may also be subject to other laws, such federal laws as the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibit, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof, as well as federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant civil, criminal or administrative sanctions, including exclusions from government-funded healthcare programs. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace.

Coverage and adequate reimbursement may not be available for our product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these product and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. While no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Therefore, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs and biological products, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, because certain of our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Healthcare legislative reform measures may have a negative impact on our business, financial condition, results of operations and prospects.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the United States. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high-cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, the CMS, published a final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA. Congress may consider additional legislation to repeal or repeal and replace other elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, which will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which will be fully operational in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement.

Further, in the United States there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug and biological product pricing, reduce the cost of prescription drugs and biological products under government payor programs and review the relationship between pricing and manufacturer patient programs. At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation. In addition, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional

proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services has started soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified a CMS policy change that was effective January 1, 2019. While some of these measures may require additional authorization to become effective, the U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug and biological product costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs, biological products and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future product candidates or additional pricing pressures. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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

We are subject to anti-corruption, anti-bribery, anti-money laundering, and similar laws, and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act and other anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption and anti-bribery laws have been enforced aggressively in recent years and are interpreted broadly to generally prohibit companies and their employees and third-party intermediaries from authorizing, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize such activities.

While we have policies and procedures to address compliance with such laws in the United States, we cannot assure you that all of our employees and agents will not take actions in violation of our policies and applicable law, for which we may be ultimately held responsible. Detecting, investigating and resolving actual or alleged violations can require a significant diversion of time, resources and attention from senior management. In addition, noncompliance with anti-corruption, anti-bribery or anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, financial condition, results of operations and prospects could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Enforcement actions and sanctions could further harm our business, financial condition, results of operations and prospects.

Risks Related to Our Dependence on Third Parties

We intend to rely on third parties to produce clinical and commercial supplies of our product candidates.

We are currently manufacturing material for product candidates of three different modalities: mAbs, HCMV-based vaccines and siRNAs. Except for limited process development and quality control testing capabilities in certain of our facilities, we do not own or operate facilities for product manufacturing, storage and distribution, or testing. We are dependent on third parties to manufacture the clinical supplies of our current and any future product candidates. We have established relationships with multiple contract development and manufacturing organizations, or CDMOs, that have produced material to support our preclinical, Phase 1 and Phase 2 clinical trials. We have not yet manufactured our product candidates on a commercial scale, and we do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates. Certain of our product candidates may have to compete with existing and future products, such as the annual flu vaccine, that may have a lower price point. The actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA or BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the cGMP requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

We also intend to rely on third-party manufacturers to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization. We do not yet have a commercial supply agreement for commercial quantities of our product candidates. If we are not able to meet market demand for any approved product or if we are not able to produce supply at low enough costs, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business, financial condition, results of operations and prospects.

In addition, we currently rely on foreign CDMOs, including a CDMO in China, and will likely continue to rely on foreign CDMOs in the future. Foreign CDMOs may be subject to trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, or delay the procurement of such material. Additionally, the biopharmaceutical industry in particular in China is strictly regulated by the Chinese government. Changes to Chinese regulations affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our partnerships in China which could have an adverse effect on our business, financial condition, results of operations and prospects.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- inability of our third-party manufacturers to execute our manufacturing procedures and other logistical support requirements appropriately;

  inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for product components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single-source supplier;

- lack of ownership to the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- disruptions to operations of our third-party manufacturers or suppliers by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

We cannot be sure that single source suppliers for our product components will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these components for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results.

Furthermore, there are a limited number of manufacturers that supply synthetic siRNAs. Alnylam is currently supplying clinical material for our VIR-2218 Phase 1/2 clinical trial through its CDMOs. We will assume responsibility for technology transfer and manufacturing ahead of any Phase 3 clinical trials for VIR-2218. Alnylam currently relies on a limited number of CDMOs for our supply of synthetic siRNAs. There are risks inherent in pharmaceutical manufacturing that could affect the ability of Alnylam and Alnylam's CDMOs to meet our delivery time requirements or provide adequate amounts of synthetic siRNAs to meet our needs. Included in these risks are potential synthesis and purification failures and/or contamination during the manufacturing process, as well as other issues with the CDMO's facility and ability to comply with the applicable manufacturing requirements, including use of the proper raw material components, which could result in unusable product. This would cause delays in our manufacturing timelines and ultimately delay our clinical trials and potentially put at risk commercial supply, as well as result in additional expense to us. To fulfill our siRNA requirements, we may need to secure alternative suppliers of synthetic siRNAs and such alternative suppliers are limited and may not be readily available, or we may be unable to enter into agreements with them on reasonable terms and in a timely manner.

In addition, manufacturers may have little or no experience with viral vector products and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our HCMV vector-based product candidates. The challenges to HCMV-based vaccine manufacturing include the large size of the virus, which precludes terminal sterile filtration, and the attenuation of the engineered human virus, which dramatically reduces high growth yields during manufacturing. To address these challenges, we have made significant internal investments in process development and scale-up, largely funded by grants from the Bill & Melinda Gates Foundation. We have established a cGMP process in support of Phase 1 and Phase 2 clinical trials that has been successfully transferred and executed at two CDMOs specializing in live vaccine manufacturing (IDT Biologika and Advanced Bioscience Laboratories, Inc.). However, the existing process will require scale-up for later stages of clinical development and commercial supply.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure or total or partial suspension of production.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the generation, storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds and wastes. We and our manufacturers and suppliers are subject to environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, generation, storage, handling, transportation, discharge and disposal of these hazardous materials and wastes and worker health and safety. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination or injury, which could result in an interruption of our commercialization efforts, research and development efforts and business operations, damages and significant cleanup costs and liabilities under applicable environmental, health and safety laws and regulations. We also cannot guarantee that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials and wastes generally comply with the standards prescribed by these laws and regulations. We may be held liable for any resulting damages costs or liabilities, which could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Failure to comply with these environmental, health and safety laws and regulations may result in substantial fines, penalties or other sanctions. We do not currently carry hazardous waste insurance coverage.

We rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We do not currently have the ability to independently conduct any clinical trials. We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We rely on CROs to monitor and manage data for our clinical programs, as well as the execution of future preclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the good laboratory practices, or GLPs, and GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our reliance on third parties to conduct clinical trials will result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with CROs and other third parties can be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Such parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues; or
- undergo changes in priorities or become financially distressed.

These factors may adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines or fail to comply with regulatory requirements, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. While we will have agreements governing their activities, our CROs will not be our employees and we will not control whether or not they devote sufficient time and resources to our future clinical and preclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology.

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

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval or rejection of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates.

Risks Related to Our Intellectual Property

If we breach our license agreements or any of the other agreements under which we acquired, or will acquire, the intellectual property rights to our product candidates, we could lose the ability to continue the development and commercialization of the related product candidates.

We license a number of technologies to form our antibody platform and T cell platform, and the technology we use in our siRNA platform is licensed from Alnylam. We have also developed certain product candidates using intellectual property licensed from third parties. A core element of our business strategy includes continuing to acquire or in-license additional technologies or product candidates for the treatment and prevention of serious infectious diseases.

If we fail to meet our obligations under these agreements, our licensors may have the right to terminate our licenses. If any of our license agreements are terminated, and we lose our intellectual property rights under such agreements, this may result in a complete termination of our product development and any commercialization efforts for the product candidates which we are developing under such agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under such agreements, we may not be able to do so in a timely manner, at an acceptable cost or at all.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those related to:

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

If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the U.S. Patent and Trademark Office, or USPTO, itself, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from infringing our patents in all countries outside the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In addition, if the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our owned and in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will have to be paid to the USPTO and various government patent agencies outside the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our service providers or our licensors to pay these fees. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or technologies, we may not be able to use such patents and patent applications or stop a competitor from marketing products that are the same as or similar to our product candidates, which would have an adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, any of the foregoing could expose us to liability to the applicable patent owner.

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent and the protection it affords is limited. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations could be adversely affected.

Given the amount of time required for the development, testing and regulatory review of our product candidates, such as VIR-2218, VIR-3434, VIR-2482, VIR-1111 and VIR-2020, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. In the United States, the Hatch-Waxman Act permits a patent term extension of up to five years beyond the normal expiration of the patent, provided that the patent is not enforceable for more than 14 years from the date of drug approval, which is limited to the approved indication (or any additional indications approved during the period of extension). Furthermore, only one patent per approved product can be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of others with whom we may collaborate to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference proceedings, post grant review and inter partes review before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this is a high burden and requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that our product candidate or technology platform infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all, and if such an instance arises, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Parties making claims against us may also seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have an adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. We may also have to redesign our products, which may not be commercially or technically feasible or require substantial time and expense. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time-consuming and would divert management's attention from our core business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities.

In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly and could put our owned or licensed patent applications at risk of not issuing. The initiation of a claim against a third party might also cause the third party to bring counterclaims against us, such as claims asserting that our patent rights are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is or will be no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license, or if the license offered as a result is not on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail and, even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business, financial condition, results of operations and prospects.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own, have licensed or might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our current and any future product candidates and technology platforms in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Because we rely on third parties to help us discover, develop and manufacture our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing or commercialization of our current or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements.

We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of these parties to use or disclose our confidential information, including our trade secrets. We also enter into invention or patent assignment agreements with our employees, advisors and consultants. Despite our efforts to protect our trade secrets, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally or unlawfully obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

In addition, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business, financial condition, results of operations and prospects.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our current or any future product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our current or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents, should they issue, that we own or license;
- others may be able to develop technologies that are similar to our technology platforms but that are not covered by the claims of any patents, should they issue, that we own or license;
- we or our licensors might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license;
- we or our licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

The exercise by the Bill & Melinda Gates Foundation of its licenses to certain of our intellectual property and its development and commercialization of products that we are also developing and commercializing could have an adverse impact on our market position.

We entered into a letter agreement with the Bill & Melinda Gates Foundation, or the Gates Agreement, in December 2016 in connection with the Bill & Melinda Gates Foundation's investment in us through the purchase of $20.0 million of shares of our convertible preferred stock. We are obligated to use the proceeds of the Bill & Melinda Gates Foundation's investment in furtherance of its charitable purposes to (i) conduct our programs to develop products to treat or prevent infectious disease caused by HIV and TB, respectively, with at least 50% of the funds to be used for such programs, and (ii) develop our HCMV-based vaccine technology platform in a manner reasonably expected to result in the generation of products for the treatment or prevention of other specified infectious diseases, in each case for use in specified developing countries. We agreed to use reasonable efforts to achieve specified research and development milestones with respect to our HIV program and TB program and, if requested by the Bill & Melinda Gates Foundation, to work with the Bill & Melinda Gates Foundation on an additional mutually agreeable infectious disease program. Additionally, we agreed to specified global access commitments including a commitment to provide any products developed using the proceeds of the Bill & Melinda Gates Foundation's investment at an affordable price to the people most in need within the specified developing countries, not to exceed a specified percentage over our fully burdened manufacturing and sales costs.

If we fail to comply with (i) our obligations to use the proceeds of the Bill & Melinda Gates Foundation's investment for the purposes described in the paragraph above and to not use such proceeds for specified prohibited uses, (ii) specified reporting requirements or (iii) specified applicable laws, or if we materially breach our specified global access commitments (any such failure or material breach, a Specified Default), we will be obligated to redeem or arrange for a third party to purchase all of our stock purchased by the Bill & Melinda Gates Foundation under the Gates Agreement, at the Bill & Melinda Gates Foundation's request, at a price equal to the greater of (1) the original purchase price plus 5% compounding interest or (2) the fair market value as determined by an independent third-party, which amount may increase in the event of certain underwritten public offerings of our common stock or a sale of our company or all of our material assets relating to the Gates Agreement. Additionally, if a Specified Default occurs or if we are unable or unwilling to continue the HIV program, TB program or, if applicable, the mutually agreed additional program (except for scientific or technical reasons), or if we institute bankruptcy or insolvency proceedings, then the Bill & Melinda Gates Foundation will have the right to exercise a non-exclusive, fully-paid license (with the right to sublicense) under our intellectual property to the extent necessary to use, make and sell products arising from such programs, in each case solely to the extent necessary to benefit people in the developing countries in furtherance of the Bill & Melinda Gates Foundation's charitable purpose.

The exercise by the Bill & Melinda Gates Foundation of any of its non-exclusive licenses to certain of our intellectual property (or its right to obtain such licenses), and its development and commercialization of product candidates and products that we are also developing and commercializing, could have an adverse impact on our market position.

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

We are highly dependent on our key personnel, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our management, scientific and medical personnel, including our Chief Executive Officer, Dr. Scangos. Our key personnel may currently terminate their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

Recruiting and retaining other senior executives, qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations.

We have in the past and may in the future acquire or invest in other companies or technologies, which could divert our management's attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We have in the past and may in the future seek to acquire or invest in additional businesses and/or technologies that we believe complement or expand our product candidates, enhance our technical capabilities or otherwise offer growth opportunities in the United States and internationally. The pursuit of potential acquisitions and investments may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated.

For example, we acquired TomegaVax, Inc., or TomegaVax, in September 2016, Humabs BioMed SA, or Humabs, in August 2017, Agenovir Corporation, or Agenovir, in January 2018 and Statera Health, LLC, or Statera, in February 2018. Realizing the benefits of these acquisitions will depend upon the successful integration of the acquired technology into our existing and future product candidates. Furthermore, we may not be able to integrate the acquired personnel, operations and technologies successfully, or effectively manage the combined business following the acquisition. We also may not realize the anticipated benefits from any acquired business. The risks we face in connection with acquisitions and investments, whether or not consummated, include:

- unanticipated costs or liabilities associated with the acquisition;
- diversion of management's attention from other business concerns;
- adverse effects to our existing strategic collaborations as a result of the acquisition;
- assimilation of operations, intellectual property and products of an acquired company;
- the potential loss of key employees;
- difficulty integrating the accounting systems, operations and personnel of the acquired business;
- the assumption of additional indebtedness or contingent or unknown liabilities, or adverse tax consequences or unfavorable accounting treatment;
- claims and disputes by stockholders and third parties, including intellectual property claims and disputes;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals;
- increased operating expenses and cash requirements;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

A significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. If our acquisitions do not yield expected returns, we may in the future be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our business, financial condition, results of operations and prospects.

In addition, our acquisitions of TomegaVax, Humabs and Agenovir included the following future contingent payments: up to $30.0 million in milestone payments related to the TomegaVax acquisition, up to $240.0 million in milestones payments related to the Humabs acquisition, and up to $270.0 million in milestones related to the Agenovir acquisition. The milestone payments related to the TomegaVax acquisition are dependent on the per share price of our common stock. We may in the future be required to make these payments, which could adversely affect our financial condition.

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our business, financial condition, results of operations and prospects may suffer. We cannot assure you that we will be successful in integrating the businesses or technologies we may acquire. The failure to successfully integrate these businesses could have a material adverse effect on our business, financial condition, results of operations and prospects.

We expect to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of September 30, 2019, we had 217 full-time employees. As the clinical development of our product candidates progresses, we also expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. In addition, we also expect to hire additional personnel in order to operate as a public company. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. In addition, we must effectively integrate, develop and motivate a growing number of new employees, and maintain the beneficial aspects of our corporate culture. The expansion of our operations may lead to significant costs and may divert our management and business development resources. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CDMO, CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our ability to develop our product candidates could be disrupted if our operations or those of our suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Our internal computer systems, or those of our collaborators, service providers or other contractors or consultants, may fail or suffer security breaches, which could result in a significant disruption of our product development programs and our ability to operate our business effectively, and adversely affect our business, financial condition, results of operations and prospects.

Our internal computer and information technology systems, cloud-based computing services and those of our current and any future collaborators, service providers and other contractors or consultants are potentially vulnerable to malware, computer viruses, data corruption, cyber-based attacks, natural disasters, terrorism, war and telecommunication and electrical failures that may result in damage to or the interruption or impairment of key business processes, or the loss or corruption of confidential information, including intellectual property, proprietary business information and personal information. We have in the past experienced security breaches of our information technology systems. Any significant system failure, accident or security breach could have a material adverse effect on our business, financial condition and results of operations. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

In addition, our internal computer and information technology systems, cloud-based computing services and those of our current and any future collaborators, service providers and other contractors or consultants are potentially vulnerable to data security breaches, whether by employees, contractors, consultants, malware, phishing attacks or other cyber-attacks, that may expose confidential information, intellectual property, proprietary business information or personal information to unauthorized persons. For example, we have experienced phishing attacks in the past and we may be a target of phishing attacks or other cyber-attacks in the future. In addition, our software systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks. If a data security breach affects our systems, corrupts our data or results in the unauthorized disclosure or release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media or individuals pursuant to various federal, state and foreign data protection, privacy and security laws, regulations and guidelines, if applicable. These may include state breach notification laws, and the GDPR. Accordingly, a data security breach or privacy violation that leads to unauthorized access to, disclosure or modification of personal information (including protected health information), that

prevents access to personal information or materially compromises the privacy, security, or confidentiality of the personal information, could result in fines, increased costs or loss of revenue and we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Furthermore, federal, state and international laws and regulations, such as the GDPR, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail.

We receive, process, store and use personal information and other data, which subjects us to governmental regulation and other legal obligations, liability and risks related to privacy, security, and data protection, and our actual or perceived failure to comply with such obligations could harm our business.

We receive, process, store and use personal information and other data about our patients, employees, partners and others. We must comply with numerous foreign and domestic laws and regulations regarding privacy and the storing, sharing, use, processing, disclosure, security, and protection of personal information and other data, such as information that we collect about patients and healthcare providers in connection with clinical trials in the United States and abroad. We strive to comply with all applicable requirements and obligations; however new laws, policies, codes of conduct and legal obligations may arise, continue to evolve, be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and conflict with one another. Any failure or perceived failure by us or third parties working on our behalf to comply with applicable laws and regulations, any privacy and data security obligations pursuant to contract, our stated privacy or security policies or obligations to third parties may result in governmental enforcement actions (including fines, penalties, judgments, settlements, imprisonment of company officials and public censure), civil claims, litigation, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, operations and financial performance. With substantial uncertainty over the interpretation and application of these laws, regulations and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices, and may incur significant costs and expenses in our efforts to do so.

The global data protection landscape is rapidly evolving, and we expect that there will continue to be new and proposed laws, regulations and industry standards concerning privacy, data protection and information security, and we cannot yet determine the impact that such future laws, regulations and standards may have on our business. For example, in May 2018 the GDPR went into effect in the EU. The GDPR imposes stringent data protection requirements for processing the information of EU subjects, including clinical trial data, and to date, has increased compliance burdens on us, including by mandating burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. The GDPR also provides for more robust regulatory enforcement and greater penalties for noncompliance than previous data protection laws, including fines of up to €20 million or 4% of global annual revenue of any noncompliant company for the preceding financial year, whichever is higher. Further, following a referendum in June 2016 in which voters in the United Kingdom approved an exit from the EU, the government of the United Kingdom has initiated a process to leave the EU, or Brexit, which has created uncertainty with regard to the regulation of data protection in the United Kingdom, including with respect to whether laws or regulations will apply to us consistent with the GDPR in the future and how data transfers to and from the United Kingdom will be regulated. The type of challenges we face in Europe will likely also arise in other jurisdictions that adopt laws similar in construction to the GDPR or regulatory frameworks of equivalent complexity. In the United States, on June 28, 2018, California adopted the California Consumer Privacy Act of 2018, or CCPA, which will take effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase litigation involving misuse of personal information of California residents. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend of states adopting more stringent privacy legislation in the United States, which could increase our compliance costs, potential liability and adversely affect our business. Similar privacy legislation has been proposed in a number of states.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures, reckless and/or negligent conduct or unauthorized activities that violates (i) the laws and regulations of FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (iv) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, creating fraudulent data in our pre-clinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

The Tax Cuts and Jobs Act, or the Tax Act, could adversely affect our business and financial condition.

In December 2017, the Tax Act was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (with certain exceptions, including for certain small businesses), (iii) limitation of the deduction for post-2017 net operating losses, or NOLs, to 80% of current-year taxable income and elimination of net operating loss carrybacks for post-2017 NOLs, (iv) one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time and (vi) modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). We continue to examine the impact the Tax Act may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business, financial condition, results of operations and prospects could be adversely affected. We urge our stockholders to consult with their legal and tax advisors with respect to the Tax Act and the tax consequences of investing in our common stock.

Our ability to use our NOLs to offset future taxable income may be subject to certain limitations.

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We may have experienced ownership changes in the past and may experience ownership changes as a result of the IPO and/or subsequent changes in our stock ownership (some of which shifts are outside our control). In addition, Agenovir has experienced at least one ownership change in the past resulting in a limitation under Section 382 of the Code, which has been accounted for in calculating our available NOL carryforwards. As a result, if, and to the extent that we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations.

The Tax Act, among other things, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards. For NOLs arising in tax years beginning after December 31, 2017, the Tax Act limits a taxpayer's ability to utilize NOL carryforwards to 80% of taxable income. In addition, NOLs arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. NOLs generated in tax years beginning before January 1, 2018 will not be subject to the taxable income limitation, and NOLs generated in tax years ending before January 1, 2018 will continue to have a two-year carryback and 20-year carryforward period. Deferred tax assets for NOLs will need to be measured at the applicable tax rate in effect when the NOL is expected to be utilized. The changes in the carryforward/carryback periods, as well as the new limitation on use of NOLs may significantly impact our ability to utilize our NOLs to offset taxable income in the future.

Risks Related Ownership of Our Common Stock

Our financial condition and results of operations may fluctuate from quarter to quarter and year to year, which makes them difficult to predict.

We expect our financial condition and results of operations to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The market price of our common stock is likely to be volatile. The stock market in general and the market for biopharmaceutical and pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price you paid for your shares. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, the market price for our common stock may be influenced by the following:

- the commencement, enrollment or results of our planned or future preclinical studies or clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate supply for any approved product or inability to do so at acceptable prices;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems, including coverage and adequate reimbursement for any approved product;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

A public market may not develop or be sustained, or be liquid enough for you to sell your shares quickly or at market price.

Prior to the IPO, there had not been a public market for our common stock. If an active trading market for our common stock does not develop or is not sustained following the IPO, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares of our common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

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

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock beneficially own a significant percentage of our outstanding common stock. If these persons acted together, they may be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways with which other stockholders disagree.

If research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or financial analysts publish about us or our business. If any of the analysts who cover us issue and adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if the clinical trials and operating results fail to meet the expectations of analysts, our stock could decline. If analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of November 15, 2019, we had 109,678,822 shares of common stock outstanding. This includes the shares that we sold in the IPO, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. The remaining 102,535,964 shares are currently restricted as a result of securities laws or lock-up agreements. Moreover, holders of an aggregate of approximately 88.2 million shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We further intend to register all shares of common stock that we may issue in the future or have issued to date under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not EGCs, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of some or all of these reporting exemptions until we are no longer an EGC. We will remain an EGC until the earlier of (i) December 31, 2024, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (iii) the date on which we first qualify as a large accelerated filer under the rules of the U.S. Securities and Exchange Commission, or the SEC, and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

In addition, under Section 107(b) of the JOBS Act, EGCs can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not EGCs.

As a public company, we are now subject to more stringent federal and state law requirements.

As a public company, we are now subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd–Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of The Nasdaq Stock Market LLC, or Nasdaq, and other applicable securities rules and regulations. Despite reforms made possible by the JOBS Act, compliance with these rules and regulations will nonetheless increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an ECG.

As a result of disclosure of information in this Quarterly Report on Form 10-Q and in filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business, results of operations, financial condition and prospects could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our brand and reputation, business, results of operations, financial condition and prospects.

We also expect that being a public company and the associated rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain adequate coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

We may also be subject to more stringent state law requirements. For example, on September 30, 2018, California Governor Jerry Brown signed into law Senator Bill 826, which generally requires public companies with principal executive offices in California to have a minimum number of females on the company's board of directors. By December 31, 2019, each public company with principal executive offices in California is required to have at least one female on its board of directors. By December 31, 2021, each public company is required to have at least two females on its board of directors if the company has at least five directors, and at least three females on its board of directors if the company has at least six directors. The new law does not provide a transition period for newly listed companies. We are currently compliant with the requirements, but there are no assurances that we will be compliant in the future. If we fail to comply with this new law, we could be fined by the California Secretary of State, with a $100,000 fine for the first violation and a $300,000 for each subsequent violation, and our reputation may be adversely affected.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and we will continue to incur significant legal, accounting, investor relations and other expenses that we did not incur as a private company, particularly after we are no longer an ECG. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Stockholder activism, the current political environment and the current high level of U.S. government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may in turn lead to additional compliance costs and impact the manner in which we operate our business in ways we do not currently anticipate. Our management and other personnel will need to devote a substantial amount of time to comply with these requirements. Moreover, these requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the Sarbanes-Oxley Act, the requirements of being a reporting company under the Exchange Act and any complex accounting rules in the future, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. We are currently in the process of hiring additional accounting and finance staff as we grow our business. If we are unable to hire the additional accounting and finance staff necessary to comply with these requirements, we may need to retain additional outside consultants. If we or, if required, our auditors, are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses in our internal control over financial reporting in the future. Our previous acquisitions and strategic transactions and resulting international operations have increased the complexity of our accounting, and additional acquisitions and transactions and further geographic expansion will likely increase this complexity and the related accounting challenges. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines that we have a material weakness in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.

Generally accepted accounting principles in the United States are subject to interpretation by the Financial Accounting Standards Board, or FASB, or the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations and may require us to make costly changes to our operational processes and accounting systems.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;

- prohibit our stockholders from calling a special meeting of our stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66⅔% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and
- any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, unless we consent in writing to the selection of an alternative forum.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. For example, the Court of Chancery of the State of Delaware recently determined that a provision stating that U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court. If a court were to find the exclusive-forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

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

Recent Sales of Unregistered Equity Securities

During the three months ended September 30, 2019 and pursuant to our 2016 Equity Incentive Plan, as amended, we granted stock options to purchase up to an aggregate of 1,031,758 shares of our common stock to our employees and directors at a weighted-average exercise price of $10.40 per share. The sales of these securities were deemed to be exempt from registration under Rule 701 under the Securities Act as transactions pursuant to compensatory benefit plans or contracts relating to compensation as provided under Rule 701, or under Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering.

In August 2019, we issued and sold 38,888 shares of our common stock to one accredited investor as partial consideration for entry into a license agreement and the investor granting us certain license rights. The issuance and sale of these shares was deemed to be exempt from registration under Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D under the Securities Act as a transaction by an issuer not involving a public offering.

Use of Proceeds from the IPO

On October 10, 2019, we completed the IPO and issued 7,142,858 shares of our common stock at an initial offering price of $20.00 per share. We received net proceeds from the IPO of approximately $127.2 million, after deducting underwriting discounts and commissions of approximately $10.0 million and expenses of approximately $5.6 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates. Goldman Sachs & Co. LLC, J.P. Morgan Securities LLC, Cowen and Company, LLC and Barclays Capital Inc. acted as book-running managers for the IPO.

Shares of our common stock began trading on The Nasdaq Global Select Market on October 11, 2019. The offer and sale of the shares were registered under the Securities Act on Registration Statement on Form S-1 (Registration No. 333-233604), which was declared effective on October 10, 2019.

There has been no material change in the planned use of proceeds from our IPO as described in our Prospectus. We invested the funds received in cash equivalents and other marketable securities in accordance with our investment policy.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

(a) Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39083), filed with the SEC on October 16, 2019).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-39083), filed with the SEC on October 16, 2019).
4.1	Form of Common Stock Certificate of the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 30, 2019).
4.2	Amended and Restated Investors' Rights Agreement, by and among the Company and certain of its stockholders, dated November 29, 2017 (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
4.3	Amended and Restated Warrant, issued to Takeda Ventures, Inc (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
4.8+	Vir Biotechnology, Inc. 2019 Equity Incentive Plan, (incorporated herein by reference to Exhibit 4.8 to the Company's Form S-8 (File No. 333-234212), filed with the SEC on October 15, 2019).
4.11+	2019 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 4.11 to the Company's Form S-8 (File No. 33-234212), filed with the SEC on October 15, 2019).
10.1+	Form of Indemnity Agreement by and between the Company and its directors and executive officers (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.3+	Forms of Option Grant Notice and Option Agreement under Vir Biotechnology, Inc. 2019 Equity Incentive Plan, (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.4+	Form of Restricted Stock Unit Grant Notice and Unit Award Agreement under Vir Biotechnology, Inc. 2019 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.8+	Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.9+	Amended and Restated Employment Letter Agreement between the Company and George Scangos, dated August 27, 2019 (incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.10+	Amended and Restated Employment Letter Agreement between the Company and Howard Horn, dated August 27, 2019 (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.11+	Amended and Restated Employment Letter Agreement between the Company and Michael Kamarck, dated August 28, 2019 (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.12+	Amended and Restated Employment Letter Agreement between the Company and Phil Pang, dated August 27, 2019 (incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.13+	Amended and Restated Employment Letter Agreement between the Company and Jay Parrish, dated August 27, 2019 (incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.14+	Amended and Restated Employment Letter Agreement between the Company and Herbert Virgin, dated September 3, 2019 (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).

Exhibit Number	Description
10.15+	Vir Biotechnology, Inc. Change in Control and Severance Benefit Plan (incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.21†	Second Revised and Restated Master License Agreement between the Company and Oregon Health & Science University, dated August 27, 2019 (incorporated herein by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.44†	Patent License Agreement between the Company and Xencor, Inc., dated August 15, 2019 (incorporated herein by reference to Exhibit 10.44 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
31.1	Certification of Principal Executive Officer 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.
31.2	Certification of Principal Financial Officer 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.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer 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 - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

+ Indicates a management contract or compensatory plan.
† Certain portions of this exhibit (indicated by "[***]") have been omitted pursuant to confidential treatment.
* The certification attached as Exhibit 32.1 accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

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

Vir Biotechnology, Inc.

Date: November 19, 2019

By: /s/ **George A. Scangos**
George A. Scangos, Ph.D.
Chief Executive Officer

Date: November 19, 2019

By: /s/ **Howard Horn**
Howard Horn
Chief Financial Officer

Exhibit 31.1

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

I, George Scangos, Ph.D., certify that:

1. I have reviewed this Form 10-Q of Vir Biotechnology, Inc;

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

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

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

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

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

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

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

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

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

Date: November 19, 2019

/s/ **George Scangos**
George Scangos, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Howard Horn., certify that:

1. I have reviewed this Form 10-Q of Vir Biotechnology, Inc;

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

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

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

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

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

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

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

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

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

Date: November 19, 2019

/s/ **Howard Horn**
Howard Horn
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), George Scangos, Ph.D., President, Chief Executive Officer and Director of Vir Biotechnology, Inc. (the "Company"), and Howard Horn, Chief Financial Officer and Secretary of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2019, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: November 19, 2019

In Witness Whereof, the undersigned have set their hands hereto as of the 19th day of November 2019.

/s/ **George Scangos**
George Scangos, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

/s/ **Howard Horn**
Howard Horn
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Vir Biotechnology, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."